A RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *LAKSHADI MALHAR* IN *VYANGA*

A Thesis

SUBMITTED TO THE

TILAK MAHARASHTRA VIDYAPEETH PUNE

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

In AYURVEDA - RASASHASTRA

Under the Board of AYURVEDA Studies

BY

Dr. GAYATRI SANTOSH GAONKAR

P.R.N. 05614007210

UNDER THE GUIDANCE OF

Dr. VILAS A DOLE

DEPARTMENT OF AYURVEDA

AUGUST 2022

CERTIFICATE OF THE SUPERVISOR

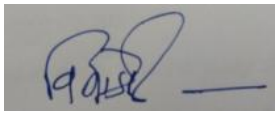
It is certified that work entitled, "**A Randomized Controlled Clinical Study To Evaluate The Efficacy Of *Lakshadi Malhar* In *Vyanga*.**" is an original research work done by **Dr. Gayatri Santosh Gaonkar**,

Under my supervision for the degree of Doctor of Philosophy in Ayurveda-Rasashastra,

to be awarded by Tilak Maharashtra Vidyapeeth, Pune.

To best of my knowledge this thesis-

- Embodies the work of candidate herself
- Has duly been completed
- Fulfills the requirement of the ordinance related to Ph. D. degree of the TMV up to the standard in respect of both content and language for being referred to the examiner.



Signature of the Supervisor

Dr. Vilas A Dole.

UNDERTAKING

I, **Dr. Gayatri Santosh Gaonkar** is the Ph. D Scholar of the Tilak Maharashtra Vidyapeeth in **Rasashastra (Ayurveda)** subject.

Thesis entitled , **"A Randomized Controlled Clinical Study To Evaluate The Efficacy Of *Lakshadi Malhar* In *Vyanga*."** under the supervision of **Dr. Vilas A Dole**, Solemnly affirm that the thesis submitted by me is my own work. I have not copied it from any source. I have gone through extensive review of literature of the related published / unpublished research works and the use of such references made has been acknowledged in my thesis. The title and the content of research is original.

I understand that, in case of any complaint especially plagiarism, regarding my Ph.D. research from any party, I have to go through the enquiry procedure as decided by the Vidyapeeth at any point of time.

I understand that, if my Ph.D. thesis (or part of it) is found duplicate at any point of time, my research degree will be withdrawn and in such circumstances, I will be solely responsible and liable for any consequences arises thereby. I will not hold the TMV, Pune, responsible and liable in any case.

I have signed the above undertaking after reading carefully and knowing all the aspects therein.

Signature of the Research Scholar:

Dr. Gayatri Gaonkar

Address : Hazel 203, Kesar Garden, Plot 53, Sector 20. Kharghar.

Pin Code. 410210.

Ph.No. : 9987544098 **e-mail** : shilpagaikwad229@gmail.com

Date : 10/02/2022 **Place** : Pune.

ACKNOWLEDGEMENT

Whenever we do any work or take up any task there are many people who are involved in helping you complete that task. Some give ideas, some give hope, some mere words that keep you go. Therefore I have to admit today that as much as this PhD is my baby there have been many, many who helped me conceive and deliver this one.

And today I take an opportunity to thank all those who played their part in forming this Thesis, I present today.

I express my gratitude to Ayurved Department of Tilak Maharashtra Vidyapeeth, for opening the doors of PhD for us. Right from the PhD entrance exam, Pre PhD Workshops, Projects, Exams and later Guide allotment they have been very persistent. During this whole process we really felt that we were been polished to perform our best in our PhD Thesis. I would especially like to acknowledge the Ex Dean. Dr. Sadanand Sardeshmukh Sir, his opening speech after Guide allotment was very encouraging. Dr. Abhijit Joshi, Hon.Registrar and Dean, Ayurveda Department. He was the backbone of the Pre PhD Workshops conducted for us and he really did see to it that all of us were well disciplined and sincere in our participation in the Workshops. Dr. Manoja Joshi who would always give suggestions and guidance regarding any queries regarding Thesis submission, Pathak mam, she is the link between us students and the Ayurveda Department. No matter how many queries I had she would always answer them calmly.

I would also like to acknowledge here the efforts of HOD Madam and all the staff of PhD Department for their timely help and cooperation.

I am very grateful to my Guide Dr. Vilas Dole. He has been very supportive right from the selection of the topic and very much respecting of my perspective of the study. He was always available and welcoming each time I visited his home. He and his wife Dr. Mrs. Dole too gave me a homely treatment always. Sir never criticized me but always encouraged me to do better and better. He was the first one who believed my thesis will one day be complete. And this belief he had in me kept me perceiving my task till it reached its destination.

The Dean of our Institute, Dr. Mukund Bamnikar for allowing me to pursue my PhD along with my job.

My colleagues Dr. Archana Gharote, Dr. Subhash Madavi, Dr. Aditi Kulkarni who gave me ideas for my thesis topic. My many PG students of Dept. of Rasashastra at R.A.Podar Medical College Dr. Chinmay, Dr. Sanjana, Dr. Priyanka, Dr. Ruchi, Dr. Abhishek for helping me in Packaging of drug, Labelling, sending samples for Analysis and sometimes keeping track of Trial Patients' follow up too.

Many of my friends and colleagues Dr. Prachi Dalvi, Dr. Jyoti Bande, Dr. Priya Naik, Dr. Pradeep, Dr. Pradnya Kapse for helping me collect the raw material needed for the study.

The doctors from M A Podar hospital for providing me patients for my trial. Especially Dr. Geeta Parulkar for allowing me to screen patients during her medical camps.

My friend Dr. Ranjeet Sawant for helping and encouraging me write my first research article which was needed to be done during the course of this study.

My mother Nancy Gaikwad who always kept herself updated regarding my study and kept encouraging me to complete it on time. She always nagged me for it, which was irritating at times but which constantly reminded me that I have a task at hand which needs to be completed.

My father Mr. Pradeep Gaikwad for soothing me each time I went into depression with regards to my study. He told me to accept and face any situation that may arise with a smile and brave heart.

My in-laws Seema and Anil Gaonkar for taking care of my child each time I was in Pune for my PhD study. My brother in law Rohit and his wife Ridhima too.

My aunty Helen D'souza and uncle Louis D'souza at whose residence I stayed each time I visited Pune. My aunt literally pampered me with lovely food and great comfort always.

My daughter Lakshita for her understanding and love. She was 4 years when my PhD started. She is the one who had to suffer my loss the most as she did not like the idea

of me leaving her and going elsewhere for days for whatever reasons and yet as she grew she accepted this fact. She took interest sometimes, emotionally blackmailed me to take her along sometimes but she did support. So she too played a crucial role by her sacrifice.

And last but the most support I got was from my husband Dr. Santosh Gaonkar. He was by my side though not actively involved during each step of my Phd. During the two 7 days Pre PhD workshop, my exams, entrance and Pre PhD. All the times when I had to visit Pune. Not once did he burden me with any family affairs that could be a hindrance for completing my study. At times when I had given up hope of completing my study he was the one to uplift me and remind me of my capability and strength. He was always understanding of my problems but scolded me whenever he found I was losing my grip over my study. He has been THE person who helped me sail this ship of PhD. And so as much as this thesis is mine, it's his too.

There was a point when I had thought I will not be able to complete my study and that I must give up as it was getting on my nerves but then I thought of all the sacrifices that so many of my loved ones had made so that I could get my PhD. How could I allow all those wishes and hopes to wean off? And then I made up my mind to complete what I had began.

Thank you all for all that you have done. I dedicate my thesis to all of you.

ABBREVATIONS

Sr. No.	Abbreviation	Full Form
1	Ch. Su	Charak Sanhita Sutrasthan
2	Su. Su	Sushrut Sanhita Sutrasthan
3	Su. Ni.	Sushrut Sanhita Nidansthan
4	Su. Sha.	Sushrut Sanhita Sharirsthan
5	Su. Chi.	Sushrut Sanhita Chikitsasthan
6	A. S.U	Ashtanga Sangraha Uttarsthan
7	A. H. U	Ashtanga Hruday Uttarsthan
8	Y.R.	Yogratnakar
9	B.S.	Bhavprakash Sanhita
10	B.N	Bhavprakash Nighantu
11	R.N.	Raj Nighantu

ABSTRACT

The disease *Vyanga* has been described in Sushrut Sanhita, Madhav Nidan, Ashtanga Hruday, under the heading *Kshudra Rog*. The symptom complex of *Vyanga* consists of thin, painless and blackish discolouration of various sizes and shapes over the face. Vitiation of *Vaat* and *Pitta* are supposed to be the main etiological factors as per these Texts. This symptom complex is akin to Melasma as described in Modern medicine. No specific etiology has been mentioned for this, however excessive exposure to sun, hormonal imbalance, etc have been mentioned as attributing factors.

In Ayurveda the treatment part of this disease is mainly applications of *Lepa*, *Malhar*. In Chikitsa Prabhakar various medicinal substances have been mentioned for use of external application such as Mango seed(Magnifera indica), *Jamun* seed(Syzygium cumini), *Dadim* peels(Punica granatum), *Yashtimadhu* root(Glycyrrhiza glabra), *Bala* root(Sida cordifolia) and *Laksha*(Laccifera lacca). Hence it was decided to convert these substances into a cream form. This cream was named as *Lakshadi Malhar*. A cream prepared from E wax, PEG 150 stearate, EDTA, Teel oil, Glycerine and preservative was used as a Control drug. Both the drugs were analysed and standardized.

The patients were told to apply this cream twice in a day. Total 200 patients of known *Vyanga* were divided into 2 groups and a randomized controlled double blind clinical trial was conducted. The final results were statistically analyzed and evaluated. Though the results were encouraging in both the groups the trial group showed better results than the Control group.

INDEX

INTRODUCTION

When we see a person what is the first thing that we notice about them?

It is their "looks". Their face, skin colour, then the clothes, overall appearance and then rest.

But the first thing that we notice is the face. And that does put an impression on our mind. Now, we could have an argument here on how the external looks doesn't matter but the beauty within does. Which is true too and yet, it does matter.

Everyone wants to look good. Everyone wants to put a positive impression on the people they meet. No one likes when someone comments something negative about how they look. Although we try to ignore this fact, it is true and has been proved from time to time.

Good skin makes you feel beautiful. Good skin helps you become more confident. Good skin is a key component of overall beauty and good health, and it can also affect your emotional and mental well-being.

From acne as a teenager to fine lines in middle age, skin problems can affect your confidence and self-esteem. When you have healthy skin, you are able to face daily activities and life's challenges with more confidence. Good skin is part of a healthy lifestyle too.

Unhealthy habits take a toll on us both physically and emotionally. A poor skin care regimen, frequent breakouts, age spots, fine lines and other skin issues can be symptoms of an unhealthy overall lifestyle.

Experts say that whenever you develop a skin condition, it will not only affect your skin or your physical appearance but your emotional and mental well-being as well. Proper skin care can go a long way in improving your overall beauty and good health and it can also affect your self-confidence.

The "Skin Ego"[1] is part of our specific identity, it expresses the mutual relationship between our psyche, thoughts and emotions and the skin and it is part of the most

modern trends in cosmetic care. Our perception of our body influences whether and how we accept our identity. This positive relationship with the body, which is a true driving force of life, in fact shapes our relationship with others.

Proper skin care facilitates the full development of this "cooperation" between the psyche and the skin, allowing you to be satisfied, happy and full of self confidence…. in other words – beautiful.

Now some might ask, "Whom does this really matter to?". Urban crowd? Rural crowd? Youngsters?..Middle age?...Models?.. I say "everyone". Although some might deny, it still holds true. I work in a "Skin Out patient Department" at my institute and I have seen people of both sexes, various socio economical background, from different places approach the OPD for problems related to their looks. Could Be Acne, darkening of skin, Skin tan, Some rash, moles, warts, etc.

Bottom line, everyone wants to look good.

Keeping the above aspects and experiences in mind I decided to work on something related to skin and cosmetic. And finally took *Vyanga* (Mealsma) for my study.

Vyanga has been described under *Kshudra Roga* as *Aruja* (painless), *Tanu* (thin layered), *Shyava* (Dark coloured/Brown) or *Shyamal* (Dark coloured/black), *Mandal* (circular patches) that appear on the face.[2] It is caused due to anger, physical exertion which vitiates *Vaat* and *Pitta dosha* and which in turn reflects on the face in the form of *Vyanga*. *Kshudra roga* are generally non significant, small diseases and yet we see that these diseases are difficult to get rid off.

Melasma which is similar to *Vyanga* is nothing but hypermelanosis of the skin caused due to human melanogenesis.[3] It reflects on the skin in the form of light to dark brownish patches on the cheeks, nose, forehead, chin and even upper lip. This melanogenesis is caused due to number of reasons such as exposure to sun, hormones, genetic, etc.

From the above description we can very well consider that the signs and symptoms of *Vyanga* are similar to that of Melasma described in Modern Medicine. Hence for this particular project Melasma and *Vyanga* are considered as synonyms.

This disease affects the face, the first thing that is noticed about anyone and thus getting rid of this skin condition is a priority for everyone.

Statistics show that in Northern India 6.9% , Western India 10.8% adults have pigmentary disorders whereas in Southern India 3.28% suffer from hypopigmentary disorders and 1.54% have hyperpigmentary disorders.[4,5]

Melasma is the most common pigmentary disorder in India and South-East Asia with prevalance ranging from 0.25% to 4% respectively.[4] Common among women aged 20-50 yrs than men (10%).[6] Common pattern being Centero-facial(64%). Some studies suggest that upto 75% of women may develop Melasma during pregnancy.[7] Though many triggering factors have been identified such as sun exposure, pregnancy, hormone therapy, yet the chief cause of Melasma is not yet clear.

Most of the time Melasma disappears after discontinuation of the triggering factors but for many it stays for long. Also there are 6% chances of relapse. Currently Asia alone accounts for 37% of the overall worldwide sales in the number of products in the market to treat pigment issues.[8]

There have been many studies before to explore various formulations in *Vyanga*. Oral formulations alone or along with local application or just local applications. In skin diseases local applications play a vital role as they come directly in contact with the affected part.

In Ayurveda local applications have been described in the form of *Lepa, Malhar, Upanaha, Avachoornan, Avagharshan.* For local applications in *Vyanga, Lepa* and *Malhar* could be used. Amongst these, applying *Lepa* is a bit inconvenient as it requires time, impractical to apply when in travel or outside home, has to be prepared fresh each time, also the *choorna* used for the *Lepa* have a low shelf life. *Malhars* on the other hand are easy to apply, could be carried along, has a long shelf life but they are very oily, one cannot apply it and then go out to work.

The effect of *Lepa* lasts only till it becomes dry and so to increase the duration of effect, it was decided to use these same drugs in *Malhar* form. Effect of *Malhar* lasts for about 5 to 6 hours and due to effect of *sneha dravya* present in the *Malhar* the dryness of the skin is reduced and penetration of the drugs through skin pores is facilitated.

Nowadays people prefer oil in water creams as they are less greasy, easy to apply, easy to wash off, comfortable and thus cosmetically more acceptable. Such creams have more water and less oil as against the traditional *Malhar kalpana*.

Multiple therapies are available in both Ayurveda and Modern medicine for treating *Vyanga* (Melasma). I wanted to prepare a formulation which would be economical, feasible, easy and ready to use and also easy to carry around.

So, after giving a deep thought to all the pros and cons of the drug formulation that could be useful as well as acceptable to the current population of *Vyanga* I decided to prepare an Ayurvedic cream which is an oil in water emulsion.

Therefore six *dravya* which have been indicated for *Vyanga* in various Ayurved texts were selected and composed into a cream. This cream was named as "*Lakshadi Malhar"* as *Laksha* was the first ingredient.

To find a relation between *Prakruti* and *Vyanga*, "*Prakriti* examination" was conducted and keeping in mind the psychological effects of skin disease on people the "Quality of life Questionnaire" was also taken into consideration.

This study attempts to find a true remedy for *Vyanga*, to evaluate the various causes that could have triggered them, to see the role of diet in curbing them and to observe the after effects too when the treatment is stopped.

REVIEW OF PREVIOUS WORK DONE before synopsis submission in 2015 [9,10,11]

The published work on local application in *Vyanga* was reviewed during the synopsis submission ie. 2015. Total 3 published trials were discovered. Among these 1 was single armed and the other 2 were comparative studies. Age group of patients was 16 to 60years. 15 to 40 patients were recruited in each of these trials. Duration of the study was 15 days, 21days and 45days each. Among these trials 2 trials were only *Lepa* application and the last one was lepa plus oral drug.

The medicines selected in the above trial were *Varnya gana, Arjun twak, Raktachandan, Jatiphala choorna* for *Lepa* and *Panchanimba choorna* for oral consumption.

From the above trials it was assessed that none of them studied the drugs involved in this trial and no cream was ever used for local application.

REVIEW OF PREVIOUS WORK DONE From 2015(Synopsis submission) till 2020 [12-20]

Total 9 clinical trials have been conducted and published in the given 5 years. Among these 2 are comparative studies between 2 drug groups and 7 are single armed.

The Age group for the study is in the range of 18 to 60 years. Number of patients in the trial range from 10 to 60 patients. In 1 trial though 100 patients were recruited in a single armed group. The duration of the study varied from 15 days(2 trials), 30days(4 trials), 60 days(2 trials) and 90 days(1 trial). Among the studies, 6 trials were of *lepa* application single group or comparative study, 1 trial of *lepa* as well as oral medication, 1 trial of Ointment and Oral medication and 1 trial of cream application.

The medicines selected for the above trial were *Arjun twak choorna*(3 trials), *Manjishta choorna(*3 trials), *Varun twak choorna, Ingudi Phalamajja, Vatankur choorna, Varnya gana*(2 trial), *Mukha kanti lepa* and *Anantamul Ghana*.

From the above studies it was assessed that none of the studies included the drugs selected in this trial and thus the trial drug in this study is first of its own kind. Also since cream is used in the current trial the comparative is done with the additive drugs as a control.

AIMS AND OBJECTIVES

AIM

- To study the efficacy of *Lakshadi Malhar* (cream) on *Vyanga* (Melasma).

OBJECTIVES

- To correlate *Vyanga* with Melasma
- To prepare *Lakshadi* cream.
- To standardize the *Lakshadi* cream
- To evaluate the efficacy on signs and symptoms of *Vyanga* (Melasma)
- To see the effects of the drug on the Quality of Life of the patient.
- To study the *Prakruti* of the patients involved in the study.

HYPOTHESIS

Lakshadi Malhar containing *Bala, Yashtimadhu, Laksha, Aamra beej, Jamun beej* and *Dadim twak* (indicated for *Vyanga*) is more efficacious than the Control Group in treating *Vyanga*.

NULL HYPOTHESIS

There is no difference between the efficacy of *Lakshadi Malhar* and the Control Group.

LITERATURE REVIEW

In this chapter we study various aspects of all the terminologies related to this research.

KSHUDRA ROGA

Since *Vyanga* is described under *Kshudra rog* we will try to understand this terminology first.

Madhav Nidan, Sushrut Samhita, Ashtanga Sangraha, Ashtanga Hruday and Yogratnakar have described *Vyanga* as a *Kshudra roga*.

There are many speculations to describe the word "*Kshudra*".

- Some say they are the ones that have not been included in any particular category.
- It means small, insignificant, not much known or explained about (*alpa, swalpa, alpavadhi*).
- They are considered to be low or unholy (*Adhama*).
- Even cruel or unbearable (*Krura*)
- Some say they are diseases that occur in children only.
- Whose causes, symptoms, treatment is very simple.[1]

Kshudra roga also signifies a group of minivial or small diseases. Yet we can see diseases like *Agnirohini* and *Parivartika* included among them which are severe diseases.

Acharya Sushrut has described 44, Acharya Vagbhat 36 and Acharya Madhav 43 of *Kshudra roga*. Acharya Vagbhat has renamed many *Kshudra roga* described by Acharya Sushrut. Such as *Mashak* as *Mash, Nyaccha* as *Laachan, Andhalaji* as *Alaji* etc. Acharya Sushrut has included *Pama* and *Vicharchika* in both *Kshudra roga* and *Kushta*.[1] Charaka Samhita has not devoted a separate chapter for these diseases although he has mentioned them in different chapters.

Kshudra rog given in various Ayurvedic texts are as follows:

Table No.: 1: *Kshudra rog* in various Ayurvedic texts

Sr. No.	**Sushrut Sanhita[36] 44**	**Ashtang Sangraha[37] 36**	**Ashtanga Hruday[38] 36**	**Madhav Nidan[39] 43**	**Yogratnakar [40] 44**
1	*Ajagallika*	*Ajagallika*	*Ajagallika*	*Ajagallika*	*Ajagallika*
2	*Yavaprakhya*	*Yavaprakhya*	*Yavaprakhya*	*Yavaprakhya*	*Yavaprakhya*
3	*Andhalaji*	*Alaji*	*Alaji*	*Antraalaji*	*Andhalaji*
4	*Kachapika*	*Kachapi*	*Kachapi*	*Kachapi*	*Kachapika*
5	*Pansika*	*Pansika*	*Pansika*	*Pansika*	*Pansika*
6	*Pashan-gardabh*	*Pashan-gardabh*	*Pashan-gardabh*	*Pashan-gardabh*	*Pashan-gardabh*
7	*Yauvan-pidaka*	*Mukha-dushika*	*Mukha-dushika*	*Yuvanpidika*	*Yauvanpitika*
8	*Padmini-kantak*	*Padma-kantak*	*Padma-kantak*	*Padmini-kantak*	*Padmini-kantak*
9	*Vivruta*	*Vivruta*	*Vivruta*	*Vivruta*	*Vivruta*
10	*Masurika*	*Masurika*	*Masurika*	--	--
11	*Visphotak*	*Visphota*	*Visphota*	--	--
12	--	*Viddha*	*Viddha*	--	--
13	--	*Gardabi*	*Gardabi*	--	*Gardabhika*
14	--	*Mandala*	*Mandala*	--	--
15	*Kaksha*	*Kaksha*	*Kaksha*	--	*Kaksha*
16	--	*Gandha-nama*	*Gandha-nama*	*Gandhamala*	*Gandha*
17	--	*Rajika*	*Rajika*	--	--
18	*Jalgardab*	*Jalgardab*	*Jalgardab*	*Jalgardab*	*Jalgardab*
19	*Agnirohini*	*Agnirohini*	*Agnirohini*	*Agnirohini*	*Agnirohini*
20	--	*Irigallika*	*Irigallika*	--	*Irivellika*
21	*Vidarika*	*Vidari*	*Vidari*	*Vidarika*	*Vidarika*
22	*Sharkar-arbudh*	*Sharkar-arbudh*	*Sharkar-arbudh*	*Sharkara*	*Sharkar-arbudh*
23	*Valmikam*	*Valmik*	*Valmik*	*Valmik*	*Valmik*

24	*Kadaram*	*Kadaram*	*Kadaram*	*Kadara*	*Kadar*
25	--	*Ruddha-gudam*	*Ruddha-gudam*	--	--
26	*Chippa*	*Chippam*	*Chippam*	*Chippa*	*Chippa*
27	*Kunakha*	*Kunakha*	*Kunakha*	*Kunakha*	*Kunakha*
28	*Alasam*	*Alasam*	*Alasam*	*Alasak*	*Alas*
29	--	*Lanchanam*	*Lanchanam*	--	--
30	*Vyanga*	*Vyanga*	*Vyanga*	*Vyanga*	*Mukhavyanga*
31	*Nilika*	*Nilika*	*Nilika*	*Nilika*	*Nilika*
32	--	*Prasupti*	*Prasupti*	--	--
33	--	*Utkot*	*Utkot*	--	--
34	--	*Kot*	*Kot*	--	--
35	--	--	--	*Gardabhika*	--
36	*Indravruddha*	--	--	*Indraviddha*	*Indravruddha*
37	--	--	--	*Irivellika*	--
38	*Anushayi*	--	--	*Anushayi*	*Anushayi*
39	*Padadarika*	--	--	*Padadari*	*Padadarya*
40	*Indralupta*	--	--	*Indralupta*	*Indralupta*
41	*Darunak*	--	--	*Darun*	*Darunak*
42	*Arunshika*	--	--	*Arunshika*	*Arunshika*
43	*Palit*	--	--	*Palit*	*Palit*
44	*Jatumani*	--	--	*Jatumani*	*Jatumani*
45	*Tilkalak*	--	--	*Tilkalak*	*Tilkalak*
46	*Mashak*	--	--	*Mashak*	*Maash*
47	*Nyaccha*	--	--	*Nyaccha*	--
48	*Parivartika*	--	--	*Parivartika*	*Parivartika*
49	--	--	--	*Avapatika*	--
50	*Niruddha-prakash*	--	--	*Niruddha-prakash*	*Niruddha-prakash*
51	*Sannirudha-gudha*	--	--	*Sannirudha-gudha*	*Sannirudha-guda*
52	*Ahiputan*	--	--	*Ahiputan*	*Ahiputan*

53	*Vrushan-kacchu*	--	--	*Vrushan-kacchu*	*Vrushan-kacchu*
54	*Gudabransha*	--	--	*Gudabransha*	*Gudabransha*
55	--	--	--	*Varaha-dranshta*	--
56	*Pama*	--	--	--	--
57	*Vicharchika*	--	--	--	--
58	*Raksa*	--	--	--	--
59	*Charmakil*	--	--	--	*Charmakil*
60	*Avapatika*	--	--	--	*Avapatika*
61	--	--	--	--	*Sukardanshtra*

Majority of these are diseases of the skin. *Vyanga* is one of the skin disease.

Classification of *Kshudra rog* as per their location

Head and Face: *Khalitya, Palitya, Darunaka, Arumshika, Panasika, Pashangardabh, Valmeeka, Vyanga, Nileeka, Irrivelika, Yavanpidika*.

Upper limbs: *Chippa, Kunakha, Valmeeka*.

Madhya Shareer and genital organs: *Agnirohini, Kaksha, Ahiputana, Gudabhramsha, Charmakil, Vrushanakacchu, Niruddhaprakasha, Sanniruddaguda* and *Avapatika.*

Lower limbs: *Padadari, Alasaka, Vipadika, Anushayi, Kadara* and *Valmeeka.*

General Treatment for *Kshudra roga*.

All types of *kshudra rogas* to be treated with *Shastra*(surgery), *Kshara*(application of alkalies, or *Agnikarma, Lepana* (Applications) and *Raktasravana* (Blood letting.)

DRUGS SELECTED FOR *LAKSHADI MALHAR KALPANA*

***LAKSHA*[15]**

It is acquired from an insect named Laccifer lacca. On old trees such as Ficus virens(*Umbar*), Ficus religiosa (*Pipal*), Indian jujube (*Bor*), these insects secrete a reddish, sticky liquid around themselves for self protection. The lac found on *Pipal* tree is said to be the best.

Synonyms:

Hindi, Marathi : *Laakh*. English: Lac

लाक्षा वर्ण्या हिमा बल्या स्निग्धा च तुवरालघुः ।
अलक्तको गुणैस्तद्वद्विशेषाद्व्रयङ्गनाशनः ॥

B.N.193-195

Properties: *Sheet virya, Snigda* and *Laghu*.

***Rasa** : Kashay, **Virya**: Anushna, **Vipaak**: Katu*.

Raktapitaaghna, Jwarnashak, Urakshat, Daahashamak, Balya, Vyanga nashak, Kushtagna and *Varnya.*

Doshagnata: It is *Kaphapitaashamak.*

Because of its *Varnya* and *Vyanga nashak* property it was selected in *Lakshadi Malhar*.

***DAADIM* PEEL**

Latinname: Punica granatum

Hindi: *Anaar*. Marathi: *Dalimba*. English: Pomogranate

तत्तु स्वादु त्रिदोषघ्नं तृडदाहज्वरनाशनम ।
हृत्कण्ठमुखगन्धघ्नं तर्पणं शुक्रलं लघु ॥
कषायानुरसं ग्राही स्निग्धं मेधाबलावहम ॥

B.N.102-103

Properties: *Laghu* and *Snigdha*

***Rasa**: Madhur, Amla and Kashay **Virya**: Anushna* and ***Vipaak**: Madhur/Amla*.

It is *Pittagna* and *Shoth hara*. [16]

It is also *Grahi* and *Krumigna*. Thus used in *Atisaar* and *Pravahika*.

Doshagnata*: Tridoshshamak*

Chemical constituents: It contains Gallotannic acid 28%.[17]

It hydrates and protects the skin from pollutants and toxins, restores pH balance and locks moisture in the skin.

JAMUN **SEEDS**

Latin name: Syzygium cumini

Hindi: *Jamun*. Marathi: *Jambul*. English: Black berry.

जम्बू कषायमधुरा श्रमपित्तदाहकंठार्तिशोषशमनी कृमीदोषहन्त्री ।

R.N.

Properties: *Laghu* and *Ruksha*

Rasa*: Kashay, Madhur,Aamla* ***Virya****: Sheet* and ***Vipaak****: Katu*

Doshaghnata*: Kapha* and *Pitta shamak*

Fruit *majja* is used as a *Lepa* in *Mukhadushika*(Acne).

Chemical constituents: It contains Ellagic acid, Yellow essential oil, chlorophyll, resin, gallic acid, albumin, a glucoside Jamboline. It has astringent effects and is thus used in skin disorders.[18] and *Twakdoshahar*.[19]

MANGO SEED

Latin name: Magnifera indica

Hindi: *Aam*. Marathi: *Amba* English: Mango

आम्रबीजं कषायं स्याच्छर्द्यतीसारनाशनम ।

ईषदम्लच्च मधुरं तथा हृदयदाहनुत ॥

B.N.17

Properties: *Guru,*

Rasa*: Kashay, Madhur* and *slight Amla.* ***Virya****: Sheet* and ***Vipaak****: Madhur*

Hrudya daah, Chardi, Atisaar nashak.

Doshaghnata*: Kapha* and *Pitta shamak*

Chemical constituents: It contains Vitamin A, B,D and C, Citric acid and Galic acid.[20]

Seeds are Antihelminthic, reduces inflammation of uterus , Antidiuretic, Constipative

and useful in Menorrhagia and Leucorrhoea. Fruit is also said to be Varnya.[21]
Mango seed oil is an excellent moisturizer, nourishing and preventing drying of skin.

BALA ROOT

Latin name: Sida cordifolia

Hindi: *Bariyaar*. Marathi: *Chikna*. English: Country mallow

बलाचतुष्टय शीतं मधुरं बलकान्तिकृत ।
स्निग्धं ग्राही समीरास्त्रपित्तास्त्रक्षतनाशनम ॥

B.N. 144

Properties :

Laghu, Snigdha and *Pichhil*

Rasa*: Madhur* ***Virya****: Sheet* and ***Vipaak****: Katu*

It is *Rasayan*. The roots are indicated in *Rajyakshma, Visham jwar, Shlipad* and is *Aayu vardhak*.

Doshaghnata*: Vaat pittaghna.*

Chemical constituents: It contains alkaloids, ephedrine, pseudoephedrine, phytosterol, mucin, fatty acids, potassium nitrate and resin.

It is Analgesic and Antiinflammatory hence used externally in *Vranshotha* and Eye diseases. It also acts as *Rakta prasadak* hence used in *Vyanga*.[22]

YASHTIMADHU ROOT

Latin name: *Glycyrrhiza glabra*

Hindi: *Mulethi*. Marathi: *Jeshtimadh*. English: Liquorice root

यष्टी हिमा गुरूः स्वाद्वी चक्षुष्या बलवर्णकृत ।

B.N. 62.

Properties :

Guru and *Snigdha*.

Rasa *: Madhur* ***Virya****: Sheet* and ***Vipaak****: Madhur*.

Doshaghnata*: Vaat* and *Pitta shamak*

It is *Balya, Rasayan, Vrushya, Swarya, Netrya, Mutra janan, Stanya vardhak, Shoth har, Raktaprasadak* and *Vran ropak*.

It is 50 times sweeter than sugar.

Chemical constituents: It contains Glycyrrhizin about 10%, starch 30%, sugar

5–10%, oil, *raal* and asparagin 1%.[23]

It is *Varnya* and *Raktaprasadak* hence used in various *lepas* indicated for *Vyanga*. For its *Varnya guna* it is used both internally and externally.

Mango seed, Jamun seed and Dadim peel have been indicated by Chikitsa Prabhakar[3], *Bala* and *Yashtimadhu* by Acharya Sushrut and *Laksha* by Acharya Bhavprakash for *Vyanga.*

LAKSHA getting formed on a plant

LAKSHA

BALA plant

BALA roots

JAMUN fruits

JAMUN seeds

YASHTIMADHU plant

YASHTIMADHU roots

MANGO Fruit

MANGO Seed

POMOGRANATE Fruits

POMOGRANATE Peels

***TEEL* OIL (Sesame oil)**

It is acquired from sesame seeds. These seeds contain 37 to 57% oil. This oil is extracted from sesame seeds by cold extraction method. Teel is of 3 types white, black and red. In market the oil available is of white sesame. In Ayurveda, Teel oil is considered to be the best oil for use in all the processes.

The sesame seed, from an Ayurvedic perspective, is sweet, pungent, astringent, and bitter, and has a heating effect. Its greatest benefit is in balancing *Vata*. It grows in a dry climate, and in turn, is beneficial when the dry quality is in excess. Nourishing, calming, and warming, sesame oil is highly beneficial for massage.

तिलो रसे कटुस्तिक्तो मधुरस्तुवरो गुरूः ।
विपाको कटुकः स्वादुः स्निग्धोष्णाः कफपित्तनुत ॥

B.N.63-64

Properties:

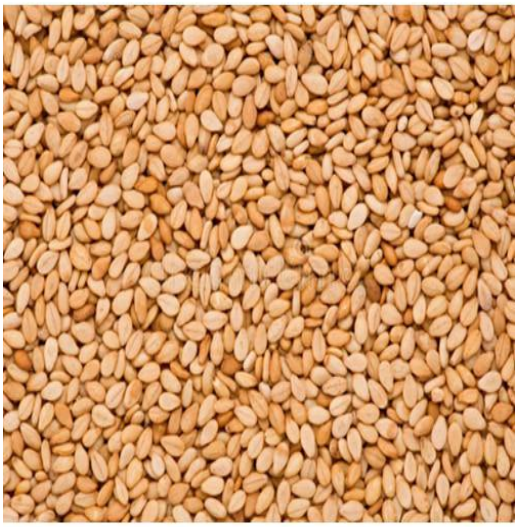
Guru, snigdha, smooth.

Sweet, bitter, astringent R***asa***. *Ushna* V***īrya***. *Sweet* V***ipāka***.. All right for moderate K*apha.*

Performs functions like *Snehan, Mutrajanan, Balya, Vranashodhan, Ropan* and *Keshavardhak.*[24]

Doshaghnata: Increases *Pitta*, decreases *Vāta*

Teel oil is used in preparation of *malhar* as an oil phase. It will act as a natural moituriser. When used topically it may reduce cell damage. It nourishes and moisturizes the skin. It may also protect our skin from UV rays. It can resist 30% of UV rays. This is likely due to its antioxidant property.[25]



SESAME seeds

SESAME Oil/TEEL oil

OTHER INGREDIENTS USED TO PREPARE MALHAR KALPANA

EMULSIFYING WAX

It is a cosmetic emulsifying ingredient. It is a white waxy solid with a low fatty alcohol odour. The ingredients for emulsifying wax are cetearyl alcohol and a polysorbate. Natural emulsifying wax are also available in the market today. It is olive oil derived and composed of cetearyl olivate and sorbitan olivate.[26]

EDTA

It is ethylene diamine tetra acetic acid. It helps to improve the stability and enhance the appearance of cosmetic products. It is a synthetic ingredient. It keeps other ingredients from causing unwanted changes to a product's texture, odor and consistency. EDTA is safe for use in cosmetics.[27]

GLYCERINE

It is used as a moisturizer to treat or prevent dry, rough,scaly, itchy skin and minor skin irritations. It is a humectants . In cosmetics it is used with occlusives to trap the moisture it draws into the skin. It is also used for skin lightening, face whitening and even skin structure. It also protects the skin from tanning. [28]

PEG 150 stearate

It is the Polyethylene Glycol Diester of stearic acid. Used in beauty products and cosmetics as an emulsifier and thickening agent. It is used upto 5% of concentration in cosmetics and is safe in the present practices and use.[29]

SODIUM BENZOATE

It is a preservative added to some sodas, packaged foods and personal care products to prolong shelf life. It is an odorless, crystalline powder made by combining benzoic acid and sodium hydroxide. The Environmental Working Group ranks the additive at a hazard level of 3 on a scale of 0 to 10. Meaning that overall risk of its use is relatively low. [30]

LAVENDER OIL

It is an essential oil derived from the lavender plant. It can be taken orally, applied to the skin and breathed in through aromatherapy. It can benefit the skin in numerous ways. It has the ability to lessen acne, help lighten skin and reduce wrinkles. Since lavender oil has antifungal and reduces inflammation, it helps in eczema and also psoriasis. Lavender oil can aid in skin lightening, it reduces dark spots and hyperpigmentation.[31]

Colour: Colour was needed to be added in Control Group *Malhar* to make it look like *Lakshadi Malhar*. There are certain rules to choose the colour to be added in a cream.

- All colors used in a formula must be approved by the FDA.
- All colors must meet specifications before being used.
- Colors are restricted in the ways and amounts in which they can be used.

In Drug and cosmetics Act and Rule 1945 the list of the approved colours has been published.

We chose Brown and Orange colour.

E WAX

EDTA

PEG 150 Stearate

SODIUM BENZOATE

GLYCERINE

LAVENDER OIL

VYANGA

Vyanga has been described under *Kshudra rog* by most of the *granthakaras*. Let us see their detailed evaluation as per each text.

CHARAKA SANHITA

He has described *Vyanga* in "Trishotiya chapter" in Sutrasthan. *Vyanga* along with *Pillu, Tilak* and *Nilika* have been described as *Ekadeshiya shotha* disease.[4]

Symptoms: not mentioned.

Samprapti:

यस्य प्रकुपितं पित्तं शोणितं प्राप्य शुष्यती ।
तिलका पिप्लवो व्यङगा नीलिका तस्य जायते ॥

Ch. Su.18/25

Causes

↓

Aggravates *Pitta* dosha

↓

Aggravated *Pitta* settles in *Rakta* and dries there

↓

Tilak, Pillu, Vyanga and *Nilika* occur

Causes: No specific causes

Site of expression: Not mentioned.

***Dosha**: Pitta,* ***Dushya**: Rakta*

Acharya Charak has also described *Vyanga* as a *"bahirmargaj vyadhi*", the disease that occurs in the extremities.[9]

SUSHRUT SANHITA

Acharya Sushrut has described *Vyanga* in 13th chapter of Nidansthan "*Kshudra roga nidanam*".[5]

Symptoms: *Neeruja* (Painlesss), *Tanu* (Thin), *Shyava* (Dark coloured/Brown) *Mandal* (Circular) patches that appear on face. But when the same patches appear elsewhere on the body it is known as *Nilika*.

क्रोधायासप्रकुपितो वायुः पित्तेन संयतः ।
मुखमागत्य सहसा मण्डलं विसृजत्यतः ॥
नीरूजं तनुकं श्यावं मुखव्यङ्गं तमादिशेत ॥

Su.Ni. 13/45-46

Samprapti:

Anger, Exertion

↓

Aggravates *Vaat* dosha

↓

Aggravated *Vaat* combines with *Pitta*

↓

Blackish, Painless, Thin patches on the face

↓

Vyanga

Causes: Anger and exertion

Site of expression: Face

Dosha: *Vaat* and *Pitta*

MADHAV NIDAN

Vyanga has been described in **Madhavnidan** under *Kshudra roga nidanam*.

Symptoms: Painless, small, blackish patches that appear on the face.[2]

Vyanga **Samprapti**:[3]

Anger and Exertion/Exhaustion

↓

Aggravates *Vaat* dosha

↓

Aggravates *Pitta* dosha

↓

Blackish discolouration on face

↓

Vyanga

Causes: Anger and Exertion

Site of expression: Nose and on the cheeks besides the nose.

Dosha: *Vaat* and *Pitta*

Madhavnidan and Yogratnakar have accepted the physiology similar to Sushrut Sanhita.

VAGBHAT

Acharya Vagbhat too has included *Vyanga* in *Kshudra roga* in *Uttarsthan*.[6]

Symptoms: *Shyamal* (Dark coloured/Black), *Tanu* (thin), *Mandal* (circular) patches on face.

Samprapti:

शोककोधादिकुपिताद्वातपित्तानमुखे तनु ।
श्यामलं मण्डलं व्यङ्गं ॥

A.H.U.31/28, A.S. U. 31/28

Anger, Sadness

↓

Aggravates *Vaat* and *Pitta* dosha

↓

Blackish, Thin, circular patches on the face

↓

Vyanga

Causes: Anger and Sadness--

Site of expression: Face

***Dosha**: Vaat* and *Pitta*

Types of *Vyanga*

Only Ashtanga Sangraha and Ashtanga Hruday have mentioned types of *Vyanga*[7]

1. *Vaataj Vyanga: Parush*(rough) in touch and appearance and blackish
2. *Pittaj Vyanga*: Reddish or bluish in colour
3. *Kaphaj Vyanga*: White in colour and itchy.

4. *Raktaj Vyanga*: Reddish, with tingling sensation

Location of *Vyanga*

Skin has 7 layers as per Ayurveda. *Avabhasini, Lohita, Shweta, Tamra, Vedini, Rohini* and *Mansadhara* superficial to deeper. *Vyanga* occurs in the second layer which is known as *Lohita*.

Following chart enlists the disease that occur in each layer of the skin.[8]

तस्याधिष्ठानं द्वितीया लोहिता नाम त्वक ।

Su.Sha.4/4

Table No.: 2: Skin layers and the diseases occurring in them.

Sr. No.	**Name of the skin layer**	**Diseases that occur in the layer**
1	*Avabhasini*	*Siddhma, Padmakantak*
2	*Lohita*	*Tilkalak, Nyacha, Vyanga*
3	*Shweta*	*Charmadal, Ajagallika, Mashak*
4	*Tamra*	Various *types of Kilas and Kushta*
5	*Vedini*	*Visarpa*
6	*Rohini*	*Granthi, Apachi, Arbud, Galganda*
7	*Mansadhara*	*Bhagandhar, Vidradi, Arsha*

Skin layers described by Acharya Sushruta and modern anatomists can be correlated as follows.[8]

1.	*Avabhasini* ↑			
2.	*Lohita* ↓	stratum corneum	↑	
3.	*Shweta*	stratum lucedum		Epidermis
4.	*Tamra*	stratum granulosum		
		stratum spinosum	↓	
5.	*Vedini*	papillary layer	↑	Dermis
6.	*Rohini*	reticular layer	↓	
7.	*Mansadhara*	Hypodermis		

So as per the above correlation we can say that *Vyanga* is Epidermal in occurence.

Differential Diagnosis of *Vyanga*. [10]

Vyanga needs to be differentiated from *Nyaccha, Tilkalak* and *Nilika* which seem to have similar symptoms like *Vyanga* and are yet different.

Table No.: 3: Differences between various skin discoloration diseases

Parameters	***Tilkalak***	***Nyaccha***	***Vyanga***	***Nilika***
Site	Anywhere on the body	Anywhere on the body	On face	Other than face
Colour	Black	Black or white	Blackish	Blackish
Shape	Sesame like	Round	Round	Round
Pain	Painless	Painless	Painless	Painless
Size	Sesame like	Small or big	small	small
Dosha	All 3 doshas	Not Known	*Vaat Pitta*	*Vaat Pitta*
Appears when?	By birth & After birth too	By birth	After birth	After birth

TREATMENT OF *VYANGA*

Acharya **Sushrut** has mentioned *Siraved* and *Lepa* as treatment for *Vyanga*. It has to be done on veins near the forehead. *Lepa* should be applied after rubbing the skin with *Samudraphen. Yashtimadhu* and *Haridra lepa, Krushna chandan, Gairik* and honey *Lepa, Kalka* of bark of plants having *Ksheer*, etc.[11]

न्यच्छे व्यङ्गे सिरामोक्षो नीलिकायां च शस्यते ।
यथान्यायं यथाभ्यासं लालाटयादिसिराव्यधः ।
घृष्टवा दिहयात्त्वचं पिष्टवा क्षीरीणां क्षीरसंयताम ॥
बलातिबलयष्टयाहवरजनीर्वा प्रलपपनम ।
पयस्यागुरूकालीय लेपनं वा सगैरिकम ।
क्षौद्राज्ययुक्तया लिम्पेदंष्ट्राया शूकरस्य च ॥
कपित्थराजादनयोः कल्क वा हितमुच्यते ॥

Su. Chi. 20/34-36

Ashtanga Sangraha has described treatment as per the types of *Vyanga*.[12]

In general *Raktamokshan* and *Lepa* has been mentioned for all the types of *Vyanga*.

Vataj Vyanga*: Aushadhi siddha ghrut paan, abhyanga, navan nasya* and *saghrut lepa. Devdaru, nyagrodha, badarmajja, vidanga, bilva, utpal, shatavari*, etc have been given.

Pittaj Vyanga*: Vaman, Virechan, Raktamokshan, Nasya* and *Lepa* have been indicated. *Dravya* like, *Kakmachi, Chandan, Lodhra, Madhuk, Padmak, Sariva, Bala,* etc have been given for oral consumption aswell as *Lepa*.

Kaphaj Vyanga*: Ghrutpaan, Nasya, Abhyanga* and *Lepa*. etc are used.

Raktaj Vyanga*: Sira ved* followed by *Snehapaan*, *Vaman* and *Virechan* and *Pralep*. *Chandan, Madhuk, Utpal, Kadalimool*, etc.

लांचनादित्रये कुर्याद्यथासन्नं शिराव्याधम ।
लेपयेत्क्षीर पिष्टैश्च क्षीरिवृक्षत्वमङ्कुरैः ॥

A.H.U.32/15

In **Bhavprakash Samhita** *Siraved*, *Pralep* and *Abhyanga* has been indicated for treating *Vyanga, Nilika, Tilkalak* and *Nyaccha*.[13]

Lepa such as, *Manjishta* and honey, *Vatankur* and *Masoor*, *Arkasheer* and *Haridra*, etc.

सिरावेधैः प्रलेपैश्च तथाऽभ्यङ्गैरूपाचरेत ।
व्यङ्गं च नीलिकां वाऽपि न्यच्छंच तिलकालकम ।

B.S.

Yogratnakar has described various *Lepa* for *Vyanga*. *Dravya* such as *Arjun twak, Manjishta, Vatankur, Masoor, Bhanga* leaves, *Arka dugda* have been indicated for external application. Oils such as *Kumkumadi* oil, *Manjishtadi* oil have been described too. Only local application has been given. No drugs for oral route have been given.[14]

यौवनपिटिकान्यच्छनीलिकाव्यङ्गशर्करा ।
सिरावेधैः प्रलेपश्च जयेदभ्यन्जनैस्तथा ॥

Y.R.Kshudrarogchikitsa/1

MELASMA

What is Melasma?

Melasma is a common skin problem. It is human melanogenesis dysfunction that results in localized, chronic, acquired hypermelanosis of the skin. It causes brown to gray-brown patches, usually on the face. It occurs in three distributions and has four reported patterns of pigmentation. Among the many differences between melasma and normal skin, melasma skin contains increased melanin, melanocytes, and melanosomes, as well as increased synthesis of tyrosinase. Its pathogenesis however remains largely unknown.

Occurrence:

More common in women than men. Female to male ratio is 4:1. However nowadays it is seen in men too. According to the American Academy of Dermatology, 90 percent of people who develop melasma are women.mean age of occurrence is 37.2±9.3yrs.

Also it is so common during pregnancy that Melasma is sometimes called "the mask of pregnancy" or “Chloasma”.

Mainly occurs in people having intermediate skin types (III to V)

Prevalence among paddy field workers in India reached 41%.

Higher prevalence among more prevalence pigmented phenotypes like India, Pakistan, Japan, China, etc.

Season: Worsens in summer and improves in winter.

Causes:

There is no particularly known cause for Melasma however following are some of the most widely considered etiological factors.

- Sun exposure, ultraviolet rays
- Changes in Hormones, birth control pills, pregnancy and hormone therapy.
- Darker-skinned individuals are more at risk than those with fair skin.
- Stress and Thyroid disease
- Use of cosmetics
- Family history

Symptoms:

Melasma causes patches of discoloration. The patches are darker than your usual skin color. It typically occurs on the face and is symmetrical, with matching marks on both sides of the face.

Other areas of your body that are often exposed to sun can also develop Melasma.

Brownish colored patches usually appear on the:

- cheeks
- forehead
- bridge of the nose
- chin

It can also occur on the neck and forearms.

Types:

I. Melasma is divided into three types

1. Epidermal
2. Dermal
3. Mixed Melasma.

Epidermal Melasma is the most superficial with an increase in the skin pigment which is known as melanin in the top layer of skin ie. the epidermis.

In **Dermal Melasma**, there is increased skin pigment in the second deeper layer of the skin ie. the dermis.

Mixed Melasma is a combination of epidermal and dermal melasma.

II. As per presentation 3 types

1. Centerofacial
2. Malar
3. Mandibular

Centerofacial is the most common type. It includes the forehead, cheeks, upper lip, nose, and chin.

The **Malar** pattern includes the upper cheeks.
The **Mandibular** pattern is specific to the jaw.

Diagnosis of Melasma:

Melasma is readily diagnosed by recognizing the typical appearance of brown skin patches on the face. Dermatologists are physicians who specialize in skin disorders and often diagnose Melasma by visually examining the skin.
A black light or Wood's light (340-400 nm) can assist in diagnosing Melasma, although is not essential for diagnosis. In most cases, mixed Melasma is diagnosed, which means the discoloration is due to pigment in the dermis and epidermis.
Rarely, a skin biopsy may be necessary to help exclude other causes of this local skin hyperpigmentation.[14b,14c]

Treatment:[14d]

- Sun protection: Since sunexposure is the most common cause of Melasma, sun protection is the most common treatments for Melasma.

Use of sunscreen lotions and creams, Use of wide brimmed hat that shields the face from sun, etc.

- Sun lightening creams.
- Topical steroids.
- Chemical peels, dermabrasion.
- Drugs like Hydroquinone, Azelaic acid, Kojic acid.
- Retinoids, Mequinol.

These drugs act by inhibiting the enzyme Tyrosinase.
Most of the times combination therapy of Hydroquinone, steroids and retinoids is given.

Prognosis:
For some women, Melasma disappears on its own. This typically occurs when it's caused by pregnancy or birth control pills.
None of the above treatments ensures that there will be no relapse

Also the treatment does not guarantee complete recovery.

Some dark patches do not lighten or vanish completely.

Therefore one must follow certain preventive measures such as.

- minimize sun exposure,
- use sunscreen and
- continue with certain skin treatments.
- using makeup to cover areas of discoloration

Since Melasma is a skin disease let us study the anatomy and physiology of the skin as per Ayurveda aswell as modern.

TWACHA

Ayurveda describes seven distinct layers of the skin, each with its own structure and function. The layers are designed so that each layer provides support to the layer above it.

Skin is formed in the womb itself. It is said that, just as cream is formed on the uppermost layer of milk when boiling similarly when *Rakta* is getting digested 7 layers of skin are formed.

The thickness of these layers from superficial to deep is as follows:[14a]

Table No.: 4: Skin layer and its thickness

Layer name	**Thickness vreehi/mm**
Avabhasini	1/18 v / 0.05 to 0.06mm
Lohita	1/16 v / 0.06 to 0.07mm
Shweta	1/12 v / 0.08 to 0.09mm
Tamra	1/8 v 0.12 to 0.15 mm
Vedini	1/5v / 0.2 to 0.3mm
Rohini	1 v / 1 to 1.1mm
Mansadhara	2 v / 2 to 2.1mm

1. ***Avabhasini*:** This is the outermost layer. It reflects the complexion and the quality of the *Rasa Dhatu*. It also acts as a mirror: it indicates whether the physiology as a whole is balanced or imbalanced, and whether there is inner health or disorder. The *Avabhasini* layer also shows the *chaaya* of the skin. It does not have its own color: it reflects the colors of the inner layers.
2. ***Lohita*:** This layer supports the outermost layer. It indicates the quality of *Rakta Dhatu*. If there is *ama* in the blood, it impacts the *prabha* of the outer layer and accentuates sensitivity to the sun. The color of this layer resembles molten iron.
3. ***Shweta*:** This is a white layer, and it provides balance to skin color, lightening the darker colors of the inner layers.
4. ***Tamra*:** This layer nurtures the upper layers of the skin. It supports the

immune system. This is the layer that helps the skin perform its function of being a "barrier." Skin infections reflect an imbalance in this layer. It is copper-colored.

5. ***Vedini*****:** This fifth layer sensually links the skin to the rest of the body. It is the center for transformation of sensation like feeling of pain.
6. ***Rohini*****:** This layer supports healing and regeneration. Imbalance in this layer retards healing and the disappearance of scars over time. A balanced diet, rich in nutritional value, supports the *Rohini* layer.
7. ***Mamsadhara*****:** This innermost layer is the platform for the skin's stability and firmness. When this layer is in balance, the skin looks young and supple. A skin product that has a *vayasthapana* effect nourishes this layer to help retard the aging process.

The diseases caused in the above layers as per Sushrut has already been discussed during *Vyanga* discussion.

SKIN

The skin is the external covering of a human body. Of all the organs of the body none is more easily exposed to infection than skin. Because of its visibility, skin reflects our emotions and some aspects of normal physiology.

There are 3 layers of skin:

1. Epidermis
2. Dermis
3. Hypodermis

EPIDERMIS

It is the most superficial layer of the skin and is composed of stratified epithelium. Thickest on palms and soles. There are nerve endings but no blood vessels. There are pigment forming **melanocytes**, phagocytic langerhan cells and neutrally associated Merkel cells in this layer.

Epidermis is divided into number of strata representing stages in keratinocyte maturation from deep to superficial.

a. Stratum Basale
b. Stratum Spinosum
c. Stratum Granulosum
d. Stratum Lucidum
e. Stratum Corneum.

DERMIS

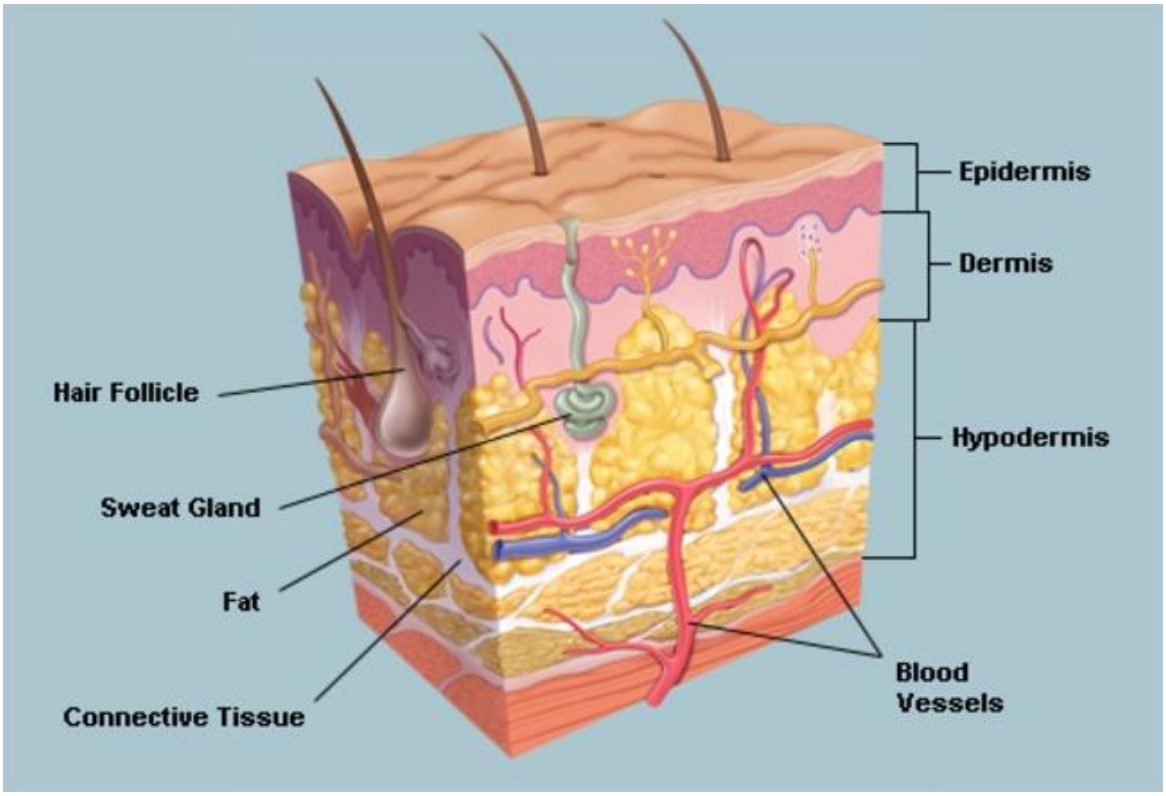
It is the second layer of the skin after epidermis. It is tough, flexible and highly elastic. It is very thick in the palms and soles. Thicker on the posterior than the anterior aspect of the body. It supports the epidermis structurally and nutritionally. The dermis consists of blood vessels, lymph vessels, sensory nerve endings, sweat glands and their ducts, hair roots, hair follicles and sebaceous glands.

HYPODERMIS

The **hypodermis**, also called the subcutaneous layer or superficial fascia is a layer directly below the dermis and serves to connect the skin to the underlying fascia (fibrous tissue) of the bones and muscles.

Although the border between the hypodermis and dermis can be difficult to

distinguish. The hypodermis consists of well-vascularized, loose, areolar connective tissue and adipose tissue, which functions as a mode of fat storage and provides insulation and cushioning for the integument.



Functions of the skin

The three main functions of the skin are:

1. Protection
2. Regulation
3. Sensation

Protection

The primary function of the skin is to act as a barrier. The skin provides protection from: mechanical impacts and pressure, variations in temperature, micro-organisms: infections, radiation and chemicals.

Regulation

The skin regulates several aspects of physiology, including: body temperature via sweat and hair, and changes in peripheral circulation and fluid balance via sweat. Increased evaporation of the secreted sweat decreases the body temperature. Vasodilatation in the dermis makes it easier for the body to release some heat and lower the body temperature whereas vasoconstriction leads to retention of the internal body temperature.

It also acts as a reservoir for the synthesis of Vitamin D.

The fatty subcutaneous layer of the skin also acts as an insulation barrier, helping to prevent the loss of heat from the body and decreasing the effect of cold temperatures.

Sensation

The skin contains an extensive network of nerve cells that detect and react to changes in the environment. There are separate receptors for heat, cold, touch, and pain. This sensation in the skin plays a role in helping to protect us from burn wounds. Damage to these nerve cells is known as neuropathy, which results in a loss of sensation in the affected areas.

The skin is the body's largest organ. It's a protective wrapper that defends the body against injury and infection and modulates environmental influences such as ultraviolet light, heat and cold, and air pollution. It's also involved in a range of complex biological processes. The skin contains sweat glands and blood vessels (which help regulate body temperature), cells that use the sun to manufacture vitamin

D, nerve endings that are in constant contact with the brain, and an array of immune system cells that help ward off invaders such as bacteria and viruses.

The brain and nervous system influence the skin's immune cells through various receptors and chemical messengers — neuropeptides, for example. Scientists are investigating these and other substances in the skin that may respond to psychological stress. They have already found that certain types of stress can interfere with the immune system, affecting the skin's capacity to heal. One study found that surgical patients who felt less stress in the month before surgery had higher levels of IL-1 (an immune system chemical that promotes healing), less postoperative pain, and a shorter recovery. Research also suggests that chronic negative stress can disrupt the function of the skin's permeability barrier, which normally keeps out harmful substances and prevents the loss of fluid from skin cell layers. This kind of disruption is thought to be a major factor in many skin diseases.-[14e]

MALHAR KALPANA

Malhar kalpana is described under *bahyopachar kalpana*(external application). It has been derived from Unani medicinal methods where it is known as *Marham* or *Malham*. The medicines in the *Malhar kalpa* get absorbed through the skin therefore it is also known as "*Abhyanjan*".

It was described for the first time by Yogratnakar.

It literally means something that eradicates "*mala*" (dead or diseased cells).

It is also worthy to note here that in *Charak Sanhita*, in *Vaat rakta* treatment Tail has been mentioned which contains bees wax, thus making the *Pinda tail* has semisolid *malhar* like product. However he has not literally mentioned the name of *Pinda Malhar kalpana*. Also here, *Pinda tail* is used as an analgesic however all the *malhar* that have been described later are chiefly used for skin ailments.

It comprises chiefly of two components:

1. *Aadhar dravya* : The *sneha* component in which medicinal drugs are mixed to prepare *malhar*. Eg. Oil, Ghee, Wax, *Shatdhaut ghrut, Sahastradhaut ghrut.Raal, Sikta,* Etc.
2. *Aadheya dravya* : The component that is mixed with the *sneha* component, mostly medicines in *choorna* form. Eg. *Gairik, Gandhak, Kajjali, Kampillak, Tutha, Phitkari* etc. [32]

Procedure: Both the above components are mixed together either by heating or without heating.

In Ayurveda many *malhar kalpana* have been described. Their details have been given in the table below:[33,34]

Table No. 5: Various *Malhar* and their indications

Sr. No	***Malhar***	**Indication**
1	*Sikta tail*	*Vran ropak, Visarpa, kandu, Kushta, Vaatrakta*
2	*Gandhak Malhar*	*Darun, Pama*
3	*Shatdhaut Ghrut*	*Daha, Visarpa*

4	*Sarjaras Malhar*	*Bhagandhar, Pitika, Burns.*
5	*Rasapushpa Malhar*	Syphilis wounds
6	*Rasapushpadya Malhar*	*Vicharchika,* Syphilis wounds
7	*Tuthamrut Malhar*	*Pama*
8	*Tuthakadyo Malhar*	*Vrana*
9	*Dadruvidravan malhar*	*Dadru*
10	*Gandhakadya malhar*	*Pama*
11	*Hinguladya malhar*	Syphilis wounds
12	*Hingulamrut malhar*	*Nadivran,Bhagandar, Vran*
13	*Tankanamrut malhar*	*Dushta malhar*
14	*Tankanamlasya malhar*	*Agnidagda vran*
15	*Yashadamrut malhar*	*Vran*
16	*Sinduradya malhar*	*Vran*
17	*Mrugshrungadya malhar*	*Pama, Bhagna, Tvachya, Arsha*
18	*Gairikadya malhar*	*Kandu, Daaha, Vran*

Besides these, many more malhars containing herbs and minerals are been made nowadays as it is easy to use, easy to carry around, more acceptable and has a good shelf life.

CREAMS

Creams are semisolid dosage forms, containing one or more drug substances, dissolved or dispersed in a suitable base. It is usually used for application on skin, although creams for application to mucous membranes are also used .
It is an emulsion of oil and water. Nowadays it is said to be an emulsion of oil(20%) and water(80%). It penetrates the outer layer of the skin wall.

They are divided into **two types**:

1. **oil-in-water (O/W**) creams which are composed of small droplets of oil dispersed in a continuous water phase, and
2. **water-in-oil (W/O)** creams which are composed of small droplets of water dispersed in a continuous oily phase.

Difference between these two types is given in the table below:

Table No.6: Difference between O/W and W/O Creams

Oil in Water (O/W)	**Water in Oil (W/O)**
Oil 20%, Water 80%	Oil 80%, Water 20%
Less Greasy	More greasy
More comfortable	Less comfortable
Cosmetically acceptance is more	Cosmetically acceptance is less
Less moisturising	More moisturizing
Day creams are usually O/W	Night creams are usually W/O

Uses:

1. It acts as a barrier to protect the skin. Eg. Sunscreen.
2. Helps in retention moisture of the skin.
3. Has cleansing effect.
4. It has emollient effect.
5. It is a vehicle for certain drugs, eg. Antifungals, antibiotics etc.

Composition:

There are four main ingredients of a cream.

1. Water
2. Oil
3. Emulsifier
4. Thickener

Other ingredients are:

1. Stabilisers
2. Colours
3. Fragrance
4. Preservatives

The Water Phase

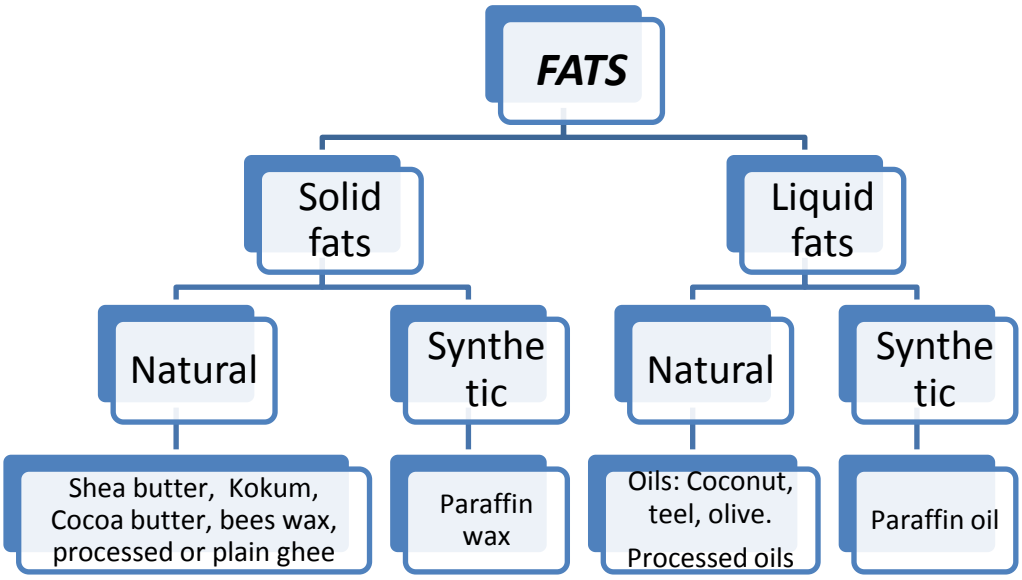
Water constitutes the major ingredient of most creams. The lighter and more cosmetic-type creams contain more water and less oil. This phase contains the water-soluble herbal ingredients or just water. The water could be just tap water or boiled water or distilled water or herb instilled water. The medicinal water could be decoction (kwatha), cold infusion (hima) or hot infusion (Phanta).

The Oil Phase

Oils are the second most important ingredient of a cream. The heavier purely medicinal creams contain a higher proportion of oil but water is still their major ingredient. Oil-soluble herbal ingredients like resins dissolve and become incorporated into this phase which gives creams a richer and heavier feel. Many oils are susceptible to oxidation or rancidification over a period of time. This could be avoided by adding Vt. E to the cream.

Oils can be taken in the form of :

1. Solid fats 2. Liquid Fats



Solid fats are fats that are solid at room temperature. Synthetic solid fats like paraffin wax does not penetrate the skin, they block the pores at times and can cause boils on the skin. Hence are not advisable for use especially in face cream. Natural Fats are either of plant origin like kokum, cocoa or animal origin like ghee.

Ghee is a natural solid fat. We can also take processed ghee in which herbal extracts are instilled.

Eg. Triphala ghrut, Brahmi ghrut.

In liquid fats various oils can be used, oils are generally extracted from plants, olive oil. Coconut oil. We can also used processed oils having herbal extracts such as manishtadi oil, varnya oil, kumkumadi oil, etc.

Synthetic liquid fat like paraffin oil is also not advisable due to its inability to penetrate the skin.

Emulsifiers

Emulsifiers are needed to mix the oil and water phase. Both these phases are immissible with each other and thus they need an agent which could make an homogeneous mixture of them. These are known as emulsifiers.

For cream preparation various emulsifiers are available. We could use any one or a combination of two or more while formulating a cream.

Emulsifying wax: One of the most essential ingredient in making creams and lotions. Think of it as the "glue" that will hold our compound together. It is an emulsifier as

well as a thickener.

Cetearyl alcohol : Cetearyl alcohol is a chemical found in cosmetic products. It's a white, waxy substance made from cetyl alcohol and stearyl alcohol, both fatty alcohols. They're found in animals and plants, like coconut and palm oil. They can also be made in a laboratory.

They are used in personal care products, mainly skin lotions, hair products, and creams. They help create smoother creams, thicker lotions, and more stable foam products.

Stearic acid : This is a stiffener that thickens the cream. It gives the cream a thicky and creamy texture. Used from 3 to 5%.

Polysorbate : Polysorbates are a class of emulsifiers used in cosmetics and food preparation to solubilize essential oils into water-based products. Polysorbates are oily liquids derived from ethoxylated sorbitan with fatty acids. Polysorbate 20 is derived from sorbitol, a natural ingredient

Thickening agent

These are substances that increase the viscocity of a liquid without changing its properties.

Thickening agents used in cosmetics or personal hygiene products include viscous liquids such as polyethylene glycol, synthetic polymers such as carbomer and vegetable gums. Some thickening agents may also function as stabilizers when they are used to maintain the stability of an emulsion. Some emollients, such as petroleum jelly and various waxes may also function as thickening agents in an emulsion.

Preservatives

Preservatives are needed to increase the shelf life of a product. There are natural aswell as synthetic preservatives. However it has been found that a natural preservative should always be combined with a synthetic preservative to increase shelf life.

i. **Natural preservatives**:

Essential oils : Its an antiseptic. Although some might be allergic to it.

Neem oil : Good for all skin types. Antiseptic, antifungal,etc.

Sweet orange oil : Calming and nice

Vit. E : Excellent antioxidant.

Honey : Antimicrobial, antibacterial and a very good moisturizer.

Rosemary extract : Prevents decomposition.

ii. Synthetic preservatives

They can give a shelf life of over 2 years to a cream.

Sodium benzoate: **Sodium benzoate** is a substance which has the chemical formula C_6H_5COONa. It is a widely used food preservative. Sodium Benzoate is a salt of Benzoic Acid, found naturally in cranberries, prunes, plums, cinnamon, ripe cloves, and apples and used as a preservative in cosmetics and personal care product formulas as a fragrance ingredient, masking ingredient, anti-corrosive agent, and most frequently, as a preservative. As a preservative, it prevents bacteria and fungi from developing in products and formulas and changing their compositions. When combined with caffeine in Caffeine Sodium Benzoate, it can have a sunscreen effect, and provide UVB protection with antioxidant activity.

DMDM hydantoin.: Is an antimicrobial formaldehyde releaser preservative with the trade name Glydant. DMDM hydantoin is an organic compound belonging to a class of compounds known as hydantoins. It is used in the cosmetics industry and found in products like shampoos, hair conditioners, hair gels, Rite Aid Liquid Lubricant, and skin care products.

DMDM hydantoin works as a preservative because the released formaldehyde makes the environment less favorable to the microorganisms.

Parabens : **Parabens** are a group of chemicals widely used as artificial preservatives in **cosmetic** and body care products since the 1920s. Since **cosmetics** contain ingredients that can biodegrade, these chemicals are added to prevent and reduce the growth of harmful bacteria and mold, increasing the shelf life of the product.

Preparation of Cream:[35]

Various formulas for cream preparation are available. Some traditional methods are also known.

General steps:

Method 1.

1. Measure all the ingredients accurately in grams or kg.
2. First warm water phase.
3. Add emulsifiers to the warm water and stir till it melts completely and the solution is soft.
4. Then put off the heat and add the oil phase, stir well.
5. When cooled down add preservatives, fragrances and colour if needed.
6. Finally blend the mixture with a blender till a fluffy, smooth cream is formed.

Method 2.

1. Heat oil phase along with emulsifiers in a beaker upto 70^0C in water bath.
2. Heat water phase with glycerine in a separate beaker upto 70^0C.
3. Then add water phase to oil phase.
4. Stir mixture continuously.
5. When temperature reduces to 40^0C add colour, preservative and fragrance.
6. Finally with a spoon beat the mixture till cream is formed.

Points to remember while preparing a cream.

1.Formulas with less emulsifier and more water are generally lotions.

2. Formulas with higher levels of oil and emulsifier and less water are generally creams and ointments.

3. It is best to heat both oil and water phases separately upto 60 to 70^0C.

4. If not heated properly the emulsifiers will not melt.

5. Always have a thermometer to measure the temperature.

6. Always measure by weight and not volume.

7. The total measure of ingredients should add upto 100.

8. Pour the cream into containers before it thickens completely.

9. To avoid contamination always spray the containers with alcohol.

10. Avoid using fresh botanicals use only dry form.
11. Always use preservatives
12. Add Vit.E, Grape fruit seed extract or rosemary oleoresin to increase shelf life.

MATERIALS AND METHODS

This chapter is divided into following parts:

1. Raw material collection
2. Raw material Authentication
3. Raw material Analysis
4. Drug Preparation
5. Drug Analysis
6. Labeling and Packing the Drug
7. Clinical Trial

1. RAW MATERIAL COLLECTION

The collection of herbal raw materials required for my study was indeed a task and needed quiet a research.

***Amra* seed (*Magnifera indica*)**

The seeds of the same were collected from friends and relatives during the *Amra* season. The *Amra* kernels were collected from the above sources, thoroughly washed and then dried in sun for 15 days. The kernels taken were chiefly of Alphonso *Amra*es.

After drying in the sun the kernels were broken and the seeds within were acquired. These seeds were then cut into small pieces and again dried in the sun covered with a cloth. Once dried thoroughly they were kept in an Air tight container.

***Jamun* Seed (*Syzygium cumini*)**

Jamun seeds were collected from a single *Jamun* tree from the campus of my college. The fruity pulp was removed, the seeds thoroughly washed and dried in the sun. After drying for 15 days, the seeds were kept in an air tight container.

***Daadim* peels (*Punica granatum*)**

The pomegranate was bought from the market, after eating the fruit the peels were washed, cut into small pieces and dried for 20 days. When devoid of any moisture kept in an air tight container.

***Bala* roots (*Sida cordifolia*)**

There are many species of *Bala* available in India. On exploring it was found that they were available at Trichur in State of Kerala. They were imported from there, were then washed properly and dried. Finally cutting them into smaller pieces they were stored in an air tight container.

***Yashtimadhu* roots (*Glycirrhizia glabra*)**

Yashtimadhu roots were acquired from an Ayurvedic medicine dealer in Shimla in Himachal Pradesh.

These were already dried when received yet they were sun dried for 10 days and finally kept in an air tight container.

***Laksha* (*Laccifer lacca*)**

Laksha was purchased from local market. It was then stored in an airtight container.

2. RAW MATERIAL AUTHENTICATION

All the raw materials were send to a Botanist for Authentication. He authenticated the raw materials and reports were acquired.

3. RAW MATERIAL ANALYSIS

All the raw materials were subjected to the following tests:

1. **Organoleptic characterization**
2. **Moisture Content**[1]
3. **Ash value**[2]
4. **Water soluble extractive value**[3]
5. **pH**[4]

6. **Phytochemical analysis**
7. **Total viable Aerobic count**
8. **Pesticide Residue**
9. **Heavy metal testing**
10. **HPTLC**

The reports of the above tests are mentioned in the tables given below.

Table No. 1. Organoleptic characters of the raw material

Characters/ Samples	***Amra* seed**	***Jamun* seed**	***Dadim* peel**	***Yashti* root**	***Bala* root**	***Laksha***
Colour	Creamy grey	Brownish	Reddish brown	Yellowish	Faint brownish yellow	Reddish brown
Taste	Bitter	Astringent	Sweet	Sweet	Tasteless	Tasteless
Odour	Pungent	Characteristic	Faint	Characteristic	Characteristic	Faint

Table No. 2. Results of Moisture content, Ash value, Water Extractive value and pH of *Amra* seeds, *Jamun* seeds and *Dadim* peels.

Characters/ Samples	***Amra* seed**	**Permissible limits[5,6]**	***Jamun* seed**	**Permissible limits[7,8]**	***Dadim* peel**	**Permissible limits[9]**
Moisture Content@ 110^0C	6.08%	8 to10%	6.30%	8 to10%	5.01%	8 to10%
Ash value	1.42%	Not more than 3%	3.12%	Not more than 5%	3.10%	Not more than 4%
Extractive value(Water soluble)	11.49%	Not less than 10%	15.21%	Not less than 15%	24.56 %	Not less than 20%
pH	5.58	3 to 5.2	5.40	2.5±0.1	4.60	3.92

Table No. 3. Results of Moisture content, Ash value, Water Extractive value and pH of *Yashtimadhu* roots, *Bala* roots and *Laksha*

Characters/ Samples	***Yashti***	**Permissible limits[10]**	***Bala***	**Permissible limits[11]**	***Laksha***	**Permissible limits[12]**
Moisture Content@110^0 C	4.59%	8 to 10%	4.26 %	8 to10%	7.50%	8 to10%
Ash value	5.30%	Not more than 10%	5.08 %	9%	8.695%	Not more than 1%
Extractive value(Water soluble)	24.44 %	Not less than 20%	5.33 %	6.32%	25.11%	4%
pH	5.40	5.5 to 8.2	6.38	6.81	4.21	

Permissible limits for Moisture content is 8 to 10%[13]

Table No. 4. Phytochemical Analysis of the raw materials.

Name of the sample	**Phytochemical test Result**
Amra seed	Tannins
Jamun seed	Saponins, Tannins
Dadim peel	Protein, carbohydrate
Yashti root	Starch, Carbohydrates
Bala root	Alkaloids

Table No. 5. Aerobic count and fungal count of the raw materials

Sample	**Total viable aerobic count**	**Total fungal count**
	$10^{7/}$gm (Std. Value) [14]	**$10^{7/}$gm (Std. Value) [14]**
Amra seed	73×10^2	8×10^2
Jamun seed	10×10^3	50×10^2
Dadim peel	40×10^2	40×10^2

Yashti root	16×10^2	65×10^2
Bala root	12×10^3	45×10^2
Laksha	10×10^2	NIL

Table No. 6. Pesticide residue report of all 6 raw materials.

Sr. No	**Pesticide name**	**Result mg/kg**	**Permissible limit mg/kg[15]**
1	Alachlor	BLQ	0.02
2	Aldrin and Dieldrin (sum of)	BLQ	0.05
3	Azinphos-methyl	BLQ	1.0
4	Bromopropylate	BLQ	3.0
5	Chlordane (sum of cis-, trans - and Oxythlordane)	BLQ	0.05
6	Chlorfenvinphos	BLQ	0.5
7	Chlorpyrifos	BLQ	0.2
8	Chlorpyrifos-methyl	BLQ	0.1
9	Cypermethrin (and isomers)	BLQ	1.0
10	DDT (sum of p,p´-DDT, o,p´-DDT, p,pDDE and p,p´-TDE)	BLQ	1.0
11	Deltamethrin	BLQ	0.5
12	Diazinon	BLQ	0.5
13	Dichlorvos	BLQ	1.0
14	Dithiocarbamates (as CS2)	BLQ	2.0
15	Endosulfan (sum of isomers and endosulfan sulphate)	BLQ	3.0
16	Endrin	BLQ	0.05
17	Ethion	BLQ	2.0
18	Fenitrothion	BLQ	0.5
19	Fenvalerate	BLQ	1.5
20	Fonofos	BLQ	0.05

21	Heptachlor (sum of heptachlor and heptachlor epoxide)	BLQ	0.05
22	Hexachlorobenzene	BLQ	0.1
23	Hexachlorocyclohexane isomers (other than γ)	BLQ	0.3
24	Lindane (γ-hexachlorocyclohexane)	BLQ	0.6
25	Malathion	BLQ	1.0
26	Methidathion	BLQ	0.2
27	Parathion	BLQ	0.5
28	Parathion-methyl	BLQ	0.2
29	Permethrin	BLQ	1.0
30	Phosalone	BLQ	0.1
31	Piperonyl butoxide	BLQ	3.0
32	Pirimiphos-methyl	BLQ	4.0
33	Pyrethrins (sum of)	BLQ	3.0
34	Quintozene (sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide)	BLQ	1.0

* BLQ: Below limit of Quantification.

Table No. 7. Heavy metal testing of all 6 raw materials

Heavy Metal	***Amra* Seed**	***Jamun* seed**	***Dadim* Peel**	***Yashti madhu* Root**	***Bala* Root**	***Laksha***	**Permissible Limits(ppm)[16]**
Arsenic	1.2	1.4	1.6	2.1	2.4	3.1	3
Cadmium	0.227	0.477	0.667	0.594	0.415	0.569	0.3
Lead	3.16	3.07	2.17	7.02	4.54	6.52	10
Mercury	1.46	1.36	0.68	1.04	1.72	1.65	1

4. PREPARATION OF DRUG

I. Preparation of Raw material *Choorna*

Before making *choorna, Laksha* was cleaned manually to remove any stone, wood or leaves mixed with it.

Equipments:

Iron Pounding apparatus, Mixer, 40 mesh size sieve, Plate

Ingredients:

1. *Amra* seeds 200gms
2. *Jamun* seeds 200gms
3. *Dadim* Peels 200gms
4. *Yashtimadhu* roots 200gms
5. *Bala* roots 200gms
6. *Laksha* 200gms

Procedure

1. Each material was pounded in the pounding apparatus separately till it was broken into smaller pieces.
2. Then these pieces were grinded in a mixer till a fine *choorna* was prepared.
3. This *choorna* was then sifted through a 40 mesh size sieve.
4. *Choorna* prepared was then kept in an air tight container.
5. Each raw material *choorna* was prepared with the same procedure separately and they were all stored separately too.

Table No. 8. Observation of Raw Material *Choorna*

Material	**Quantity Acquired**	**Colour**	**Taste**	**Odour**	**Touch**
***Amra* seed**	180 gms	Creamy grey	Bitter	Pungent	Soft
***Jamun* seed**	182 gms	Brownish	Astringent	Fragrant	Rough

***Dadim* peel**	175 gms	Reddish brown	Sweet	Mild	Soft
***Yashti* root**	160 gms	Yellowish	Sweet	Sweet	Soft
***Bala* root**	165 gms	Faint brownish yellow	Tasteless	Mild	Rough
Laksha	184 gms	Reddish brown	Tasteless	Mild	Rough

II. Preparation of *Lakshadi Malhar* : Batch I

It was prepared in 2 steps.

Step I. Preparation of *Lakshadi kwatha*

Equipments:

Steel vessels, Measuring beaker, Cotton cloth, Gas stove.

Ingredients:

1. *Dadim* peel *choorna*: 50gms
2. *Amra* seed *choorna*: 50gms
3. *Jamun* seed *choorna*: 50gms
4. *Bala* root *choorna* : 50gms
5. *Yashtimadhu* root *choorna*: 50gms
6. *Laksha choorna*: 50 gms.
7. Water: 4.8 lt

Procedure:

1. In a vessel raw material *choorna* was taken.
2. 600 ml water was then added to it.
3. This level was marked on the vessel from outside with a chalk.
4. Remaining water (4.2 lt) was then added.
5. The mixture was then heated on a medium flame with intermittent stirring.
6. When water was reduced upto the marked level heat was turned off.

7. Then the decoction was filtered through a cloth.

Observation:

Colour of *kwatha*: Red

Duration: 4 hours.

Acquired quantity : 750ml.

Similarly Batch II, III and IV of *Lakshadi Kwatha* was prepared.

***KWATHA* Analysis**

The prepared *kwatha* of first 3 bathes was analysed as a part of "I**n process"** analysis.

Following tests were conducted on the *kwatha*:

i. **Organoleptic characters**
ii. **pH**
iii. **Specific gravity**[17]
iv. **Total solid content**[18]
v. **HPTLC**

Table No. 9. Reports of *Kwatha* analysis.

Parameters	***Kwatha*** **Batch 1**	***Kwatha*** **Batch II**	***Kwatha*** **Batch III**
Appearance	Syrupy liquid with suspended particles		
Colour	Light brown	Light brown	Light brown
Odour	Aromatic	Aromatic	Aromatic
Taste	Sweet and Sour	Sweet and Sour	Sweet and Sour

pH	4.6	4.6	4.6
Specific gravity	1.01gm/ml	1.02gm/ml	1.04gm/ml
Total solid content	1.25%	1.22%	1.18%

Step II: Preparation of *Lakshadi Malhar*

Equipments : Steel vessel, Gas stove, Spoon, Digital weighing machine, Measuring beakers, Knife, Spatula, Dropper, Blender.

Ingredients:

1. *Lakshadi Kwatha* 750gms
2. Teel oil 250gms
3. Glycerine 62.5 gms (in place of light liquid paraffin)
4. Emulsifying wax 60gms (mixture of cetearyl alcohol and polysorbate)
5. PEG 150 stearate 60gms (emulsifier)
6. EDTA 7.5gms (stabiliser)
7. Sodium benzoate a pinch
8. Lavender oil Few drops

(Use of fragrance does not require FDA approval)

Procedure:

1. All the ingredients were weighed in grams.
2. *Kwatha* was heated.
3. Finely cut E wax and PEG 150 stearate were added to the *kwatha* and stirred continuously till they dissolved completely.
4. When the mixture becomes smooth, heat was stopped.
5. Then *Teel* oil and Glycerine was added and mixed well.
6. When mixture cooled down EDTA, sodium benzoate and lavender oil was added.
7. The mixture was then blended with a blender till fluffy cream was obtained.

Observation:

Colour: Pink coloured

Smell: Lavender

Touch: soft

Acquired quantity of cream : 960gms

Similarly Batch II, III and Batch IV of *Lakshadi Malhar* was prepared.

Table No. 10. *Lakshadi Kwatha* and *Lakshadi Malhar* details of the 4 batches.

Batch No.	***Kwatha dravya***	***Kwatha***	**Quantity of cream obtained**
Batch I	300gms	750ml	960gms
Batch II	240gms	600ml	840gms
Batch III	240gms	600ml	820gms
Batch IV	120gms	350ml	410gms

III. PREPARATION OF CONTROL DRUG : Batch I

Equipments:

2 Steel vessels, Gas stove, Spoon, Digital weighing machine, Glass measuring beakers, Knife, Spatula, Dropper, Blender.

Ingredients

1. Water 750gms
2. Teel oil 250gms
3. Glycerine 62.5gms
4. E wax 60gms
5. PEG 150 stearate 60gms
6. EDTA 7.5gms
7. Sodium benzoate as required
8. Lavender oil few drops

9. Colour Brown

Procedure:

1. Water was heated in a steel vessel
2. Then finely cut E wax and PEG 150 stearate were added to the water.
3. This mixture was stirred continuously till they dissolved completely.
4. When the mixture becomes smooth, heat was stopped.
5. Then Teel oil and Glycerine were added and mixed well.
6. When mixture cooled down EDTA, sodium benzoate and lavender oil was added.
7. Finally brown colour was added drop by drop until colour similar to the *Lakshadi Malhar* was obtained.
8. The mixture was then blended with a blender till fluffy cream was obtained.

Observation:

Colour: Creamish(skin colour)

Touch: Soft

Smell: Lavender

Acquired quantity: 1 kg.

This cream was then filled in sterile plastic containers,

Similarly Batch II, III and Batch IV was prepared of Control *Malhar*.

The cream both *Lakshadi Malhar* and Control *Malhar* were prepared from time to time. When the first Batch got over the second batch would be prepared. This was because the shelf life of the *Malhar* prepared by the above method is just **6 months.**

Table No. 11. Quantity of Control cream obtained Batch wise

BATCH	**Quantity of Cream Obtained**
Batch I	1000 gms
Batch II	600 gms
Batch III	620 gms

Batch IV	600 gms
Total	**2820Gms**

Stability studies

The creams before preparation Batch wise were prepared in a small quantity to check for its shelf life at room temperature.

Approximately 30 grams of cream both *Lakshadi Malhar* and Control *Malhar* were kept in 2 sterile air tight containers in a cupboard.

Every 15 days it was opened and observed for any changes.

Only after 6 months it was observed that the oil from the cream was separating out.

And so we concluded that 6 months is the shelf life of our cream.

5.ANALYSIS OF THE PREPARED DRUGS

The *Lakshadi Malhar* and Control *Malhar* were both prepared in 4 different batches as was required from time to time.

All these batches were analysed with respect to following tests:

1. **Organoleptic characters** (Colour, Odour, Touch)

Table No. 12. Organoleptic characters of the prepared *Malhar*

Organoleptic characters	***Lakshadi Malhar***			**Control *Malhar***		
Sample	**Batch 1**	**Batch 2**	**Batch 3**	**Batch 1**	**Batch 2**	**Batch 3**
Colour	Light Brown	Light Brown	Dark Brown	Light Brown	Light Brown	Light Brown
Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Touch	Soft	Soft	Soft	Soft	Soft	Soft

2. pH

In a cosmetic product knowing the pH of the product is very important. pH of our skin differs in every area. The balanced pH level of the facial skin and most parts of the body is considered to be 5.5. This value can however vary. In oily skin, the pH is between 4.0 and 5.2, in the normal skin - from 5.2 to 5.7, in the dry skin - from 5.7 to 7.0.[19]

In any case, all skincare products (unless they perform special functions) should have an acidic pH. Although research on skin's pH range cites various numbers, the collected research shows skin's average pH is 4.7.[20]

Men's skin tends to be more acidic than women's skin, and although the pH of our skin increases with age, it remains acidic. When we're born our skin has a neutral pH that becomes acidic within a couple weeks of birth.

Ideally, the products we use for skin should stay within the pH range of the skin and sit around (4.5 – 6.0) Products that we use regularly and leave on our face like sunscreen and cream should be pH balanced accordingly and sit around the (4.0 – 5.5) range.

Table No. 13. pH of the prepared *Malhar*

Sample	***Lakshadi Malhar***			**Control *Malhar***		
	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
pH	5.6	5.5	5.8	4.06	4.1	4.3

3.Acid value[21]

4. Peroxide value[22]

5. Moisture Content

6. Total Viable aerobic content

7. Test for Aflatoxins[23]

Table No. 14. Acid value, Peroxide value, Aflatoxins, Moisture content and Density of the Malhar.

	Lakshadi Malhar			**Control *Malhar***		
Sample	**Batch 1**	**Batch 2**	**Batch 3**	**Batch 1**	**Batch 2**	**Batch 3**
Acid Value	11.2	10.36	9.9	9.45	9.28	9.45
Peroxide value (meq/kg)	1.5	1.6	1.2	1.1	1.3	1.1
Aflatoxins	Negative	Negative	Negative	Negative	Negative	Negative
Moisture Content	5.7%	5.1%	5.75%	6%	5.8%	6.2%
Density gm/ml	0.8427	0.8404	0.8423	0.8825	0.8973	0.8973

Acid Value Normal limits : 4 to 15[24]

Peroxide Values should be : < 10(meq/kg)[25]

Moisture content : Upto 10%[26]

Permissible limits for Aflatoxins are:[27]

i. B1 = < 2 ppb
ii. B1+B2+G1+G2 = < 5 ppb

8. HPTLC

High Performance Thin Layer Chromatography was carried out for their qualitative analysis simultaneous finger printing analysis of extracts was carried out using newly

developed HPTLC method following the ICH guidelines. HPTLC was done of:

- **All the 6 raw material choorna.**
- ***Kwath* prepared from this choorna and**
- ***Lakshadi Malhar***

Each raw material was dissolved in various solvents to check for their solubility and accordingly the best solvent was selected for the HPTLC testing. The mixed *choorna* of all the 6 ingredients was then run in the same particular solvent and their graph compared with that of the individual *choorna* extract.

HPTLC of *Amra* seed

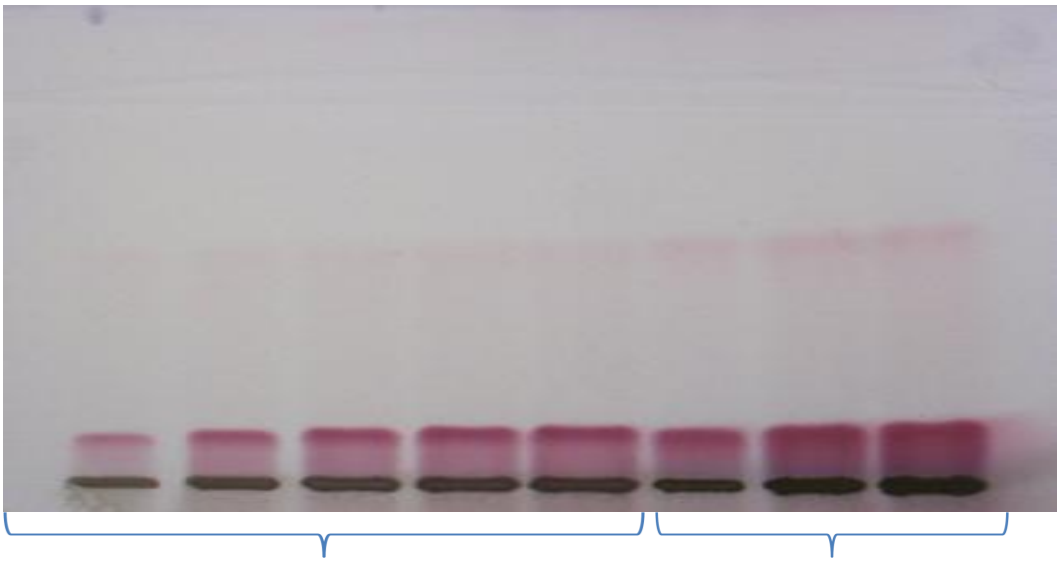


Figure 1: HPTLC by Derivatization Reagent(Vanillin Sulphuric Acid) of *Amra* seed *choorna* and Mixed *choorna* at 500 nm

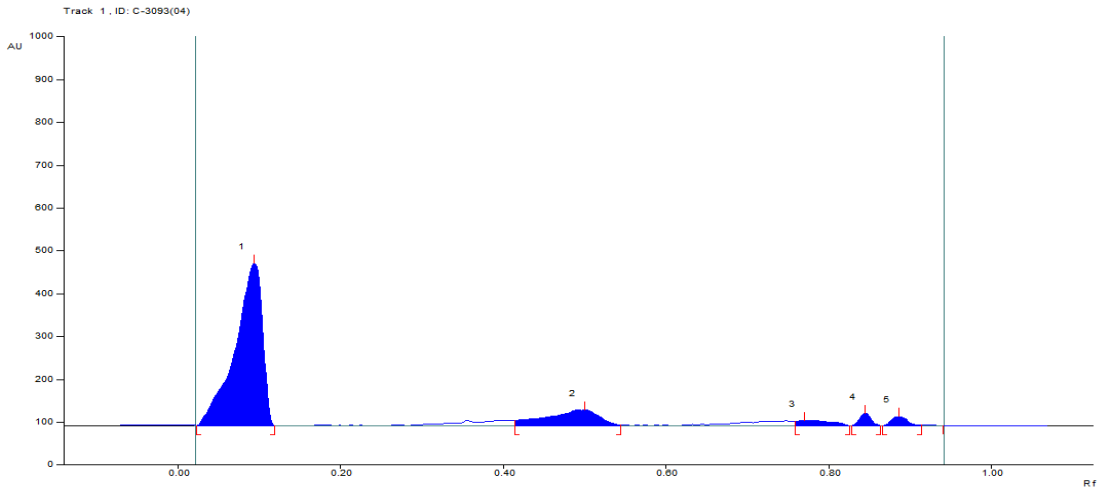


Figure 2: Chromatogram of *Amra* seed extract at 500 nm

Table 15: Rf values of *Amra* seed *choorna* at 500 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.03Rf	0.2AU	0.11Rf	380.1AU	78.96%	0.14Rf	0.6AU	10427.2AU	76.85%
2	0.49Rf	12.6A	0.59Rf	37.5A	7.78	0.64Rf	1.1AU	1988.	14.66

		U		U	%			8AU	%
3	0.90Rf	10.3AU	0.91Rf	13.2AU	2.75%	0.96Rf	0.1AU	448.8AU	3.31%
4	0.98Rf	0.4AU	1.00Rf	28.9AU	5.99%	1.02Rf	0.4AU	3428AU	2.53%
5	1.03Rf	0.0AU	1.05Rf	21.8AU	4.52%	1.08Rf	1.9AU	360.6AU	2.66%

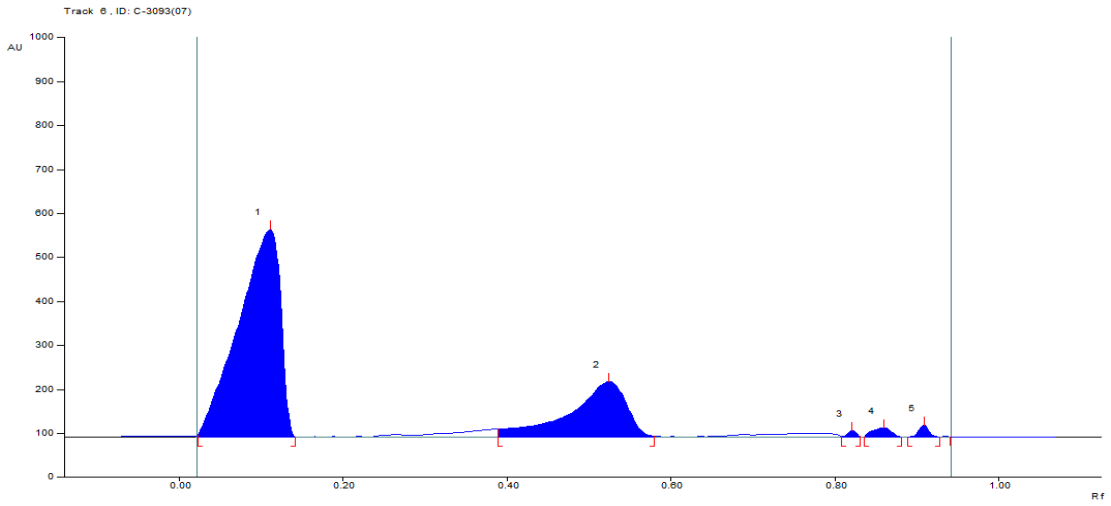


Figure 3. : Chromatogram of Mixed *choorna* extract at 500 nm

Table 15: Rf values of Mixed *choorna* at 500 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.03Rf	4.2AU	0.13Rf	472.5AU	71.44%	0.17Rf	0.6AU	10427.2AU	71.29%
2	0.46Rf	18.4AU	0.62Rf	126.5AU	19.13%	0.69Rf	2.4AU	7145.6AU	25.75%
3	0.96Rf	1.9AU	0.97Rf	14.4AU	2.18%	0.99Rf	1.1AU	132.4AU	0.48%
4	0.99Rf	1.0AU	1.02Rf	21.3AU	3.22%	1.04Rf	0.6AU	409.5AU	1.48%
5	1.05Rf	0.2AU	1.08Rf	26.6AU	4.03%	1.10Rf	0.6AU	279.1AU	1.01%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Amra* seed shows 5 peaks with Rf value ranging from 0.03 to 1.08 Rf. Maximum height is 380.1 of 1st peak. Chromatogram of Mixed *choorna* shows 5 peaks with Rf value ranging from 0.03 to 0.14Rf and maximum height of 1st peak as 472.5. Also height of 5th peak of *Amra* seed is similar to the height of 4th peak of mixed *choorna* implying presence of similar components.

HPTLC of *Jamun* seed

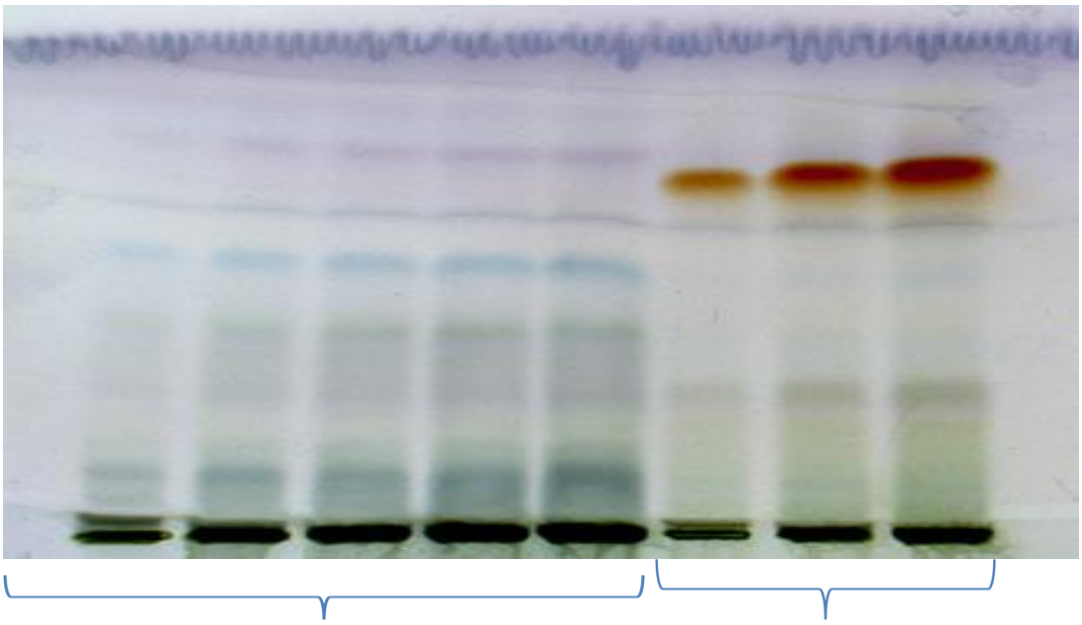


Figure 4: HPTLC by Derivatization Reagent (Anisaldehyde Sulphuric Acid) of *Jamun* seed *choorna* and Mixed *choorna* at 500 nm

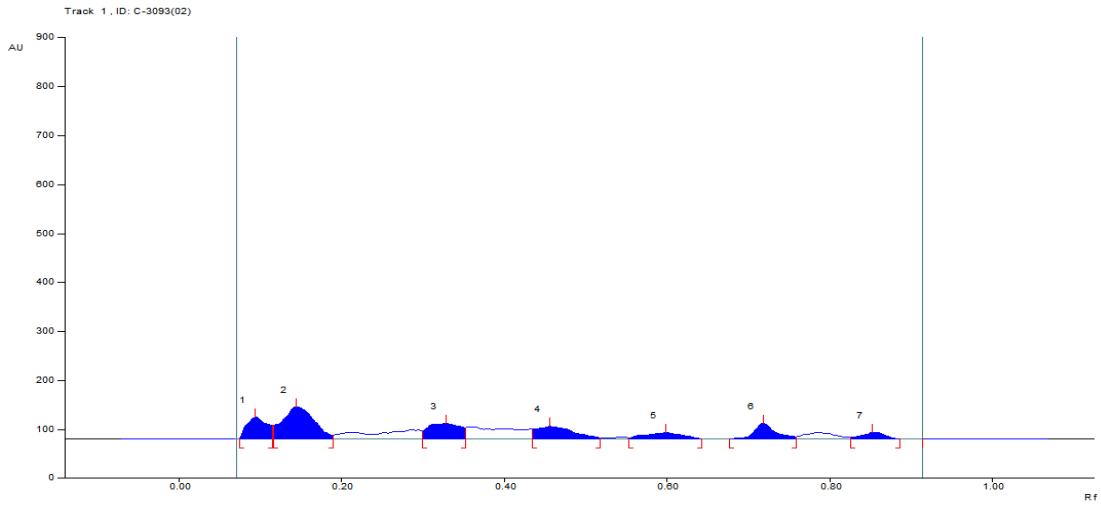


Figure 5. : Chromatogram of *Jamun* seed *choorna* extract at 500 nm

Table 16: Rf values of *Jamun* seed *choorna* at 500 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.09Rf	0.2AU	0.11Rf	44.2AU	19.63%	0.14Rf	28.2AU	914.8AU	14.14%
2	0.14Rf	28.4AU	0.17Rf	65.9AU	29.24%	0.22Rf	7.6AU	2073.5AU	32.05%
3	0.35Rf	16.9AU	0.39Rf	31.4AU	13.93%	0.42Rf	23.0AU	1057.6AU	16.35%
4	0.51Rf	19.8AU	0.54Rf	25.5AU	11.33%	0.61Rf	2.4AU	958.3AU	14.81%
5	0.65Rf	2.2AU	0.71Rf	12.8AU	5.69%	0.76Rf	0.2AU	479.9AU	7.42%
6	0.80Rf	0.3AU	0.85Rf	32.1AU	14.26%	0.90Rf	4.5AU	680.7AU	10.52%
7	0.98Rf	3.2AU	1.01Rf	13.3AU	5.92%	1.05Rf	0.1AU	305.4AU	4.72%

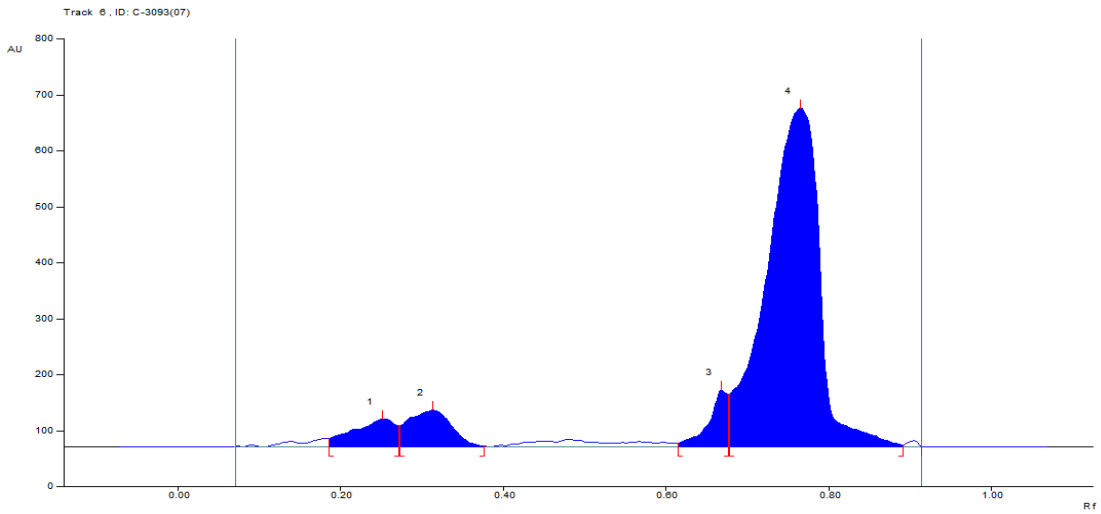


Figure 6. : Chromatogram of Mixed *choorna* extract at 500 nm

Table 17: Rf values of Mixed *choorna* at 500 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.22Rf	15.1AU	0.30Rf	50.2AU	6.10%	0.32Rf	37.7AU	2123.6AU	5.43%

2	0.32Rf	37.8AU	0.37Rf	65.5AU	7.96%	0.45Rf	1.2AU	2874.8AU	7.35%
3	0.73Rf	7.1AU	0.79Rf	101.9AU	12.38%	0.80Rf	94.4AU	1951.1AU	4.99%
4	0.80Rf	94.7AU	0.91Rf	605.7AU	73.563%	1.06Rf	3.4AU	32170.7AU	82.24%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Jamun* seed shows 7 peaks with Rf value ranging from 0.09 to 1.05 Rf. Maximum height is 65.9 of 2nd peak. Chromatogram of Mixed *choorna* shows 4 peaks with Rf value ranging from 0.22 to 1.06 Rf and maximum height of 4th peak as 605.7. Also height of 2nd peak of both *Jamun* seed and mixed *choorna* is similar implying presence of similar components.

HPTLC of Dadim peel

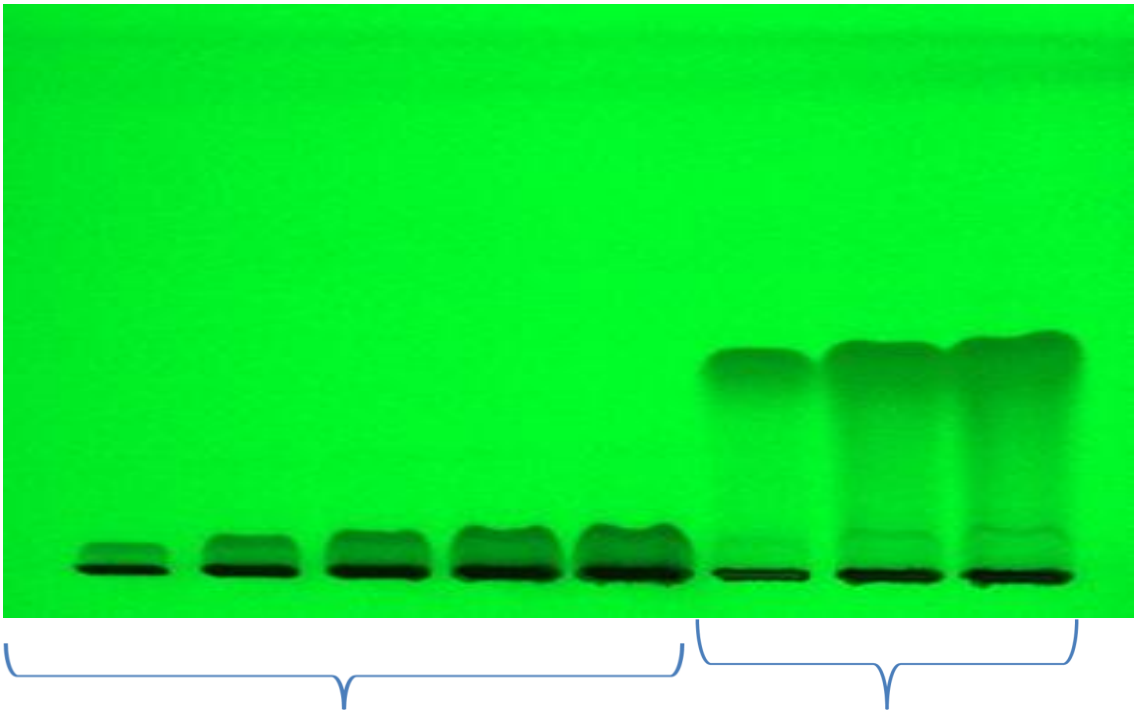


Figure 7: Finger printing of *Dadim* peel *choorna* and Mixed *choorna* at 254 nm

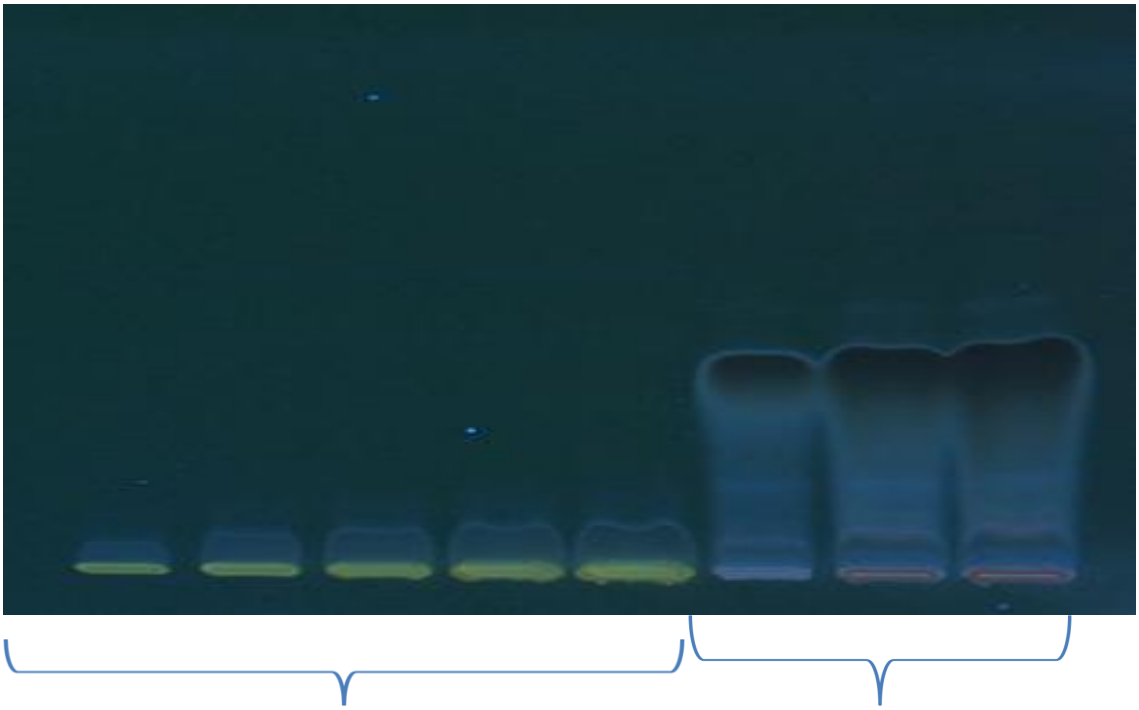


Figure 8 Finger printing of *Dadim* peel *choorna* and Mixed *choorna* at 366 nm

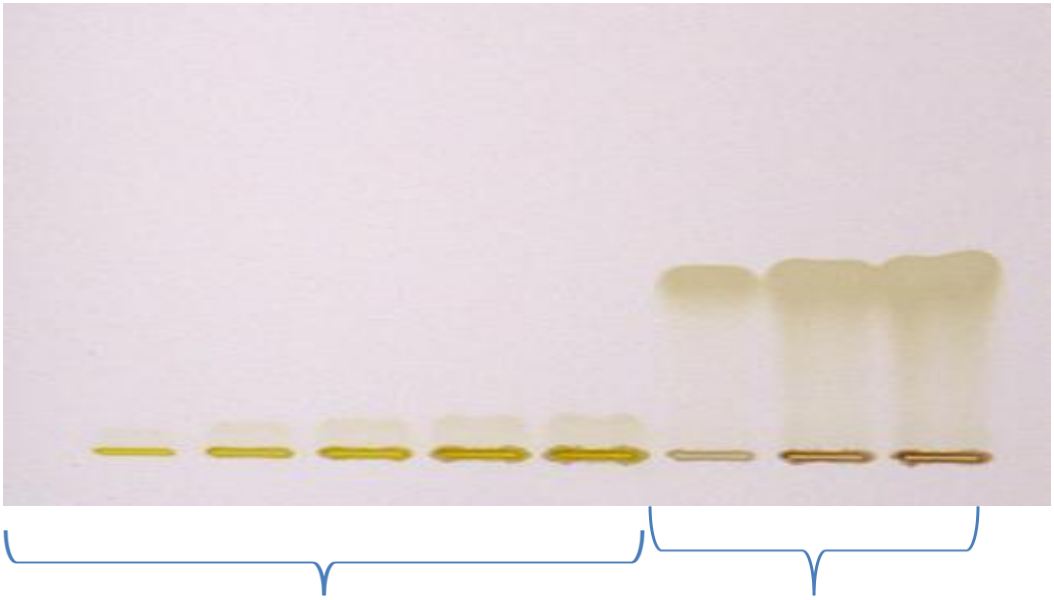


Figure 9: HPTLC by Derivatization Reagent of *Dadim* peel *choorna* and Mixed *choorna* 254nm

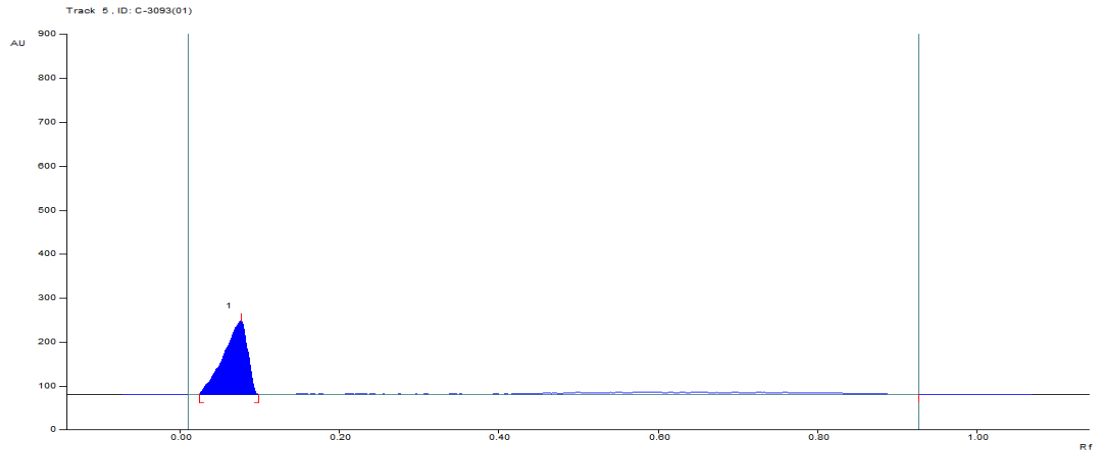


Figure 10. : Chromatogram of *Dadim* peel *choorna* extract at 254 nm

Table 18: Rf values of *Dadim* peel *choorna* at 254 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.03Rf	1.4AU	0.09Rf	168.0AU	100.00%	0.12Rf	0.1AU	4040.0AU	100.00%

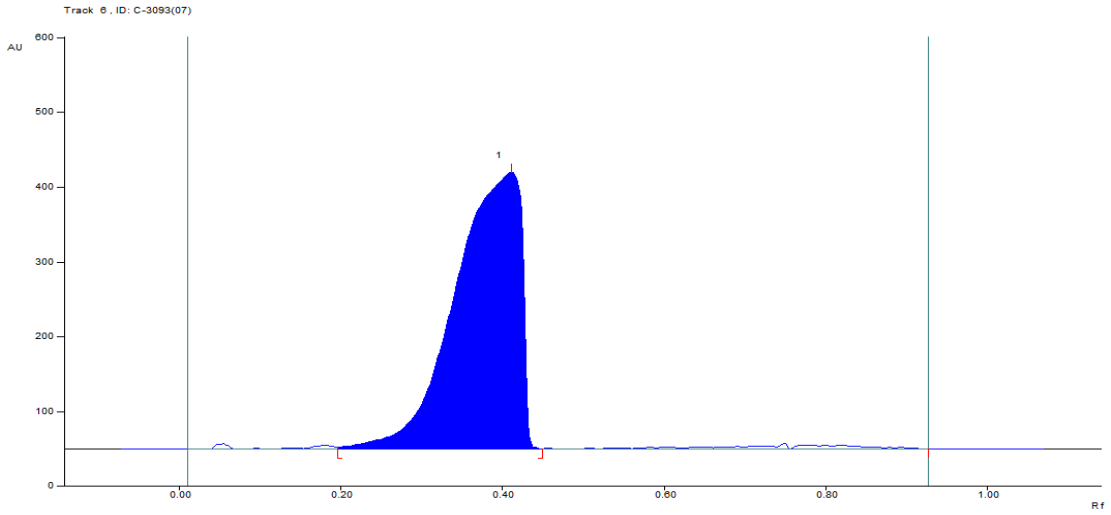


Figure 11. : Chromatogram of Mixed *choorna* extract at 500 nm

Table 19: Rf values of Mixed *choorna* at 500 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.23Rf	2.5AU	0.48Rf	369.6A	100.	0.52Rf	0.2AU	2467	100.0

				U	00%			2.2A U	0%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Dadim* seed shows 1 peak with Rf value ranging from 0.03 to 0.12 Rf. Maximum height is 168.0. Chromatogram of Mixed *choorna* shows 1 peak too with Rf value ranging from 0.23 to 0.52 Rf and maximum height as 369.6.

HPTLC of *Yashtimadhu* Root

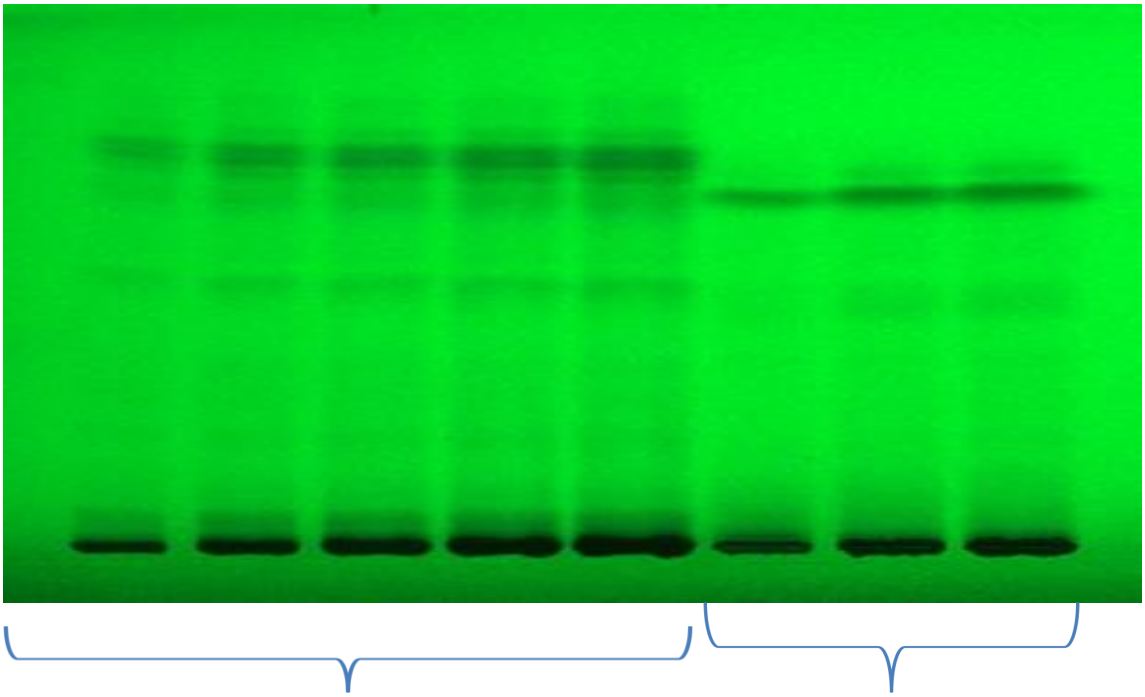


Figure 12: Finger printing of *Yashtimadhu* root *choorna* and Mixed *choorna* at 254 nm

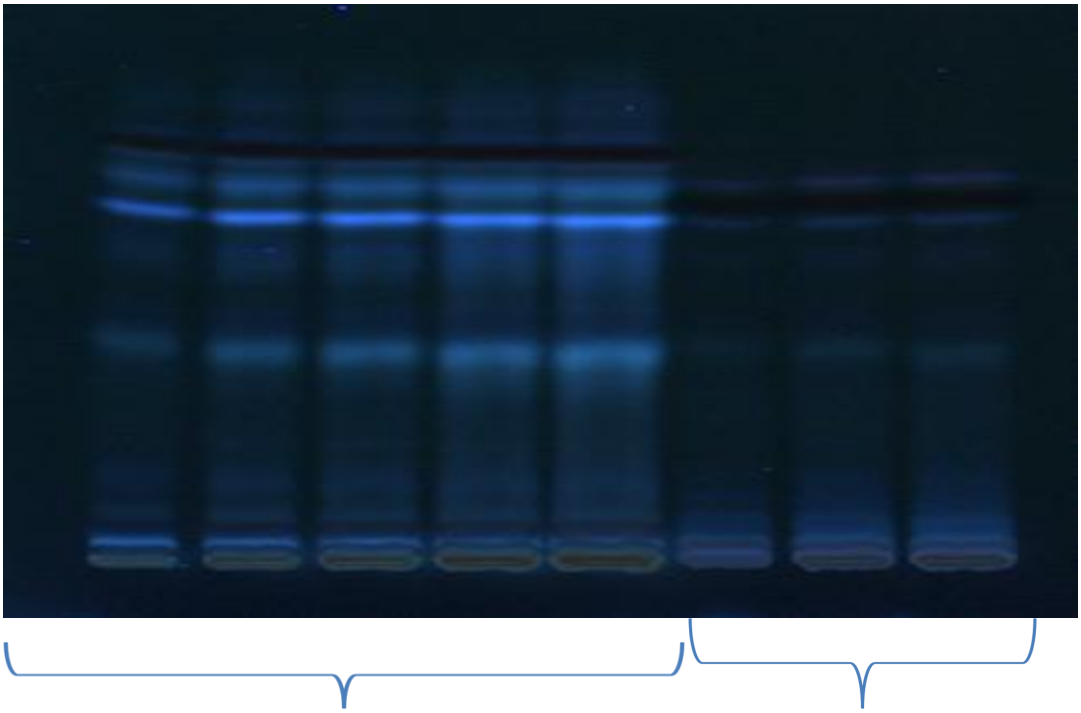


Figure 13: Finger printing of *Yashtimadhu* root *choorna* and Mixed *choorna* at 366 nm

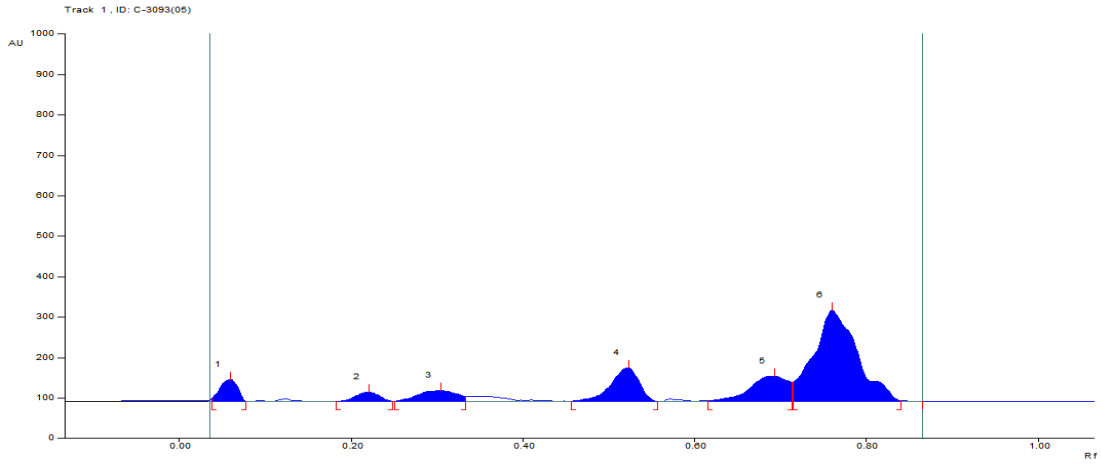


Figure 14. : Chromatogram of *Yashtimadhu* root *choorna* extract at 254 nm

Table 20: Rf values of *Yashtimadhu* root *choorna* at 254 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.05Rf	7.5AU	0.08Rf	54.7AU	11.51%	0.10Rf	0.3AU	974.7 AU	5.63 %
2	0.23Rf	0.0AU	0.28Rf	22.7AU	4.77 %	0.31Rf	0.1AU	542.9 AU	3.14 %

3	0.31Rf	0.2AU	0.38Rf	27.0AU	5.67%	0.42Rf	12.0AU	1058.7AU	6.12%
4	0.57Rf	0.3AU	0.65Rf	83.1AU	17.48%	0.70Rf	0.2AU	2374.4AU	13.72%
5	0.77Rf	1.5AU	0.87Rf	62.5AU	13.16%	0.89Rf	48.2AU	2433.0AU	14.06%
6	0.89Rf	48.4AAU	0.95Rf	225.4AU	47.42%	1.05Rf	1.8AU	9925.5AU	57.34%

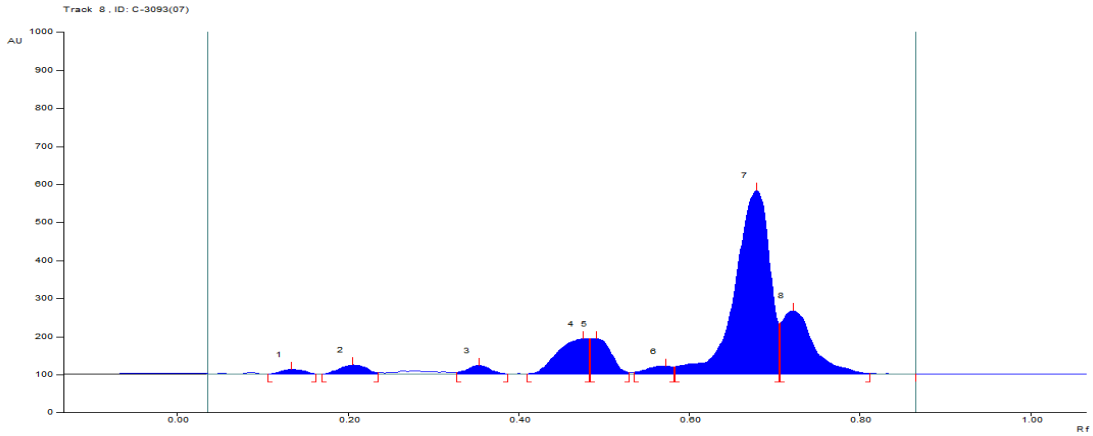


Figure 15. : Chromatogram of Mixed *choorna* extract at 254 nm

Table 21: Rf values of Mixed *choorna* at 254 nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.13Rf	0.0AU	0.17Rf	11.9AU	1.30%	0.20Rf	0.2AU	285.6AU	0.98%
2	0.21Rf	0.1AU	0.26Rf	23.8AU	2.61%	0.29Rf	4.3AU	664.7AU	2.28%
3	0.41Rf	4.8AU	0.44Rf	23.3AU	2.55%	0.49Rf	0.1AU	534.6AU	1.84%
4	0.51Rf	1.0AU	0.60Rf	92.5AU	10.12%	0.61Rf	92.1AU	2905.3AU	9.98%
5	0.61Rf	92.1AU	0.62Rf	92.6AU	10.14%	0.66Rf	4.8AU	1919.7AU	6.59%
6	0.67Rf	5.1AAU	0.72Rf	20.9AU	2.292%	0.73Rf	19.0AU	554.5AU	1.90%

7	0.73Rf	19.4AU	0.85Rf	482.6AU	52.80%	0.88Rf	33.2AU	16957.4AU	58.25%
8	0.88Rf	133.7AU	0.90Rf	166.4AU	18.20%	1.02Rf	1.1AU	5289.0AU	18.17%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Yashtimadhu* root shows 6 peaks with Rf value ranging from 0.05 to 1.05 Rf. Maximum height is 225.4 of 6th peak. Chromatogram of Mixed *choorna* shows 8 peaks with Rf value ranging from 0.13 to 1.02 Rf and maximum height of 7th peak as 482.6. Also height of 2nd peak of both *Yashtimadhu* root and mixed *choorna* is similar implying presence of similar components.

HPTLC of *Bala* Root

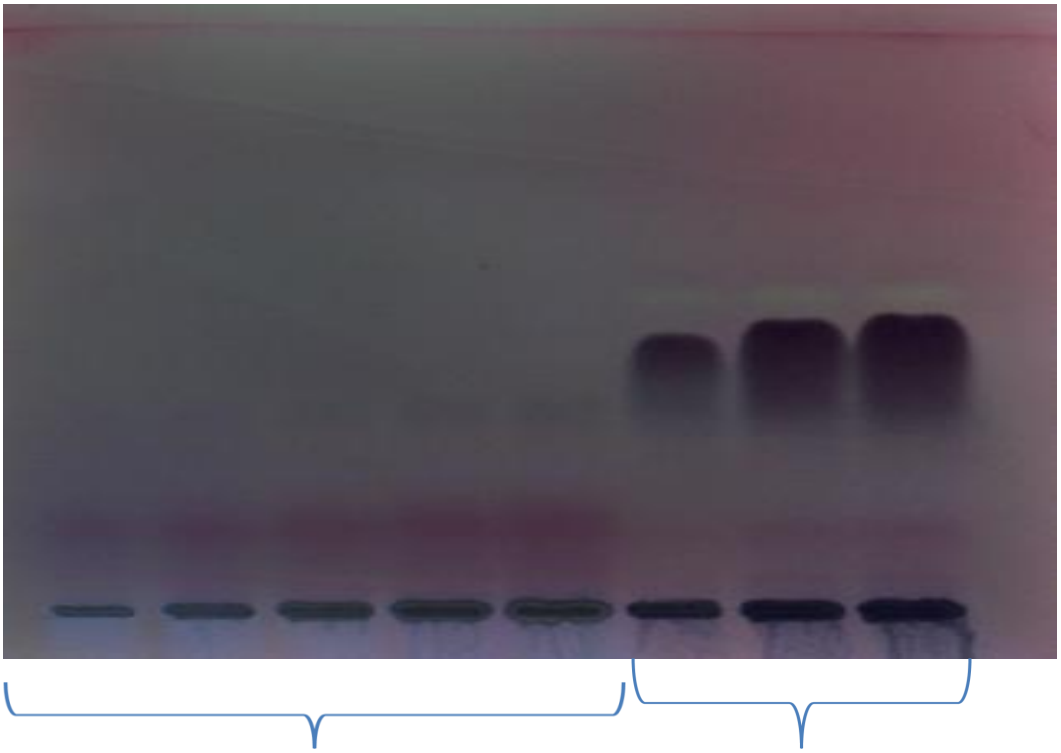


Figure 16: Finger printing of *Bala* root *choorna* and Mixed *choorna* at 366 nm

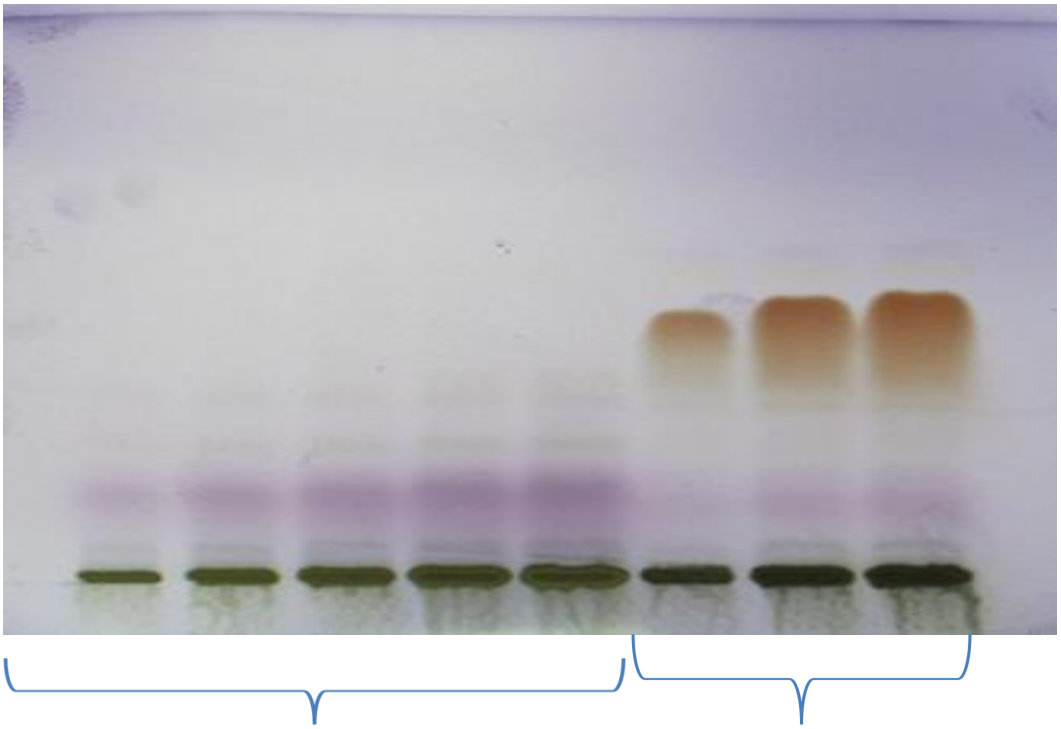


Figure 17: HPTLC by Derivatization agent (Anisaldehyde Sulphuric Acid) of *Bala* root *choorna* and Mixed *choorna* at White R

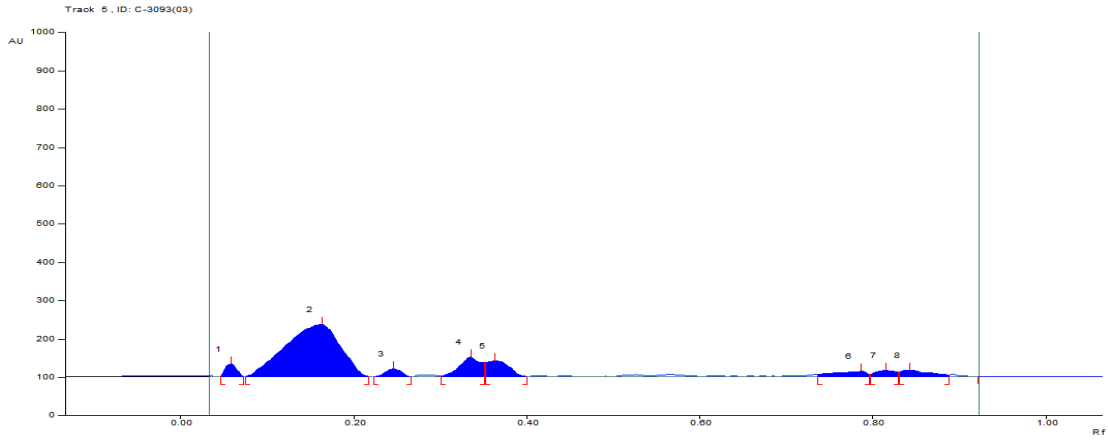


Figure 18. : Chromatogram of *Bala* root *choorna* extract at 366 nm

Table 22: Rf values of *Bala* root *choorna* at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.06Rf	1.6AU	0.07Rf	33.4AU	10.14%	0.09Rf	0.1AU	375.2AU	3.26 %
2	0.09Rf	0.3AU	0.20Rf	136.1AU	41.30%	0.27Rf	0.4AU	7491.2AU	65.13 %

3	0.28Rf	0.1AU	0.31Rf	20.2AU	6.13%	0.33Rf	0.1AU	324.1AU	2.82%
4	0.38Rf	2.8AU	0.42Rf	50.6AU	15.36%	0.44Rf	36.7AU	1088.6AU	9.46%
5	0.44Rf	36.9AU	0.46Rf	941.7AU	12.65%	0.50Rf	0.1AU	932.5AU	8.11%
6	0.92Rf	5.7AU	0.99Rf	13.9AU	4.20%	1.00Rf	5.5AU	470.5AU	4.09%
7	1.00Rf	5.8AU	1.02Rf	16.6AU	5.05%	1.04Rf	12.3AU	331.4AU	2.88%
8	1.04Rf	12.6AU	1.05Rf	17.0AU	5.17%	1.11Rf	4.5AU	488.9AU	4.25%

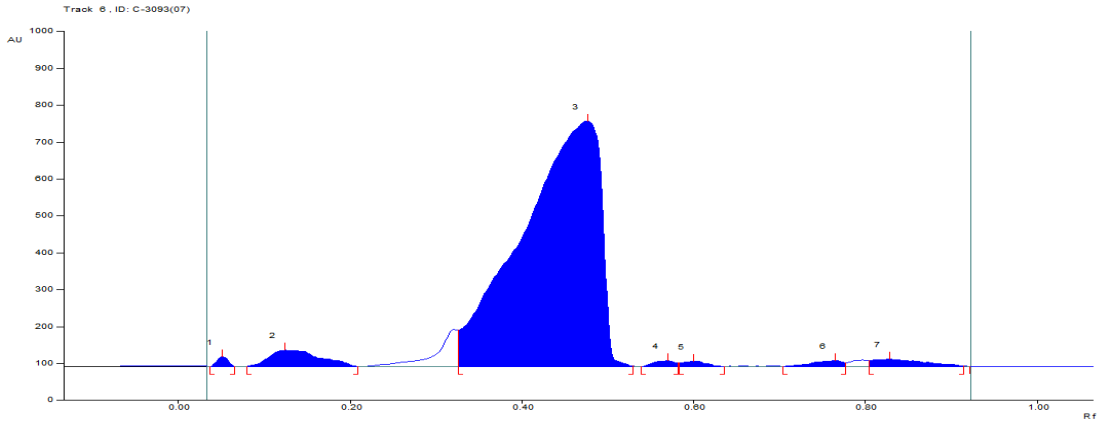


Figure 19. : Chromatogram of Mixed *choorna* extract at 366 nm

Table 23: Rf values of Mixed *choorna* at 366nm

Peak	**Start Position**	**Start Height**	**Max Position**	**Max Height**	**Max %**	**End Postion**	**End Height**	**Area**	**Area %**
1	0.05Rf	0.0AU	0.06Rf	26.8AU	3.33%	0.08Rf	0.6AU	385.4AU	0.53%
2	0.10Rf	0.3AU	0.16Rf	44.5AU	5.53%	0.26Rf	0.6AU	2320.2AU	4.02%
3	0.41Rf	99.3AU	0.60Rf	665.7AU	82.80%	0.66Rf	1.9AU	52776.9AU	91.49%

4	0.68Rf	0.4AU	0.71Rf	15.7AU	1.95%	0.73Rf	10.3AU	341.5AU	0.59%
5	0.73Rf	10.3AU	0.75Rf	15.0AU	1.87%	0.80Rf	0.3AU	352.6AU	0.61%
6	0.88Rf	0.2AU	0.96Rf	16.2AU	2.02%	0.97Rf	11.2AU	508.5AU	0.88%
7	1.01Rf	15.9AU	1.04Rf	20.0AU	2.49%	1.14Rf	1.6AU	1081.0AU	1.87%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Bala* root shows 8 peaks with Rf value ranging from 0.06 to 1.11 Rf. Maximum height is 941.7 of 5th peak. Chromatogram of Mixed *choorna* shows 7 peaks with Rf value ranging from 0.05 to 1.14 Rf and maximum height of 3rd peak as 665.7 Also height of 7th peak of *Bala* and 6th peak of Mixed *choorna* are similar implying presence of similar components.

HPTLC of *Laksha*

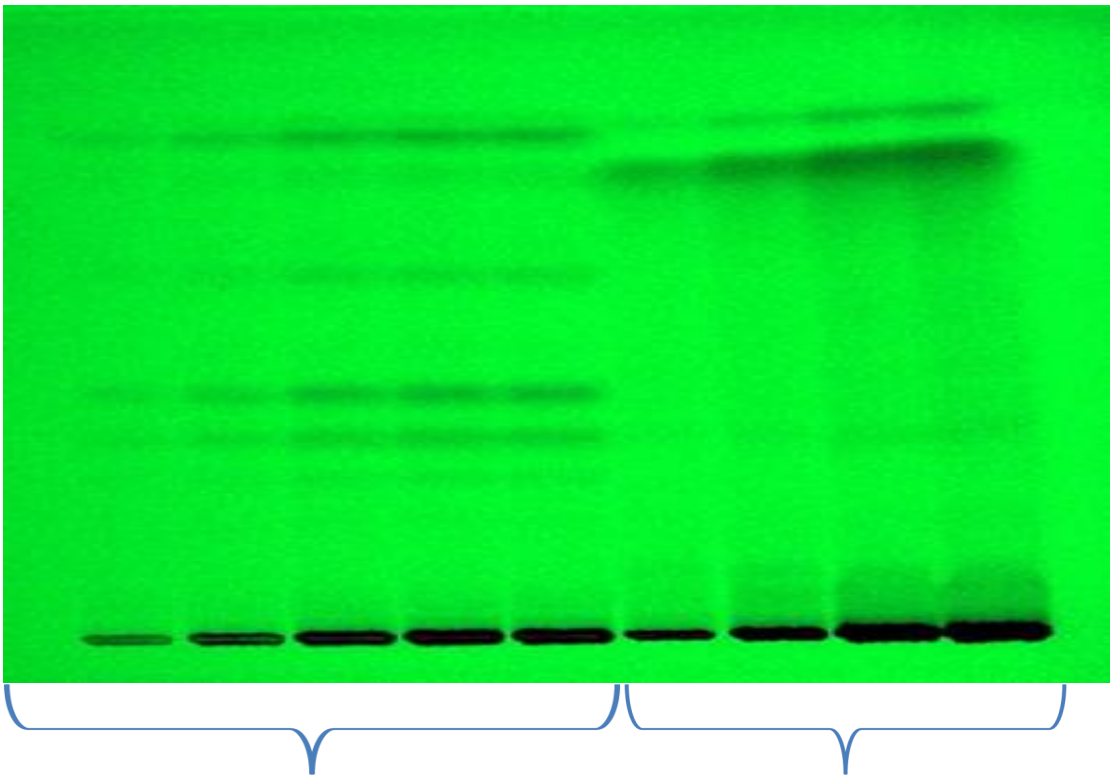


Figure 20: Finger printing of *Laksharasa choorna* and Mixed *choorna* at 254nm

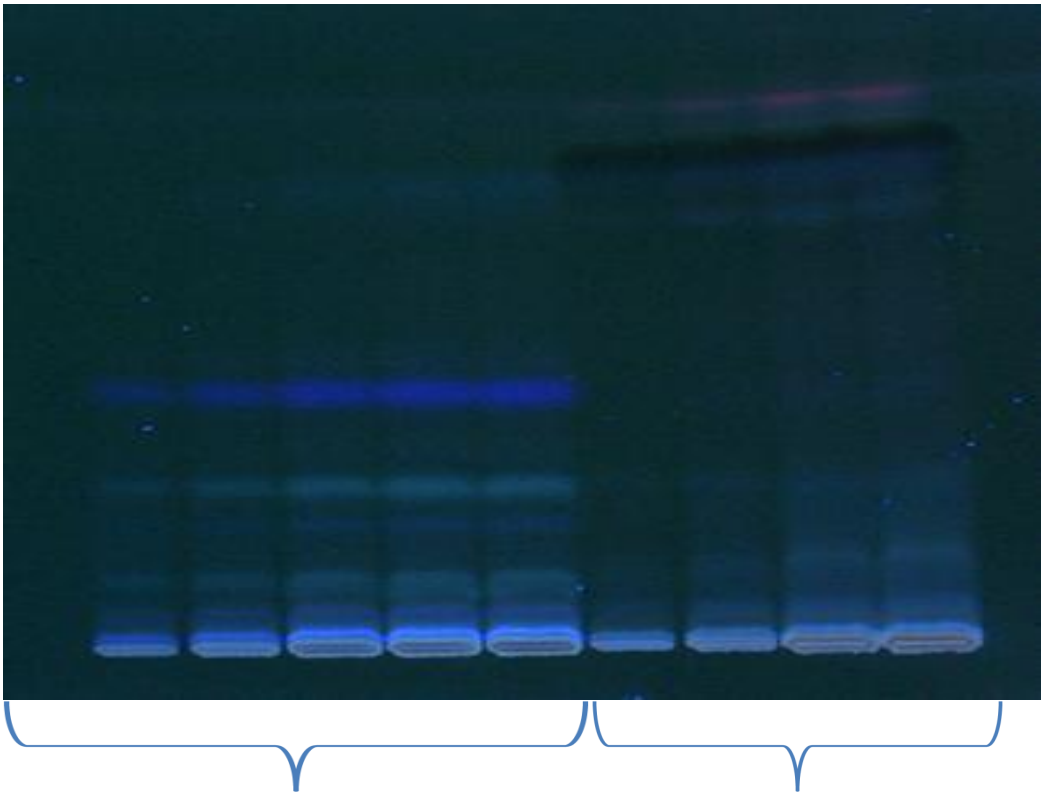


Figure 21. Finger printing of *Laksharasa choorna* and Mixed *choorna* at 366nm

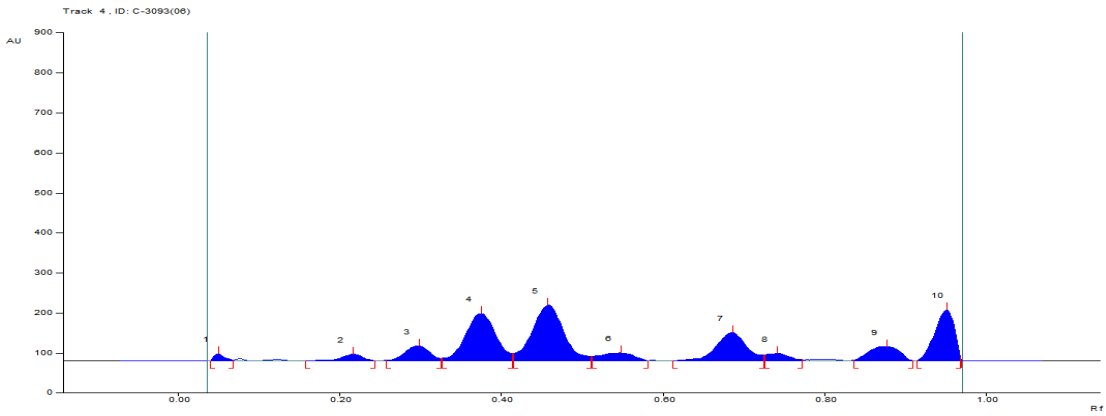


Figure 22. : Chromatogram of *Laksharasa choorna* extract at 366 nm

Table 24: Rf values of *Laksharasa choorna* at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.05Rf	0.1AU	0.06Rf	17.8AU	2.96 %	0.08Rf	2.4AU	177.6 AU	1.10 %
2	0.19Rf	0.2AU	0.25Rf	16.6A	2.75	0.28Rf	0.8AU	352.9	2.18

				U	0%			AU	%
3	0.30Rf	1.3AU	0.35Rf	37.2AU	6.19%	0.38Rf	6.3AU	921.2AU	5.69%
4	0.38Rf	6.5AU	0.44Rf	118.3AU	19.69%	0.48Rf	18.1AU	3563.2AU	22.00%
5	0.49Rf	18.3AU	0.54Rf	9.7AU	12.65%	0.50Rf	0.1AU	932.5AU	8.11%
6	0.92Rf	5.7AU	0.99Rf	139.5AU	23.21%	0.60Rf	11.5AU	4369.8AU	26.98%
7	0.71Rf	0.3AU	0.80Rf	70.4AU	11.71%	0.85Rf	14.7AU	2146.4AU	13.25%
8	1.07Rf	15.1AU	0.87Rf	18.4AU	3.07%	0.90Rf	2.8AU	413.0AU	2.55%%
9	0.98Rf	1.8AU	1.02Rf	35.6AU	5.92%	1.06Rf	0.2AU	1108.3AU	6.84%
10	1.07Rf	0.6AU	1.11Rf	127.7AU	21.25%	1.13Rf	9.9AU	2477.1AU	15.29%

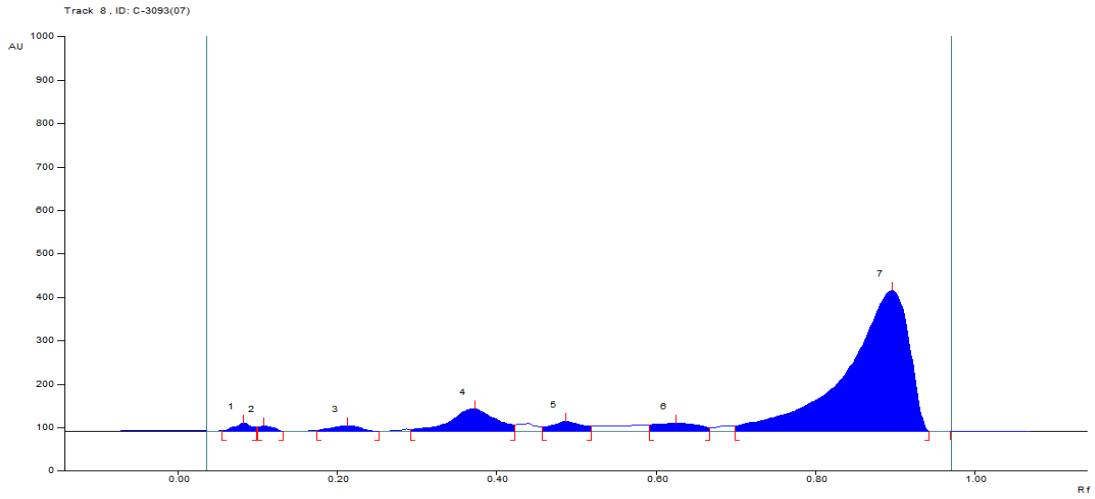


Figure 23. : Chromatogram of Mixed *choorna* extract at 366 nm

Table 25: Rf values of Mixed *choorna* at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.06Rf	1.6AU	0.10Rf	19.4AU	4.20%	0.12Rf	9.4AU	335.1AU	1.34%
2	0.12Rf	9.4AU	0.13Rf	12.0AU	2.61%	0.16Rf	0.1AU	190.6AU	0.76%
3	0.20Rf	2.4AU	0.25Rf	12.8AU	2.78%	0.29Rf	0.0AU	393.4AU	1.57%
4	0.34Rf	4.7AU	0.44Rf	51.9AU	11.25%	0.49Rf	15.3AU	2342.1AU	9.34%
5	0.54Rf	10.0AU	0.57Rf	22.5AU	4.87%	0.61Rf	11.9AU	705.7AU	2.81%
6	0.69Rf	15.2AU	0.73Rf	18.9AU	4.10%	0.78Rf	8.4AU	855.5AU	3.41%
7	0.82Rf	12.6AU	1.05Rf	323.7U	70.191%	1.10Rf	0.5AU	20249.7AU	80.77%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Laksharasa* shows 10 peaks with Rf value ranging from 0.05 to 1.13 Rf. Maximum height is 139.5 of 6th peak. Chromatogram of Mixed *choorna* shows 7 peaks with Rf value ranging from 0.06 to 1.10 Rf and maximum height as 323.7 of 7^{th} peak. Also height of 8th peak of *Laksharasa* and 6^{th} peak of Mixed *choorna* are similar implying presence of similar components

HPTLC of *Lakshadi Malhar*

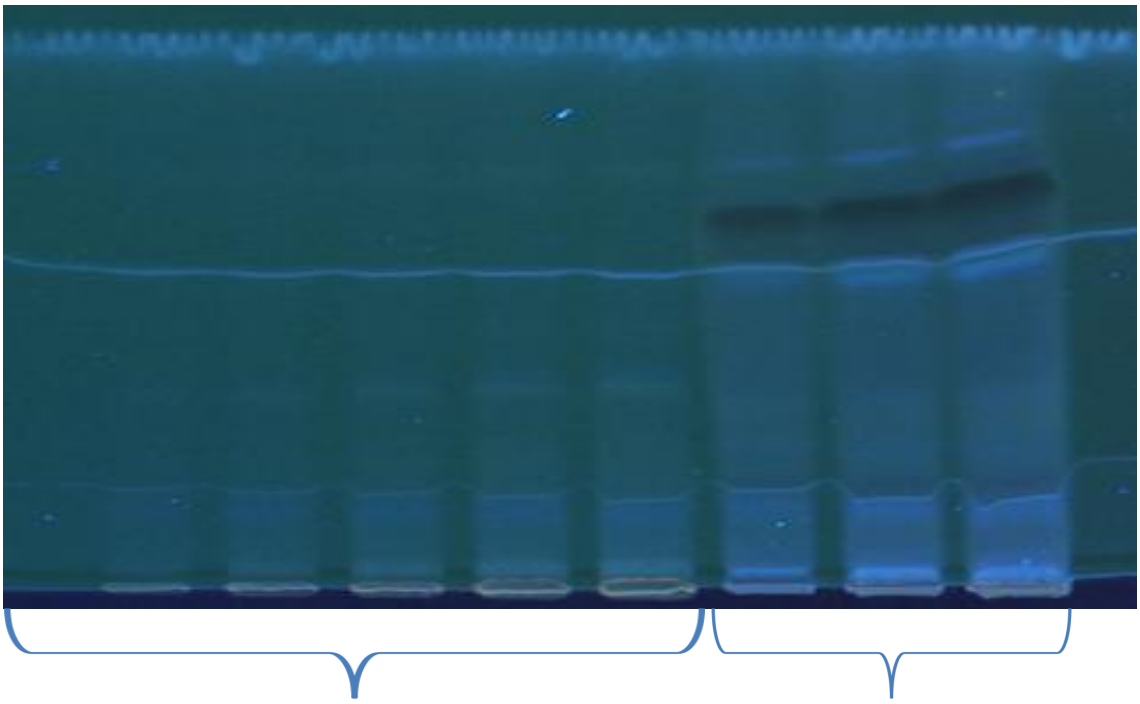


Figure 24: Finger printing of *Lakshadi Malhar* and Mixed *choorna* at 366nm

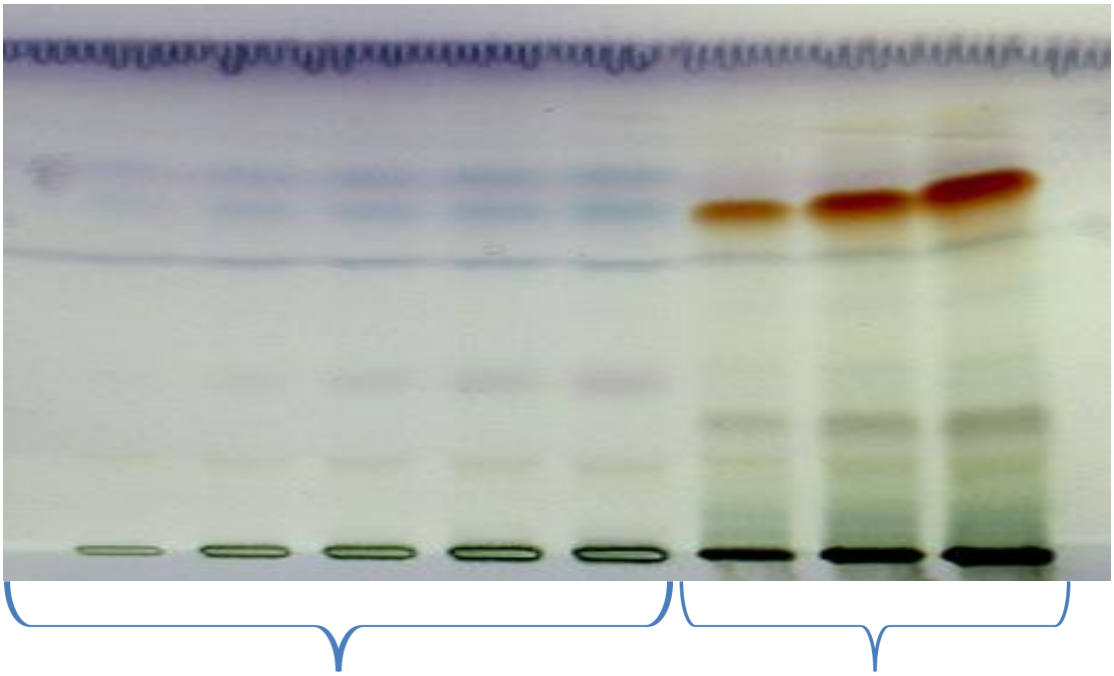


Figure 25: HPTLC by Derivatization reagent of *Lakshadi Malhar* and Mixed *choorna* at White R

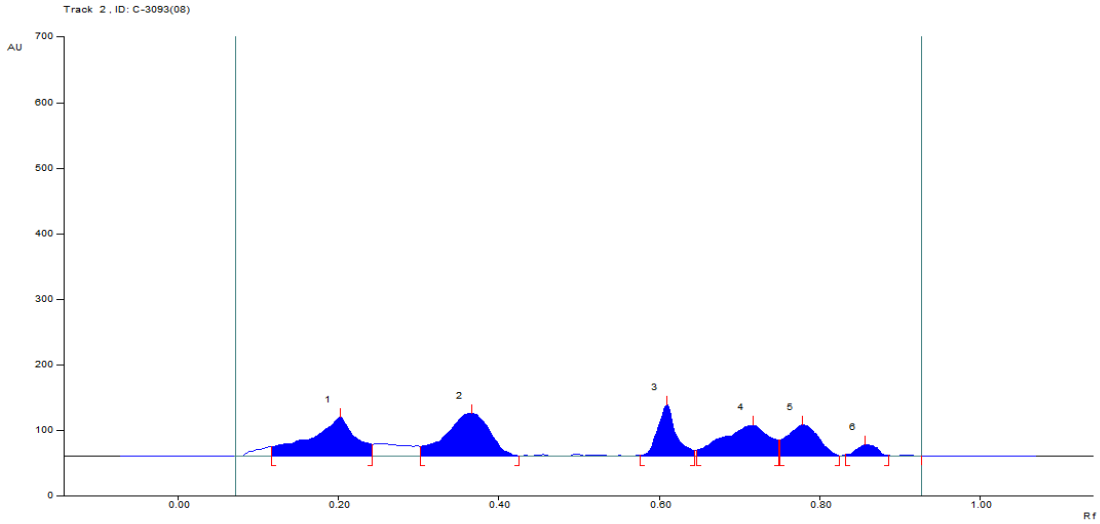


Figure 26. : Chromatogram of *Lakshadi Malhar* extract at 366 nm

Table 26: Rf values of *Lakshadi Malhar* at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.14Rf	14.1AU	0.24Rf	59.5AU	18.80%	0.28Rf	18.0AU	2681.0 AU	24.23 %
2	0.35Rf	15.1AU	0.43Rf	65.1AU	20.59%	0.50Rf	0.5AU	2854.1 AU	25,80 %
3	0.67Rf	1.1AU	0.71Rf	78.8AU	24.91%	0.75Rf	8.7AU	1432.6 AU	12.95 %
4	0.75Rf	8.9AU	0.84Rf	47.0AU	14.875%	0.88Rf	24.8AU	2218.8 AU	20.05 %
5	0.88Rf	24.9AU	0.91Rf	47.9AU	15.15%	0.96Rf	0.2AU	1512.0 AU	13.67 %
6	0.97Rf	2.4AU	1.00Rf	17.9AU	5.68 %	1.03Rf	1.2AU	365.5AU	3.30%

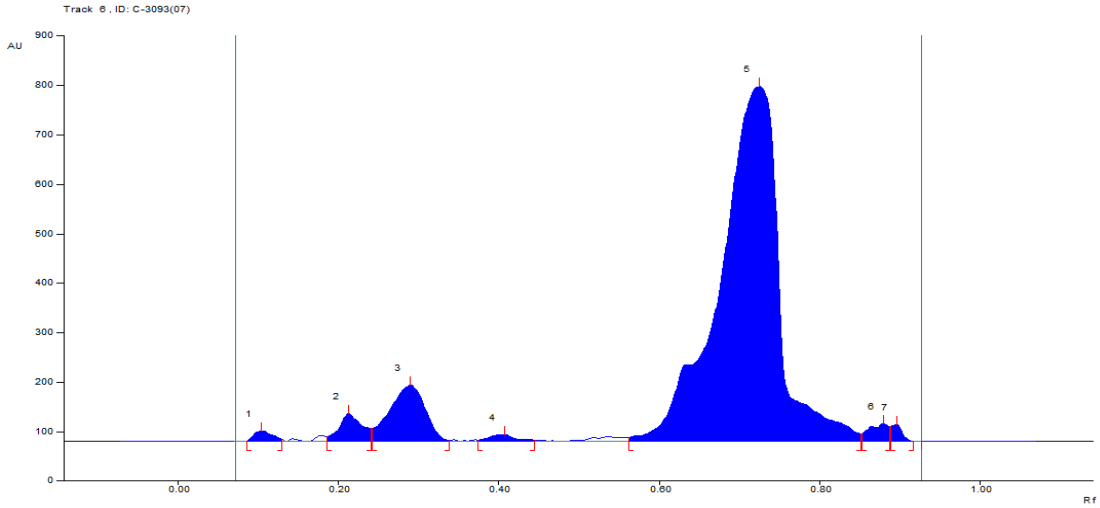


Figure 27. : Chromatogram of Mixed *choorna* extract at 366 nm

Table 27: Rf values of Mixed *choorna* at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Postion	End Height	Area	Area %
1	0.10Rf	0.3AU	0.12Rf	21.3AU	2.14%	0.15Rf	4.4AU	394.2AU	0.79%
2	0.22Rf	10.0AU	0.25Rf	56.0AU	5.65%	0.28Rf	26.3AU	1302.5AU	2.60%
3	0.28Rf	26.3AU	0.34Rf	114.3AU	11.53%	0.40Rf	1.1AU	4048.1AU	8.07%
4	0.44Rf	2.5AU	0.48Rf	13.3AU	1.34%	0.52Rf	2.6AU	357.4AU	0.71%
5	0.66Rf	8.0AU	0.85Rf	717.5AU	72.39%	1.00Rf	15.3AU	42976.0AU	85.69%
6	1.00Rf	15.8AU	1.03Rf	35.5AU	3.59%	1.04Rf	30.2AU	704.5AU	1.40%
7	1.04Rf	30.3AU	1.05Rf	33.3AU	3.36%	1.07Rf	0.2AU	371.2AU	0.74%

The various spots seen on the fingerprinting slide shows the various components present in the drug. The chromatogram of *Lakshadi Malhar* shows 6 peaks with Rf value ranging from 0.14 to 1.03 Rf. Maximum height is 78.8 of 3rd peak. Chromatogram of Mixed *choorna* shows 7 peaks with Rf value ranging from 0.10 to

1.07 Rf and maximum height as 717.5 of 5th peak. Also height of 1st peak of *Lakshadi Malhar* and 2nd peak of Mixed *choorna* are similar implying presence of similar components

LABELLING AND PACKAGING OF THE DRUGS

FILLING OF THE BOTTLES

The *Malhar* prepared were filled in sterile plastic containers.

5 gms was filled in each container. This was calculated on the basic of *Malhar* required for each patient for a period of 21 days.

In this way number of bottles filled for each batch was as follows:

***Lakshadi Malhar*:**

Batch 1: 960gms	192 bottles
Batch 2: 840gms	168 bottles
Batch 3: 820gms	164 bottles
Batch 4: 410gms	82 bottles
Total	**608 bottles**

Control *Malhar*

Batch 1: 1kg	200 bottles
Batch 2: 600gms	120 bottles
Batch 3: 620gms	124 bottles
Batch 4: 600gms	120 bottles
Total	**564 bottles**

Each patient had 7 visits. Amongst that 6 follow up visits. Medicine is stopped at Visit 6. So patient is given medicine from Visit 1 to Visit 5. So each patient required 5

bottles. Total 100 patients in each group. Hence Of each *Malhar* minimum 500 bottles were required.

LABELING OF THE DRUGS.

After the drug was filled in the sterile containers they were labeled with numbers and production date. Total numbers as per the quantity of bottles of both *Lakshadi Malhar* and Control *Malhar* were considered. A third party, volunteers assigned numbers to both the groups of drugs. As per they labeled the bottles with the respective numbers.

This list of numbers allotted to each group were sealed in an envelope and kept away. This was to ensure the blinding method. Wherein both the doctor and the patient is unaware of the numbers assigned to Drug group and Control group.

This was done each time a new batch of *Malhar* both drug and control were prepared.

The prepared drugs were kept in a dry and cool place.

Also these numbers were then written on a chit block and kept in a container. So that when a patient is recruited in a trial he / she would pick up a chit and that numbered bottle will be assigned to him/her. This was to ensure randomization in assigning the group of a study.

6. CLINICAL STUDY.

Study Design : Randomized Controlled Parallel Double Blind Experimental Study.

Total Sample size : 200 patients divided in two groups.

Groups : 2

1. Drug group ie. *Lakshadi Malhar* : n=100 patients
2. Control group ie. Control *Malhar* : n= 100 patients

Randomisation is the process of assigning clinical trial participants to treatment groups such that each participation has a known (usually equal) chance of being assigned to any of the groups. [28]

In this case there are two study groups, one drug group and the other control group.

After the drug preparation a third party had numbered the medicines both study and control (say 1 to 10) and the list of the same was kept in an envelope and sealed.

Also since 5 bottles were needed for each patient to complete the trial, (as the patient would be given medicine for each visit), one number was assigned to 5 bottles of the same group at a time.

This was to ensure that a person once assigned to a particular group would receive the medicine of that group itself.

These numbers that were assigned to the medicines were then written on chit blocks, folded and kept in a bottle. When a patient was recruited for this trial after passing the inclusion and exclusion criteria he/she was told to pick any chit from the bottle in order to assign him/her to one of the study groups.

The number he/she picked would assign him/her to that particular group and the patients would then be given medicines of that number until the trial ends.

This is a simple randomization technique.

Blinding : Double Blind Method

A double-blind study is one in which neither the participants nor the experimenters know who is receiving a particular treatment. This procedure is utilized to prevent bias in research results. Double-blind studies are particularly useful for preventing bias due to demand characteristics or the placebo effect.[29]

The drugs after manufactured were given to a third person/party to number. They numbered the drugs, both control and study after making a list of random numbers, assigning them to each group. For eg. If 50 bottles each, of drug as well as control group were prepared. And each patient needs 5 bottles then 100 bottles can cater to 20 patients and so 20 numbers will be assigned to these bottles. (1 to 20). Now the third party will randomly group these numbers. Say, 1,4,2,6,8,10,14,15.17.20 for drug group and the rest 3,5,7,9,11,12,13,16,18 and 19 to control group.

This grouping of numbers is sealed in an envelope by the third party and handed over to me. Now, when a patient picks up a chit from the bottle to select a group for

himself/herself, they automatically are assigned to a particular group which is both unknown to the researcher as well as to the participant/patient.

And this is known as double blinding method.

This blinding is broken only at the end of the trial or if any patient gets a severe adverse reaction.

Blinding helps in unbiased assessment of study. This holds true especially in case of subjective assessment parameters.

Mode of administration of drug : Topical application on the affected part of face. Before the application, the face should be washed and wiped well.

Frequency of application : Twice daily.

Morning and night or afternoon and night.

VISITS & DURATION OF STUDY

Visits : Day 0 - 1st Visit, Day of Enrollment

Day 21- 2nd Visit/ 1st Follow up

Day 42 – 3rd Visit/ 2nd follow up

Day 63 – 4th Visit / 3rd follow up

Day 84 – 5th Visit / 4th follow up

Day 105 – 6th visit /5th follow up/ Completion of treatment

Day 135 - 7th Visit /6th follow up/ Follow up post treatment completion

Total number of visits : 7

Total no. of follow up : 6

Total Duration of study : 135 days

ETHICS COMMITTEE APPROVAL

The clinical trial was initiated only after taking the Instituitional Ethics Committee approval.

PATIENT SELECTION CRITERIA

Inclusion Criteria

1. Age: 20 to 50 yrs Belonging to either of the sex
2. Patients having classical symptoms of V*yanga* (melasma).
3. Patients not using any topical treatment for melasma for 2 weeks prior to enrollment in the study.
4. Must provide written informed consent and comply to the protocol

Exclusion Criteria

1. Pregnant women, nursing mothers.
2. On treatment of any topical depigmenting agent within 2 weeks prior to enrollment.
3. Patients who have taken topical or systemic steroids within 1 month prior to enrollment.
4. Patients who have taken topical tretinoin within 3 months or topical hydroquinone within 6 months prior to enrollment.
5. Under treatment for another dermatological condition.

Diagnostic Criteria

1. Having classical symptoms of *Vyanga*
2. *Shyaav*-Brown patches
3. Painless
4. Thin-non elevated
5. Involving only face

Assessment Criteria

1. Melasma Area and Severity Index Score (MASI Score)
2. Physicians Global assessment Scale (PGA) 0-6
3. Patients Assessment Scale 1-3
4. Melasma Severity Scale 0-3
5. Fairness meter test 1-7
6. Clinical response to treatment scale -2 to 2
7. Photographs
8. Quality of life will be assessed using a Quality of Life questionnaire

All the scales above ie. No. 1-5 are used as per the ideal guidelines for melasma.

Withdrawal Criteria

1. Request of the patient
2. Repeated protocol criteria violation and non compliance.
3. Lost to follow up
4. Also if the subject does not apply the medication for a week at a stretch he will be withdrawn from the trial.
5. If any serious adverse effects arise during the study, the medication will be stopped and the patient will be withdrawn from the study.

Screening Procedure/Visit 1:

Patients coming in the M.A.Podar Hospital Out patient Department were considered for trial.

During the first visit they were screened to see if they could be enrolled in the trial on the basis of the inclusion and exclusion criteria.

If they fitted into all the criteria then they were recruited in the trial. If they did not fit the trial then they were excluded from the trial.

Once recruited, the patient was explained the trial in the language best understood by him or her. Patient Information sheet about the trial was handed over to him/her. This information sheet contained my contact number so that patient could contact me for any query. If the patient wanted to discuss it with his/her family, time was given accordingly. If the patient understood then itself then an Informed Consent Document was handed over to him or her to be signed that he understood whatever has been explained to him or her about the trial by the doctor and that he consented to participate in the trial. Also that he had the right to leave the trial whenever he wished.

On signing the Informed Consent Document(ICD) the patient got included in the trial.

Then the case record form was filled with the patient's case history details. Detailed history regarding the patient's diet, habits was noted down. Any related causes was enquired about. All the scales were assessed. *Prakriti* form as well Quality of life score form was filled.

Melasma Severity Scale, MASI Score and Fairness meter scale is measured and the score given.

Lastly the photos of the patient's picture of face was clicked.

The bottle containing the numbered chits of the medicine was then given to the patient and he was told to pick one chit.

The number in the chit was the *Malhar* to be given to the patient. Immediately patient was assigned to a particular group unknowing to the patient or the doctor due to the double blind procedure.

The drug was then given to the patient and explained how to apply the cream. The patient was also explained to inform and be alert about any reaction or untoward action that might occur after application of the cream and if so happens to inform the doctor and stop the medicine immediately.

The date of the next visit is intimidated to the patient.

Follow up Visits of Patients.

Patient had follow up after every 21 days. Total 6 follow ups. The last follow up is after 30 days. It was to see if the patient had relapse of symptoms after stopping the medication at Visit 6.

At each follow up visit, from Visit 2 to Visit 6, the patient is first asked about any reactions or discomfort that they might have experienced. If there were then these were noted in the Case Record Form.

Adverse Events

Sometimes some mild itching or burning was experienced by some patients on first application of the cream which discontinued on the second application. Such reactions were noted but since these were mild and did not reoccur these patients were continued in the study.

Some patients complained of tingling sensation on first application, but these symptoms discontinued after some time.

Some patients complained of burning of eyes even on 2^{nd} and 3^{rd} applications. Such patients were discontinued from the trial and medicine stopped immediately.

Any reaction that the patient experienced were noted in the Case Record Form and after assessing whether they were serious or not, the patients were either continued or discontinued from the trial.

Missed Doses

Patients were even enquired of any missed doses. Many had few missed applications, from 2 to 4 times or so. Such patients were explained the need to apply the cream regularly without missing. Only those patients who did not apply the cream for 7 days at a stretch were withdrawn from the trial. But none patient were observed skipping the drug for this long.

Scales assessed at each Visit

At each follow up visit Patient's Assessment scale, Physician's Assessment Scale, Clinical Response to Treatment Scale, MASI Score, Melasma Severity Scale and Fairness Meter Scale reading was taken.

Fairness Meter Scale:

This scale is used to measure the darkness or fairness of the skin. According to Ayurveda to measure the *Shyavta* of *Vyanga(*Melasma), to see the improvement or worsening of this condition during each visit. This scale ranges from 1 to 7, where 1 is lightest and 7 is darkest. For this Fairness Meter of Fair and Lovely fairness Cream Packet was used.

Melasma Severity Scale

This scale measures the darkness or *shyavta* of *Vyanga* (Melasma) lesions. It ranges from 0-3 where,

0 = melasma lesions almost equivalent to surrounding normal skin or with minimal residual pigmentation;

1 = mild, slightly darker than surrounding normal skin;

2 = moderate, moderately darker than surrounding normal skin;

3 = severe, markedly darker than surrounding normal skin.

MASI SCORE

It is the Melasma Area and Severity Index Score (MASI). It is developed by Kimbrough-Green *et al* for the assessment of Melasma. The severity of the Melasma in each of the four regions (Forehead 30%, Right malar region 30%, Left malar region 30% and Chin10%) is assessed based on three variables:

1. percentage of the total **area** involved (A),
2. **darkness** (D), and
3. **homogeneity**(H).

A numerical value assigned for the corresponding percentage **area** (A) involved is as follows:

0 = No involvement;

1 = 10% involvement;

2 = 10-29% involvement;

3 = 30-49% involvement;

4 = 50-69% involvement;

5 = 70-89% involvement;

6 = 90-100% involvement

The **darkness** of the melasma (D) is compared to the normal skin and graded on a scale of 0 to 4 as follows:

0 = Normal skin color without evidence of hyperpigmentation;

1 = Barely visible hyperpigmentation;

2 = Mild hyperpigmentation;

3 = Moderate hyperpigmentation;

4 = Severe hyperpigmentation.

Homogeneity of the hyperpigmentation (H) is also graded on a scale of 0 to 4 as follows:

0 = Normal skin color without evidence of hyperpigmentation;

1 = Specks of involvement;

2 = Small patchy areas of involvement <1.5 cm diameter;

3 = Patches of involvement >2 cm diameter;

4 = uniform skin involvement without any clear areas

To calculate the MASI score, the sum of the severity grade for darkness (D) and homogeneity (H) is multiplied by the numerical value of the areas (A) involved and by the percentages of the four facial areas (10-30%).

Total MASI score =

Forehead 30% (D+H)A + Right malar 30% (D+H)A + Left malar 30% (D+H)A + Chin10%(D+H)A

So MASI Score gives us the score given to the combined effects of Melasma, area involved(*vyapti*), darkness(*shyavta*) and the type of distribution.

Physicians Global Assessment Scale (PGA)

This Scale applies to the changes observed by the Physician in the Patient's condition. The Scale ranges from 0 to 6, where 0 is clearance of any symptoms and 6 is the worse condition. The description of the scale is as follows:

0 = Clear, except for possible residual discoloration.

1 = Almost clear, very significant clearance (90%); only minor evidence of hyperpigmentation remains.

2 = Marked improvement, significant improvement (75%); some disease evidence of hyperpigmentation remains.

3 = Moderate improvement, intermediate between slight and marked improvement; (50%) improvement in appearance of hyperpigmentation

4 = Slight improvement, some improvement (25%); significant evidence of hyperpigmentation remains.

5 = No improvement; hyperpigmented condition unchanged.

6 = Worse; condition worse than at baseline.

Patient's Assessment Scale (PA)

This Scale gives a glimpse of a Patient's perspective about the relief they have witnessed about their condition. This scale ranges from 1 to 4, where 1 is very good improvement and 4 is no change. The description of this scale is as follows:

1 = Marked/Very good improvement(> 75%)

2 = Moderate/Good improvement (>50-75%)

3 = Mild/Less improvement(>25 - 50%)

4 = No improvement (0-25%)

Clinical Response to Treatment Scale (CRT)

This Scale attempts to study the effect of the Treatment given. It ranges from -2 to 2, where below 0 ie. the negative number implies the worsening of condition and above 0 ie. 1 and 2 imply the improvement of condition. The description of the scale is as follows:

-2 = Much worse

-1 = Worse

0 = No change

1 = Improved (Upto 50%)

2 = Much improved (> 50%)

At every follow up visit fresh bottle of medicine was given to the patient.

Medication was stopped at Visit 6 and patient called after a month on Visit 7.

Photographs

Photographs of patient's face, the part where *Vyanga* occurred was taken at every visit. Right from Visit 1 to Visit 7.

Visit 7

On the last visit ie.Visit 7, Patient's Assessment scale, Physician's Assessment Scale, Clinical Response to Treatment Scale, MASI Score, and Fairness Meter Scale reading

were taken. This was compared with the results of Visit 6 to see if there is any relapse or not.

Some patients did not come for the last visit, then for such patient's follow up was taken on the phone to see whether any relapse was observed and the same was noted in their Case Record Form.

Quality of Life Score

This Form was filled first on Visit 1 and then on Visit 6. The Scores of these 2 visits were finally calculated. This form comprised of a questionnaire which was filled by the patient itself. The score was then calculated by the physician. The Scores were assessed as following:

0 to 1 = No effect on Patient's life

2 to 5 =Little/Minimal effect

6 to 10 = Moderate effect

11 to 20 = Very large effect

21 to 30 = Extremely large effect

Patients recruited in the trial and Dropouts

Total patients screened in the trial : 278

Total patients recruited in the trial: 270

Trial completed by : 200

Dropouts: 68

Discontinued due to adverse event: 2

STUDY CENTRE

Preparation of drug: In Rasashastra Laboratory at R.A.Podar Medical College, Worli, Mumbai

Analysis of Raw material and Prepared Drug: It was done from various Laboratories in Mumbai and Pune.

Patients : M.A.Podar Ayurvedic Hospital, Worli, Mumbai.

Medical Camps

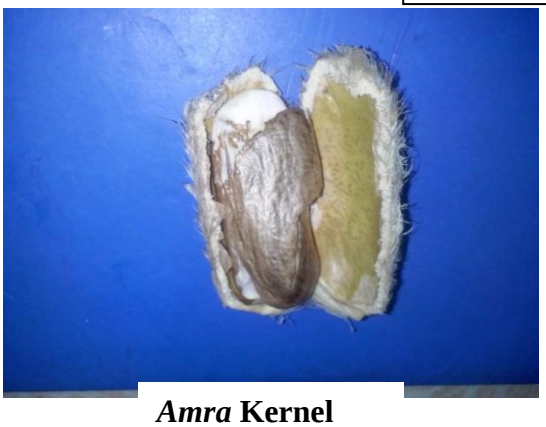
After a year the patients were even recruited from various medical camps organized by our hospital in the nearby areas.

During these camps the patient were only screened and if they fitted in the selection criteria then they were told to come to the hospital for recruitment.

These medical camps were usually organized by Medicine Department of M.A.Podar Hospital.

These camps were not necessarily for skin diseases but I attended them nevertheless. Many a times it was observed that *Vyanga*(Melasma) patients came to these camps to treat some other diseases and not Melasma, such patients were spotted and then screened.

RAW MATERIALS



***Amra* Kernel**

***Amra* seed(Magnifera Indica)**

***Jambu* seeds(Syzygium cumini)**

***Yashtimadhu* roots (Glycyrrhizia glabra)**

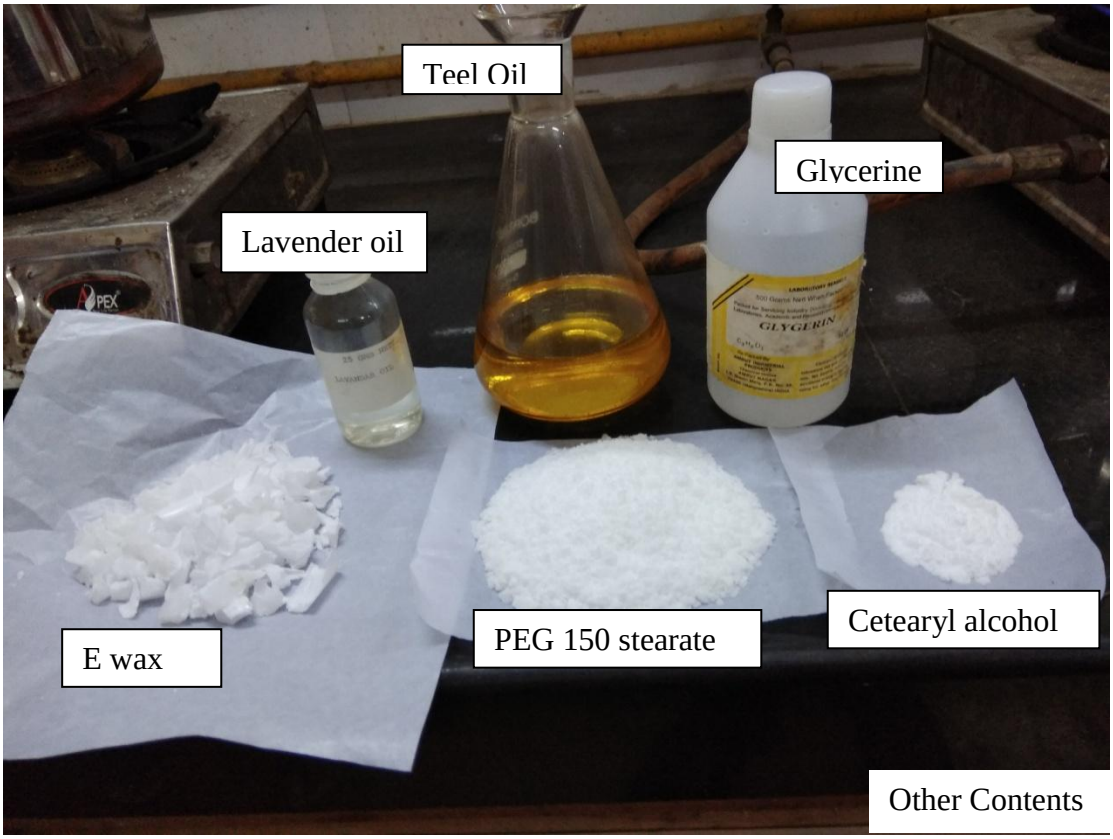
***Laksha* resin(Laccifera lacca)**

***Dadim* Peels(Punica Granatum)**

***Bala* root (Sida Cordifolia)**

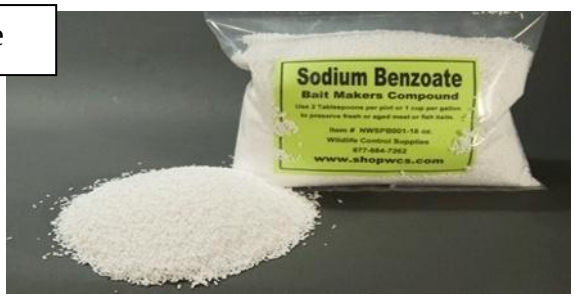
***LAKSHADI MALHAR* PREPARATION**

Kwatha Dravya



Other Contents

Preservative: Sodium Benzoate



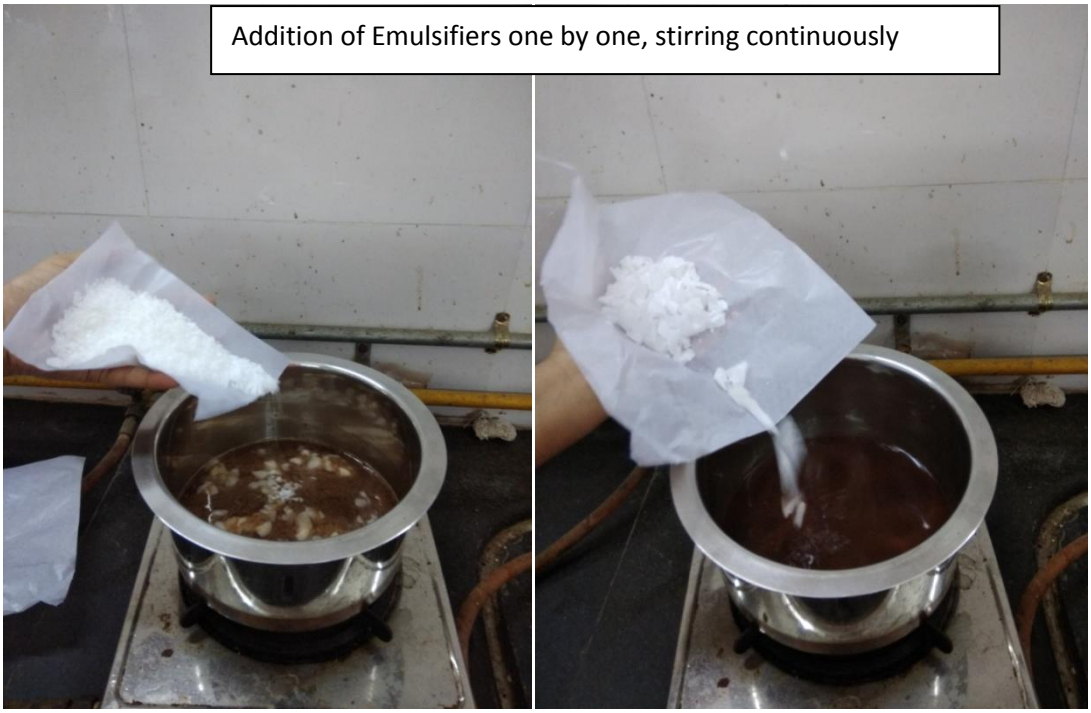
PROCEDURE OF *LAKSHADI MALHAR* PREPARATION

Powdered *Kwath Dravya*

Soaked in water for few hours

After adding 16 times water, *dravya* is boiled on medium flame

Kwath obtained after straining through a cloth


Addition of Emulsifiers one by one, stirring continuously


Stirring continuously
Until a smooth paste is formed

Addition of oil and glycerine after switching the flame off.

Cooling the mixture

Finally the preservatives and lavender oil are added on cooling

Beat the mixture with a Blender

Lakshadi Malhar formed

Bottled *Lakshadi Malhar*

CONTROL DRUG PREPARATION

Contents of Control drug

Firstly water is heated, emulsifiers added, then oil and glycerine is added. On cooling, preservatives, lavender oil and colour is added

On stirring the mixture

Blending the mixture

Bottled Control Drug

Bottled and Labeled both Control *Malhar* and *Lakshadi Malhar*

FAIRNESS METER SCALE

BALA ROOT *CHOORNA*

YASHTIMADHU ROOT *CHOORNA*

LAKSHA CHOORNA

DADIM PEEL *CHOORNA*

AMRA SEED *CHOORNA*

JAMUN SEED *CHOORNA*

ANALYSIS OF CLINICAL DATA

For the study total 200 patients completed the trial. They were divided as 100 in each group. Their demographic data was sorted in the following categories:

CATEGORY: I. Personal Information

Table No. 1: Sex Ratio of Drug Group

Sex	Total Numbers	%
Male	32	32
Female	68	68
Total	100	100

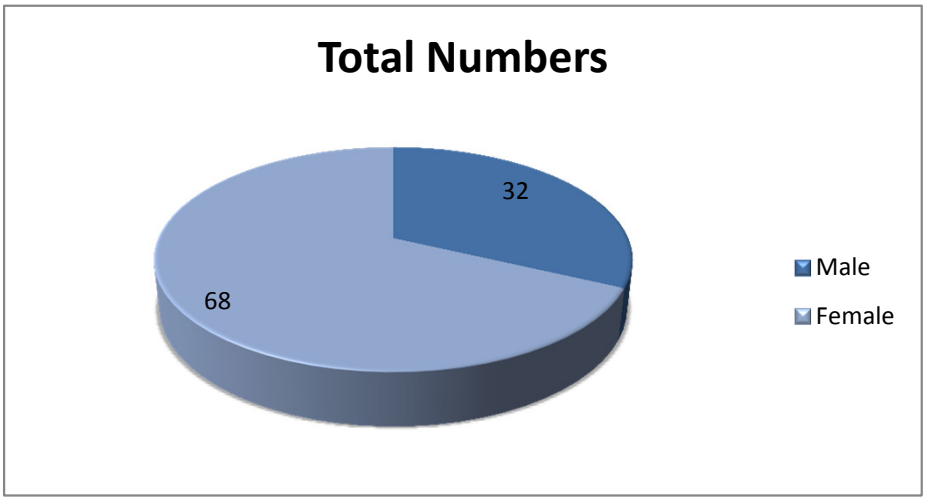


Figure No. 1.Sex Ratio of Drug Group

Table No. 2: Sex Ratio of Control Group

Sex	Total Numbers	%
Male	36	36
Female	64	64
Total	100	100

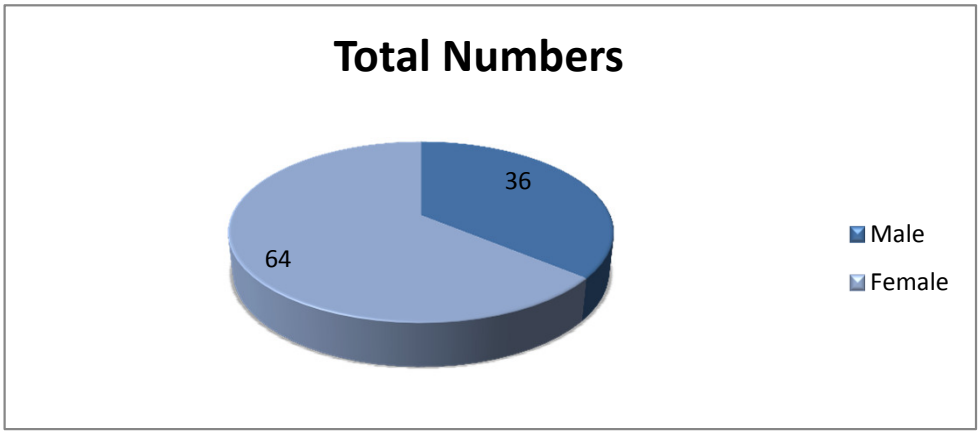


Figure No. 2.Sex Ratio of Control Group

Table No. 3: Age distribution of Drug Group

Age Group	Total Numbers	%
20 to 30 yrs	12	12
31 to 40 yrs	30	30
41 to 50 yrs	58	58
Total	100	100

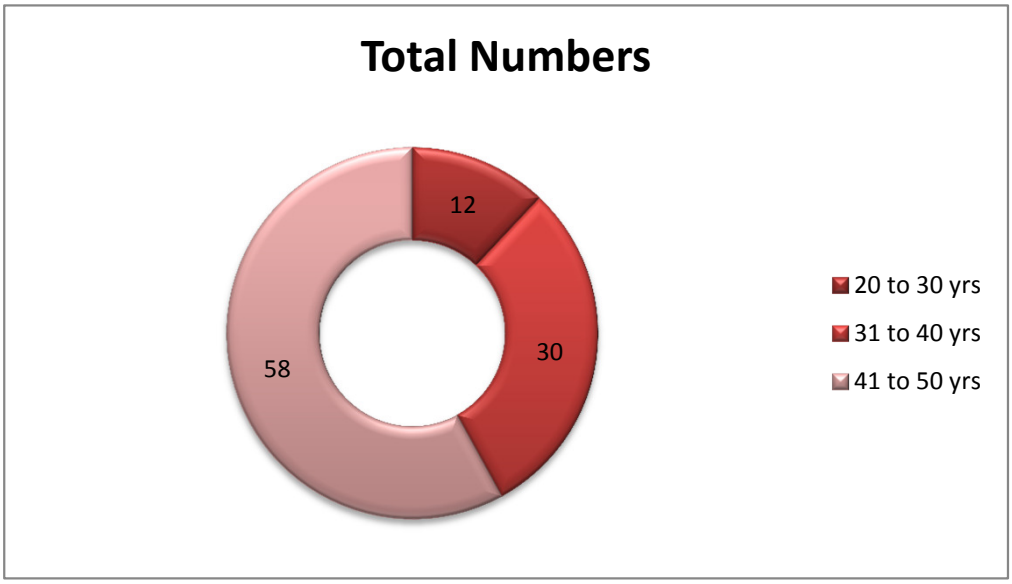


Figure No. 3. Age distribution : Drug Group

Table No. 4: Age distribution of Control Group

Age Group	Total Numbers	%
20 to 30 yrs	14	14
31 to 40 yrs	42	42
41 to 50 yrs	44	44
Total	100	100

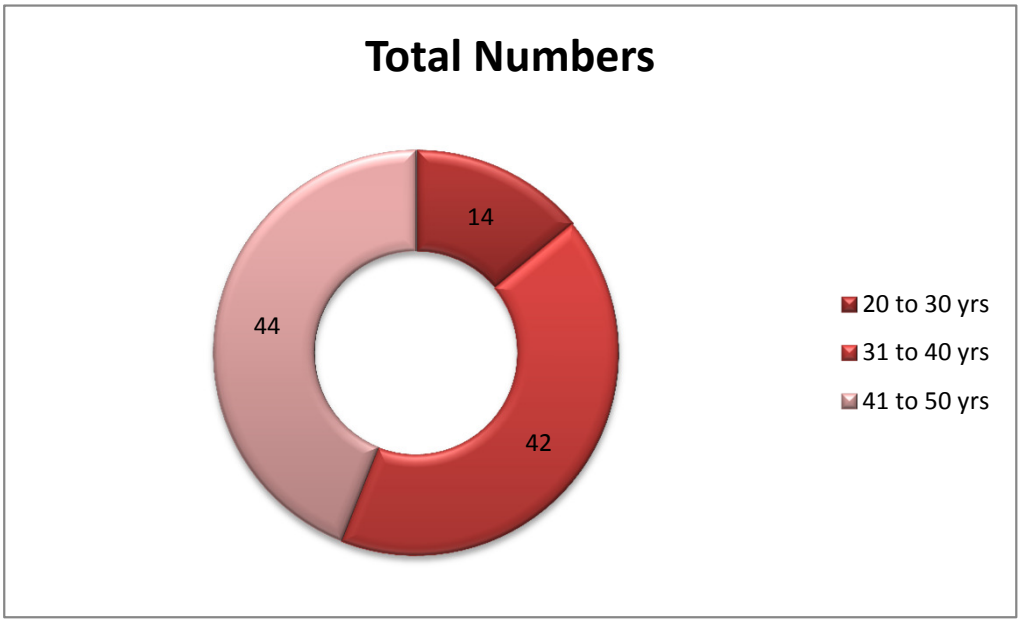


Figure No. 4. Age distribution : Control Group

Table No. 5: *Prakriti* and Melasma : Drug Group

Prakriti	Total Numbers	%
Vaat	1	1
Pitta	27	27
Kapha	3	3
Pitta Vaat	4	4
Pitta kapha	41	41
Vaat Pitta	6	6
kapha Pitta	15	15
Tridoshaj	0	0
Others	3	3
Total	100	100

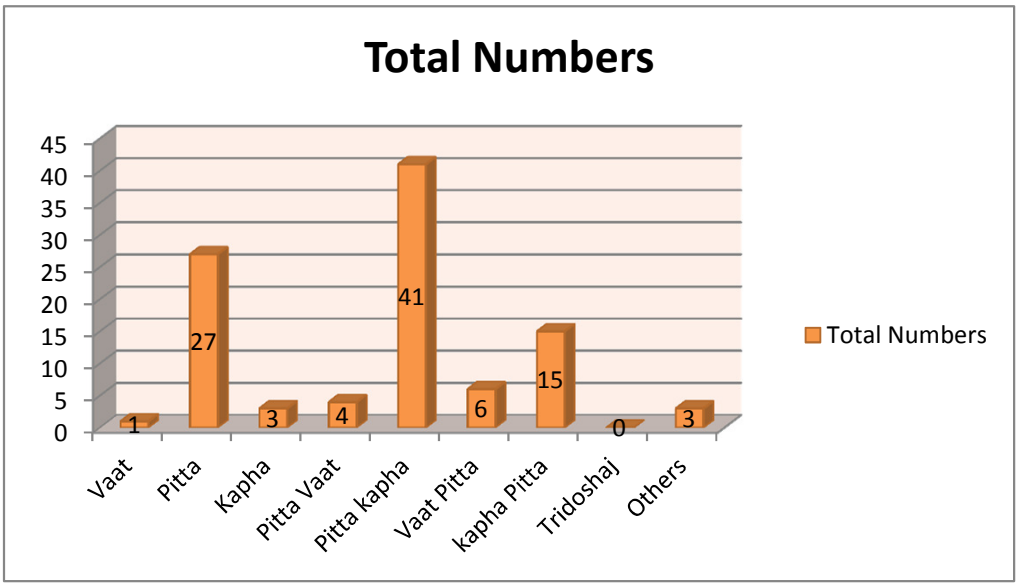


Figure No. 5. *Prakriti* and Melasma : Drug Group

Table No. 6: *Prakriti* and Melasma : Control Group

Prakriti	**Total Numbers**	**%**
Vaat	1	1
Pitta	17	17
Kapha	13	13
Pitta Vaat	9	9
Pitta kapha	28	28
Vaat Pitta	3	3
kapha Pitta	19	19
Tridoshaj	2	2
Others	8	8
Total	100	100

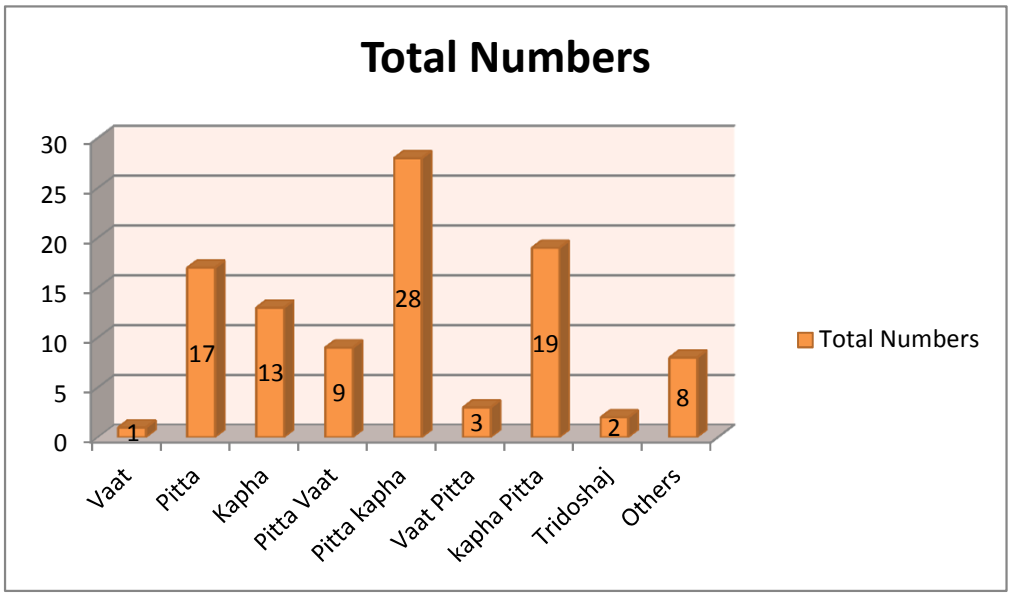


Figure No. 6. *Prakriti* and Melasma : Control Group

Table No. 7 : Melasma Patients and Diet: Drug Group

Diet Type	Total Numbers	%
Veg	34	34
Mixed	66	66
Total	100	100

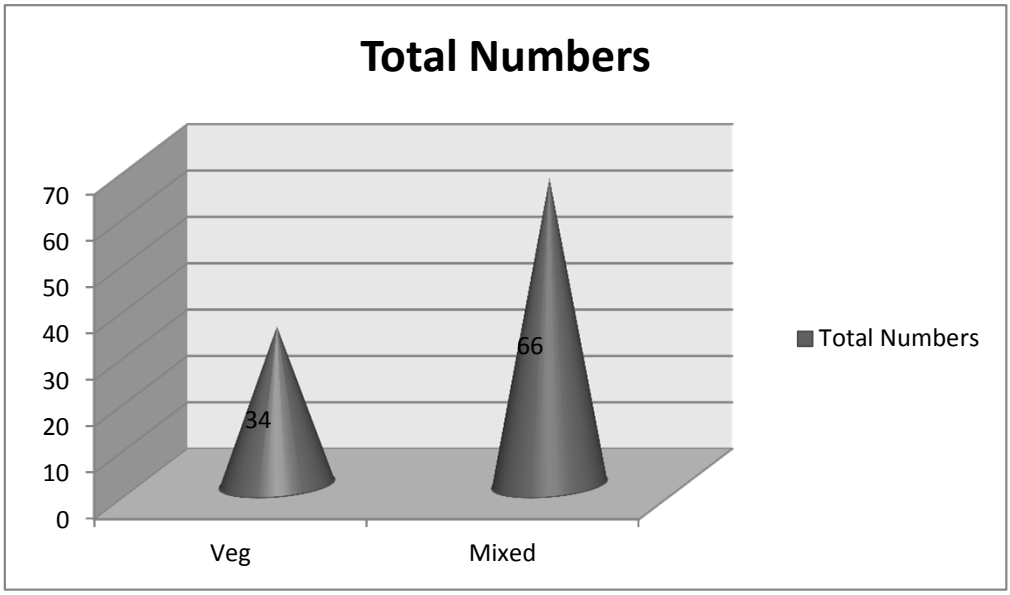


Figure No. 7. Melasma Patients and Diet: Drug Group

Table No. 8 : Melasma Patients and Diet: Control Group

Diet Type	Total Numbers	%
Veg	30	30
Mixed	70	70
Total	100	100

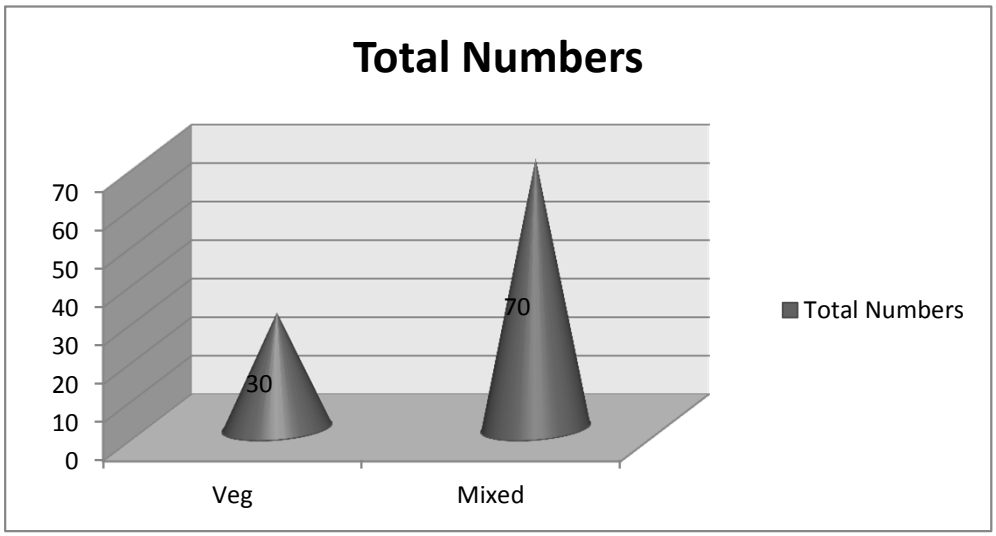


Figure No. 8. Melasma Patients and Diet: Control Group

Table No. 9. Number of Menopause Females : Drug Group

Category	%	Total No.
Menopause Females	22%	15
Total Females	100%	68

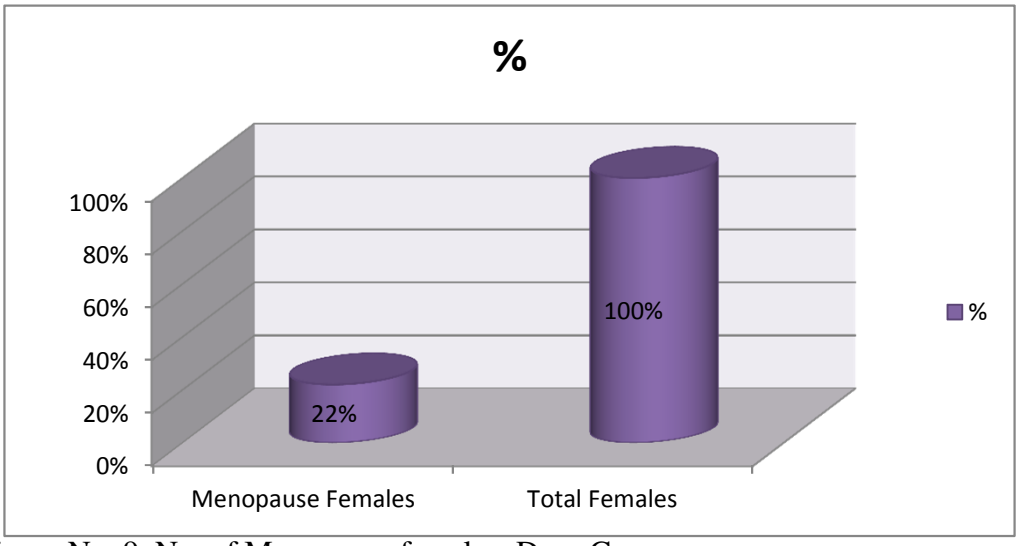


Figure No. 9. No. of Menopause females: Drug Group

Table No. 10. Number of Menopause Females : Control Group

Category	%	Total No.
Menopause Females	28%	18
Total Females	100%	64

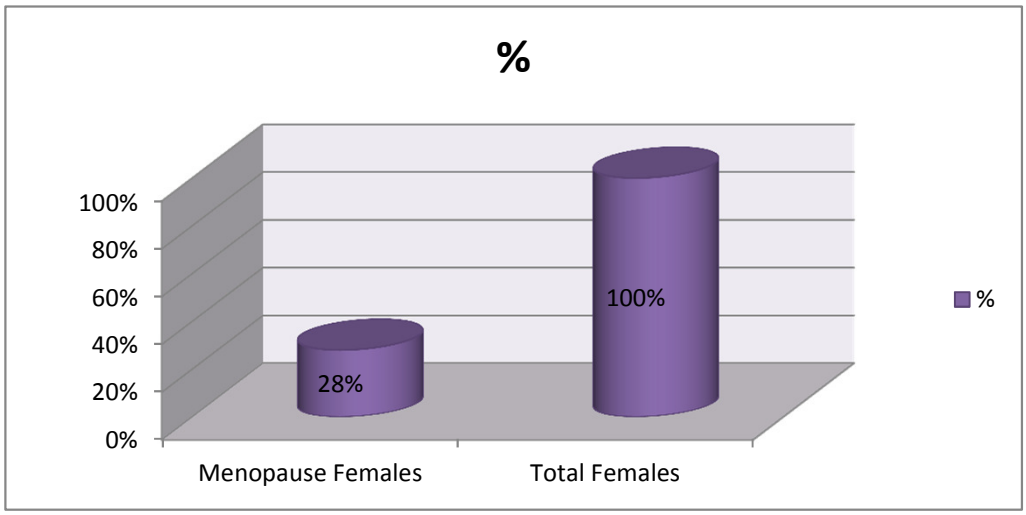


Figure No. 10.No. of Menopause females: Control Group

CATEGORY.II. Skin Data of Patients

Table No. 11 Skin Type : Drug Group

Skin Type	Total No.s	%
Dry	23	23
Oily	26	26
Moist	51	51
Total	100	100

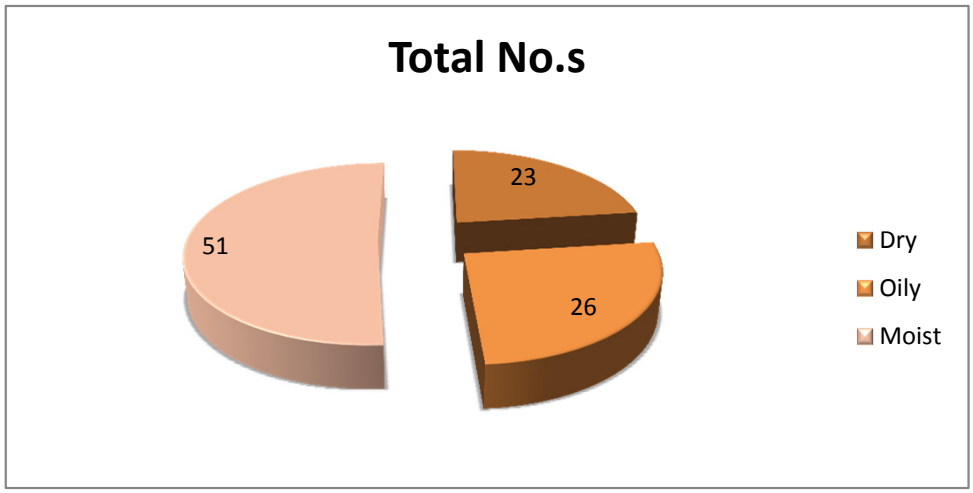


Figure No. 11. Skin Type: Drug Group

Table No. 12 Skin Type : Control Group

Skin Type	Total No.s	%
Dry	23	23
Oily	24	24
Moist	53	53
Total	100	100

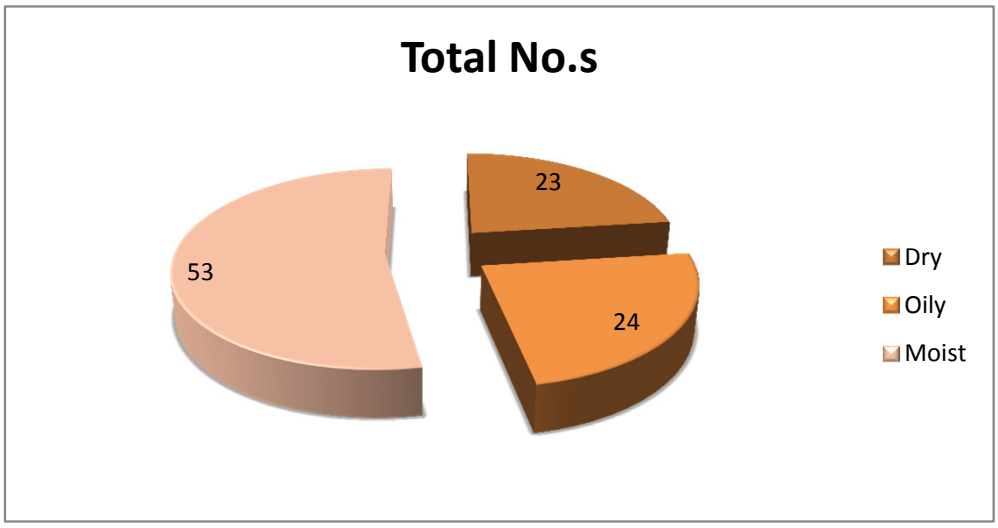


Figure No. 12. Skin Type: control Group

Table No. 13 : Skin colour- Drug Group

Skin colour	Total Numbers	%
Fair	53	53
Wheatish	35	35
Dark	12	12
Total	100	100

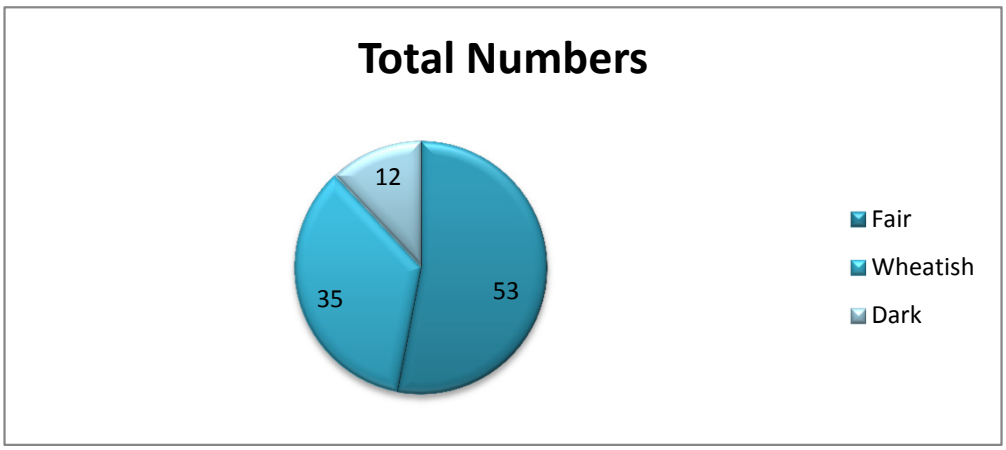


Figure No. 13. Skin Colour : Drug Group

Table No.14 : Skin colour- Control Group

Skin colour	Total Numbers	%
Fair	55	55
Wheatish	38	38
Dark	7	7
Total	100	100

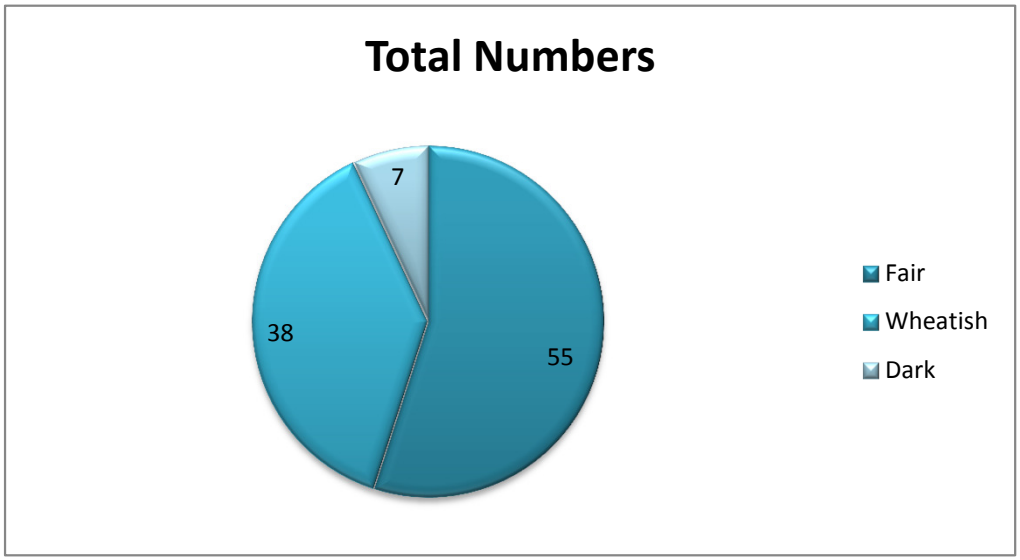


Figure No. 14. Skin Colour: Control Group

CATEGORY III. Previous Disease History

Table No. 15. Other Disease History : Drug Group

Diseases	Total No.s	%
Hypertension	2	2
Hypothyroidism	1	1
Diabetes	1	1
Tuberculosis	2	2
No Disease	94	94
Total	100	100

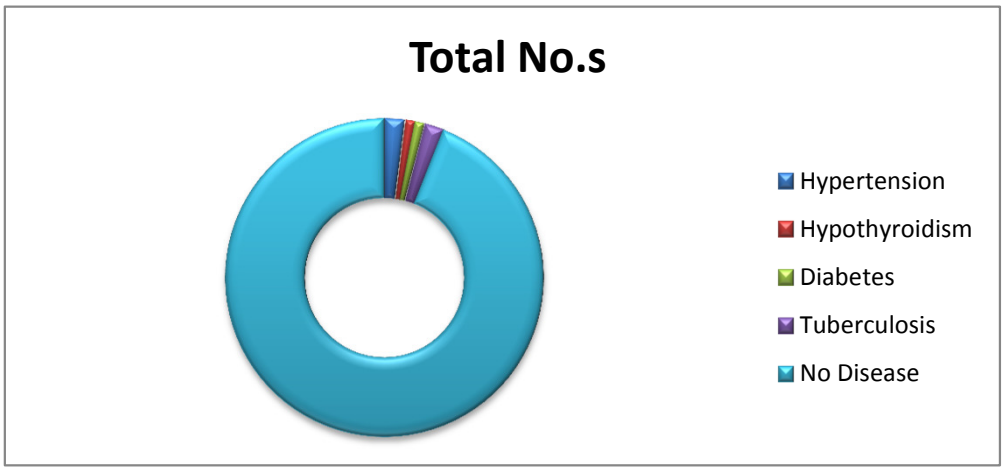


Figure No. 15. Other Disease History: Drug Group

Table No. 16. Other Disease History : Control Group

Diseases	Total No.s	%
Hypertension	1	2
Hypothyroidism	2	1
Diabetes	1	1
Tuberculosis	2	2
No Disease	94	94
Total	100	100

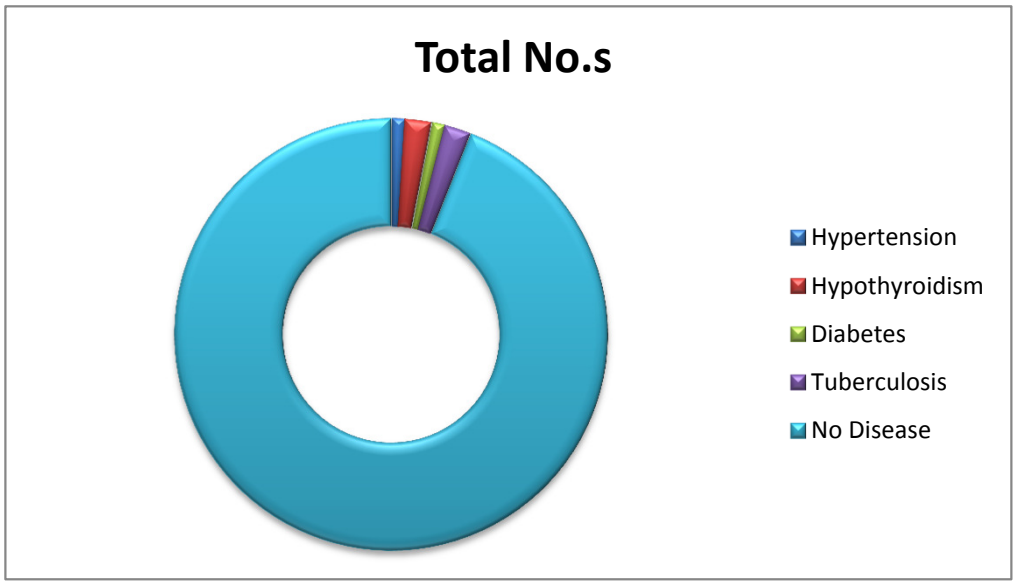


Figure No. 16. Other Disease History : Control Group

Table No. 17. Addiction : Drug Group

Type of Addiction	Total No.s	%
Tea/Coffee	10	10
Tobacco	3	3
Alcohol	0	0
Smoking	0	0
No addiction	87	87
Total	100	100

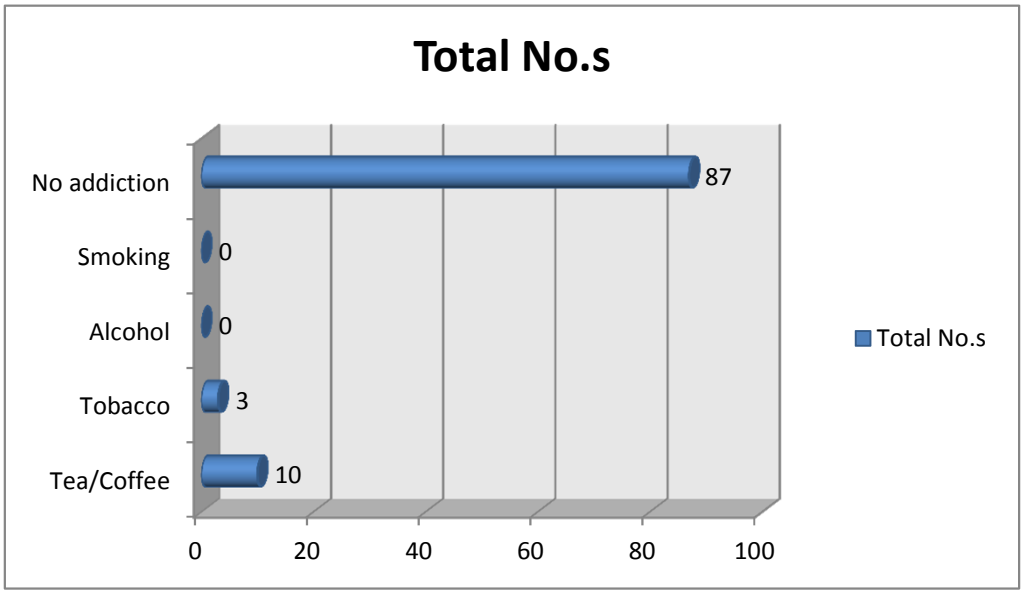


Figure No. 17 Addiction : Drug Group

Table No. 18. Addiction : Control Group

Type of Addiction	Total No.s	%
Tea/Coffee	11	11
Tobacco	3	3
Alcohol	2	2
Smoking	1	1
No addiction	83	83
Total	100	100

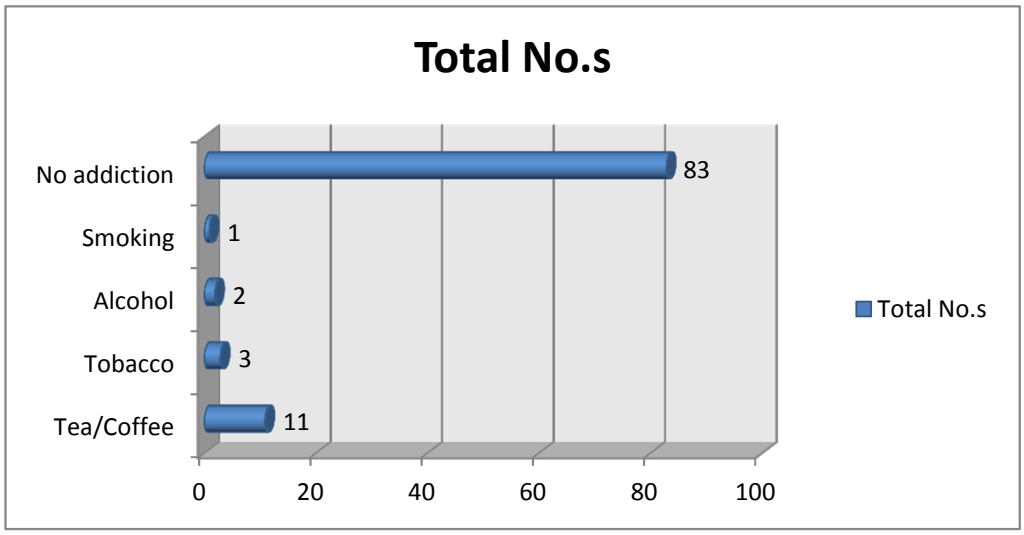


Figure No. 18. Addiction : Control Group

CATEGORY IV. Melasma History

Table No. 19: Age of Melasma-Drug Group

Age of melasma	Total numbers	%
Upto 1 yr	17	17
>1 yr-3 yrs	37	37
>3yrs-5 yrs	26	26
>5yrs-10yrs	10	10
>10yrs	10	10
Total	100	100

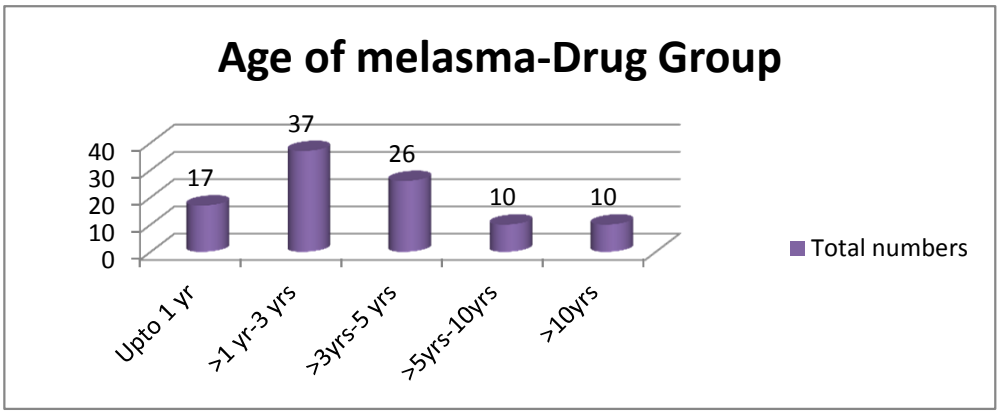


Figure No. 19. Age of Melasma : Drug Group

Table No. 20: Age of Melasma-Control Group

Age of melasma	Total numbers	%
Upto 1 yr	22	22
>1 yr-3 yrs	38	38
>3yrs-5 yrs	25	25
>5yrs-10yrs	10	10
>10yrs	5	5
Total	100	100

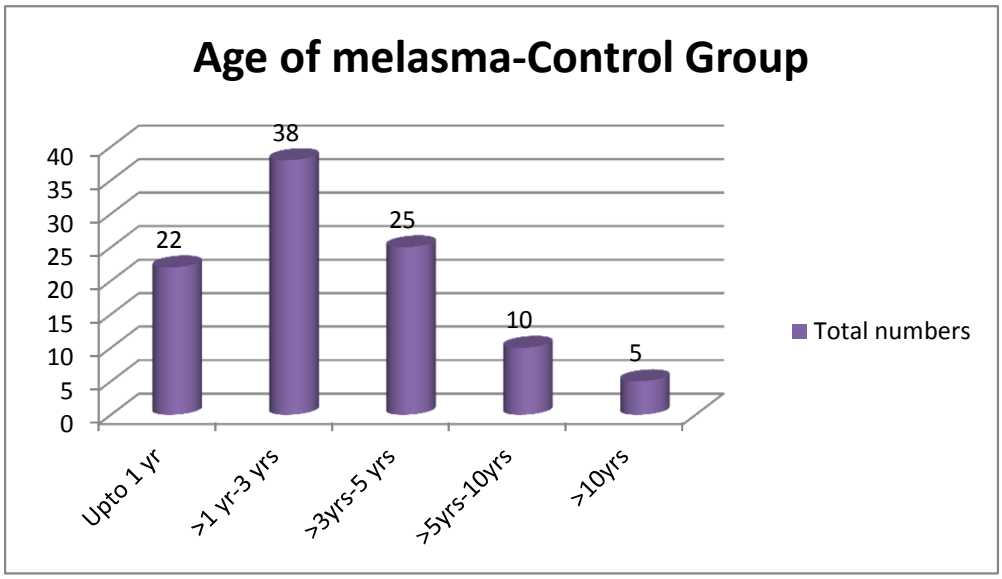


Figure No. 20. Age of Melasma : Control Group

Table 21: Area of Distribution of Melasma-Drug group

Area involved	Total numbers	%
Malar	84	84
Malar + Forhead	7	7
Malar + Nose	2	2
Malar +Forhead+Nose	6	6
Chin	1	1
Total	100	100

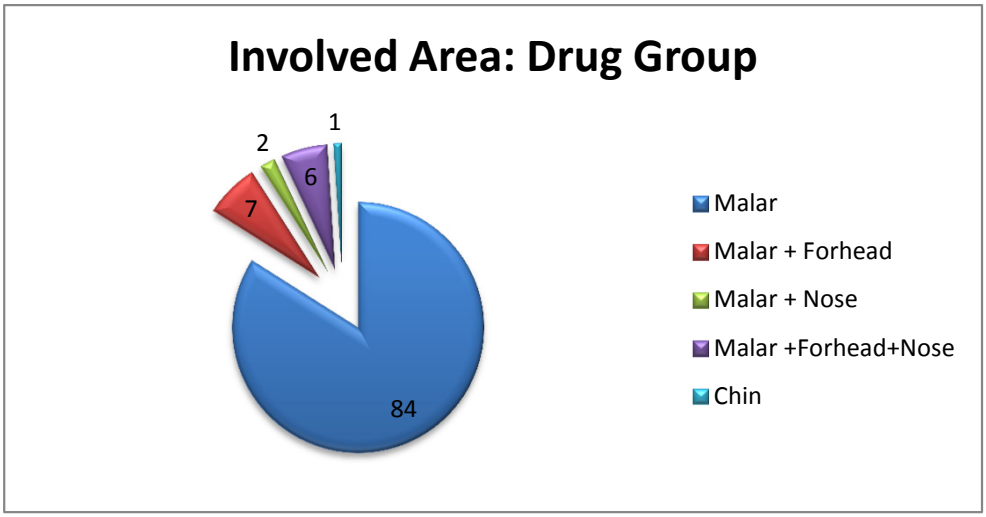


Figure No. 21. Area of Distribution : Drug Group

Table No. 22: Area of Distribution of Melasma-Control group

Area involved	Total numbers	%
Malar	74	74
Malar + Forhead	7	7
Malar + Nose	12	12
Malar +Forhead+Nose	5	5
Forhead + Nose	1	1
Forhead	1	1
Total	100	100

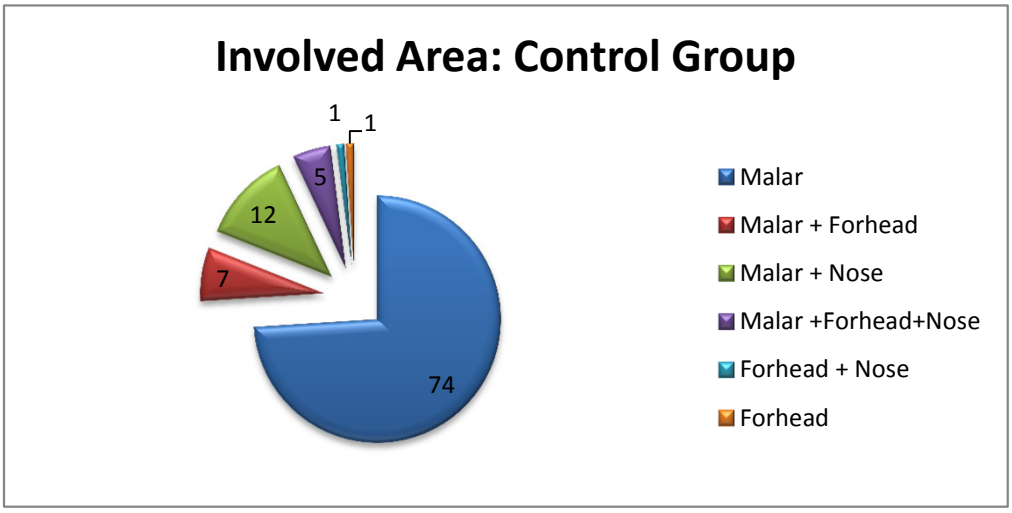


Figure No. 22. Area of Distribution : Control Group

Table No. 23. Family History of Melasma : Drug Group

Family History	Total No.s	%
Yes	6	6
No	94	94
Total	100	100

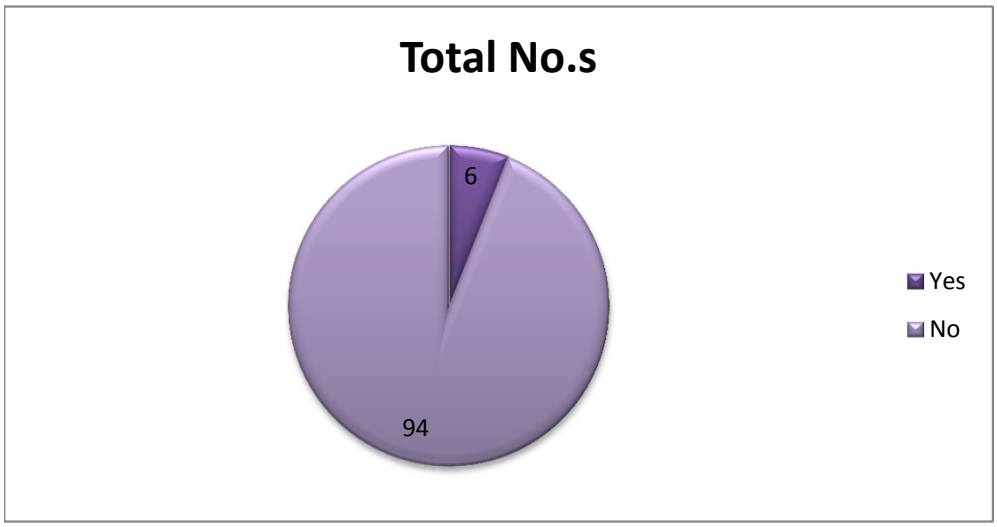


Figure No. 23. Family History of Melasma: Drug Group

Table No. 24. Family History of Melasma : Control Group

Family History	Total No.s	%
Yes	9	9
No	91	91
Total	100	100

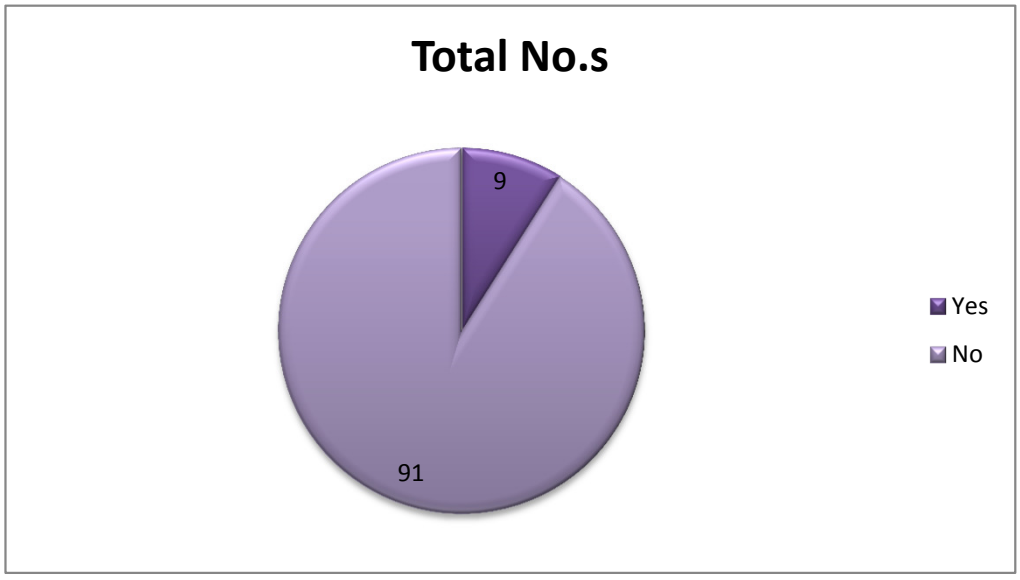


Figure No. 24. Family History of Melasma : Control Group

Table No. 25. Mode of onset of Melasma : Drug Group

Mode of Onset	Total No.s	%
Sudden	44	44
Gradual	56	56
Total	100	100

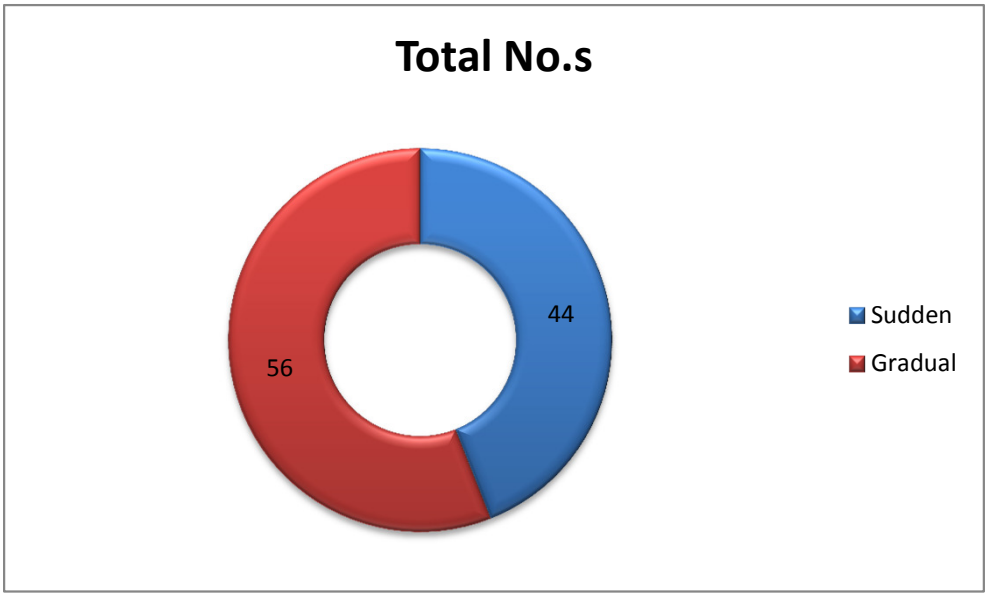


Figure No. 25. Mode of Onset : Drug Group

Table No. 26. Mode of onset of Melasma : Control Group

Mode of Onset	**Total No.s**	**%**
Sudden	49	49
Gradual	51	51
Total	100	100

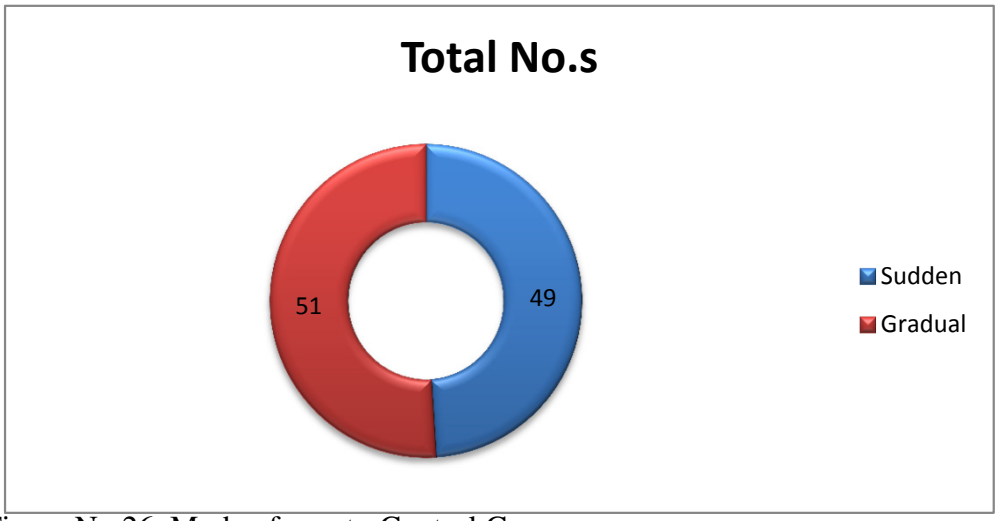


Figure No.26. Mode of onset : Control Group

Table No. 27. H/O Medication for Melasma : Drug Group

Medicine type	Total No.s	%
Ayurvedic	13	13
Homeopathy	4	4
Allopathy	23	23
No Treatment	60	60
Total	100	100

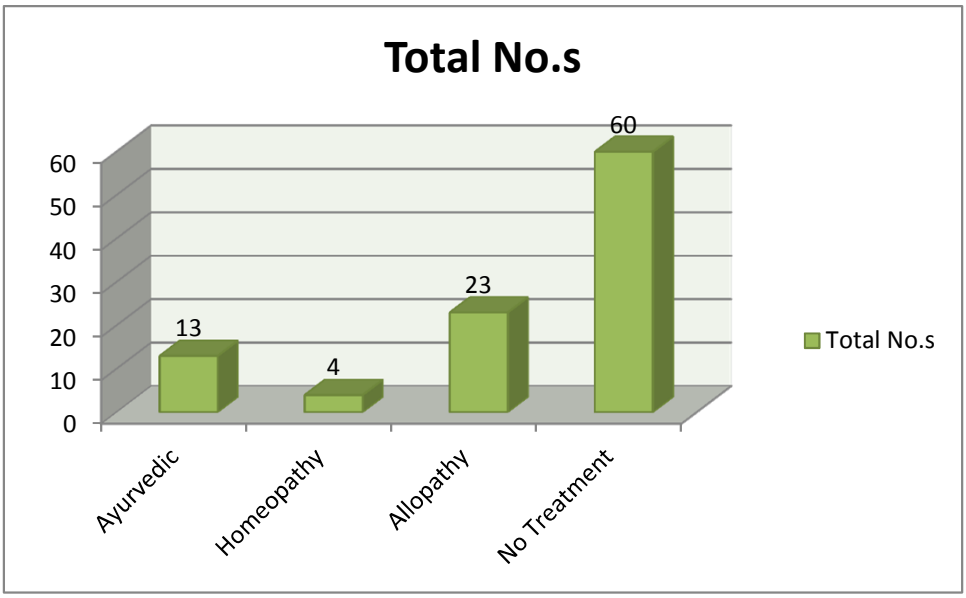


Figure No. 27. H/O Medication for Melasma : Drug Group

Table No. 28. H/O Medication for Melasma : Control Group

Medicine type	Total No.s	%
Ayurvedic	21	21
Homeopathy	0	0
Allopathy	16	16
No Treatment	63	63
Total	100	100

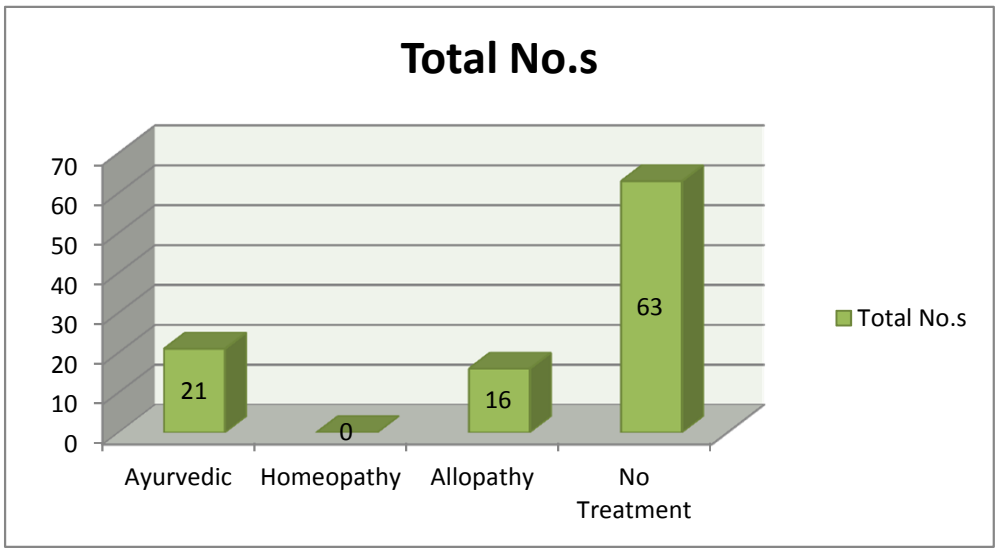


Figure No. 28. H/O Medication for Melasma : Control Group

CATEGORY V. Causes of Melasma

Table No. 29. Etiology of Melasma : Drug Group

Causes	Total Nos	%
Idiopathic	65	65
Sun Exposure	28	28
Pregnancy	4	4
Menopause	11	11
OC Pills	0	0
Total	**100**	**100**

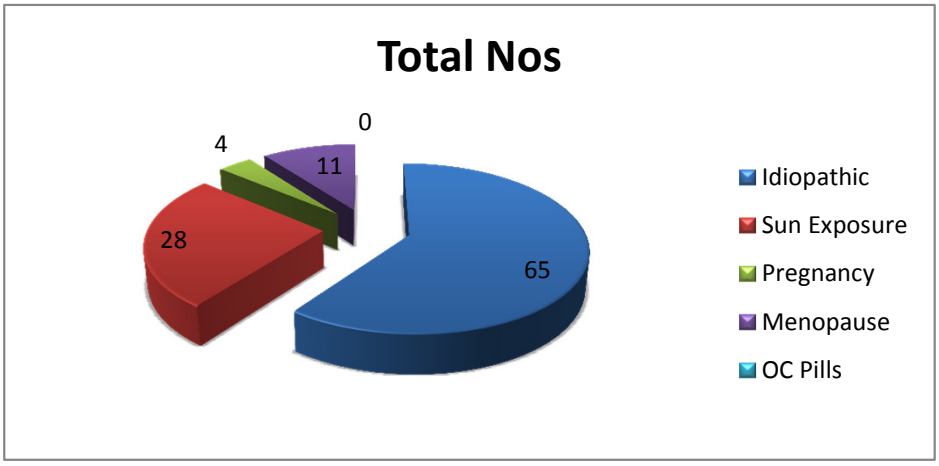


Figure No. 29. Etiology of Melasma : Drug Group

Table No. 30. Etiology of Melasma : Control Group

Causes	Total Nos	%
Idiopathic	56	56
Sun Exposure	26	26
Pregnancy	13	13
Menopause	13	13
OC Pills	2	2
Total	**100**	**100**

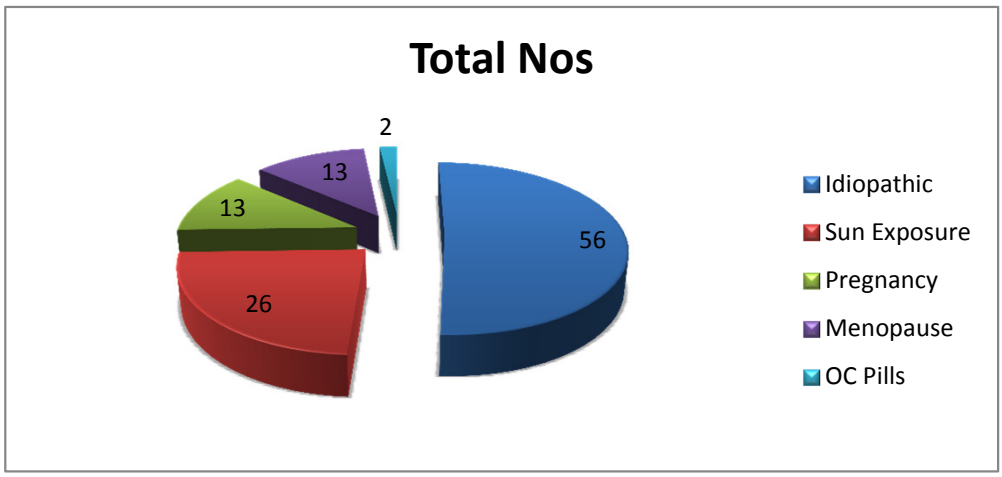


Figure No. 30. Etiology of Melasma : Control Group

Table No. 31. Probable causes : Drug Group

Cause	Total No.s	%
Disturbed sleep	19	19
Irregular menses	2	2
Computer exposure	2	2
Printing press	1	1
Trauma	0	0
Total	14	100

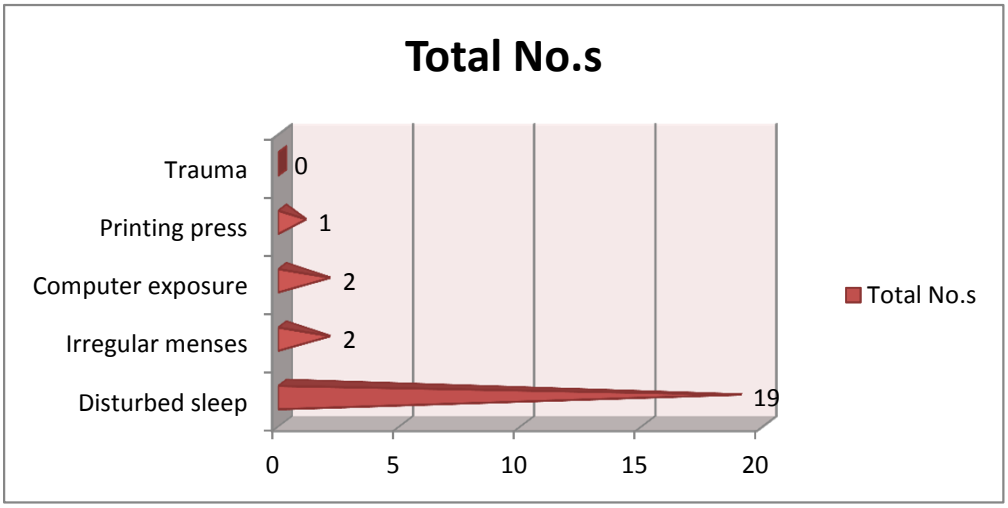


Figure No.31. Probable causes of Melasma : Drug Group

Table No. 32. Probable causes : Control Group

Cause	Total No.s	%
Disturbed sleep	22	22
Irregular menses	2	2
Computer exposure	2	2
Printing press	0	0
Trauma	2	2
Total	28	100

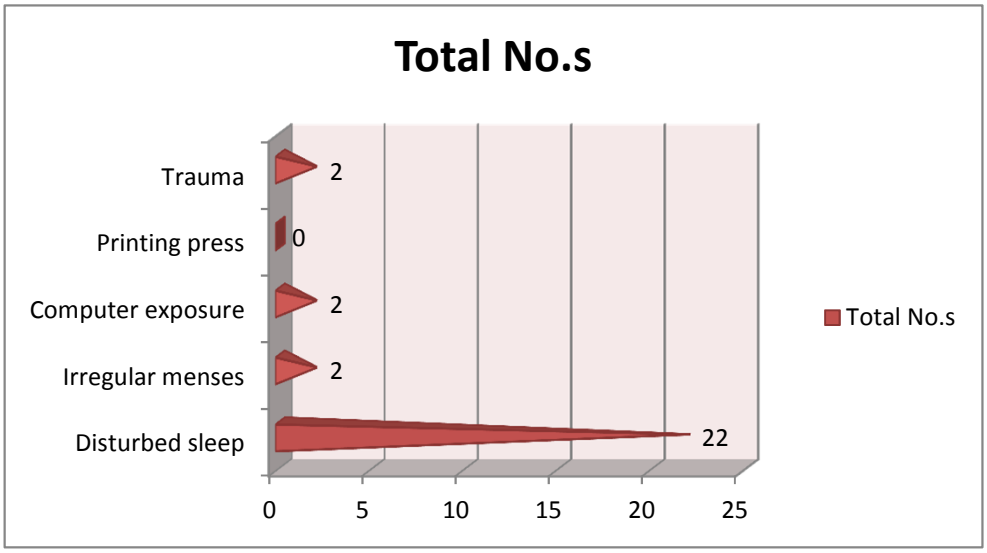


Figure No. 32. Probable causes of Melasma : Control Group

Table No. 33. Consumption of Excessive *Katu, Amla* and Lavan Rasa : Drug Group

Rasa	Total No.s	%
Ati Amla rasa	23	23
Ati Lavan Rasa	35	35
Ati Katu Rasa	30	30
Total	88	**100**

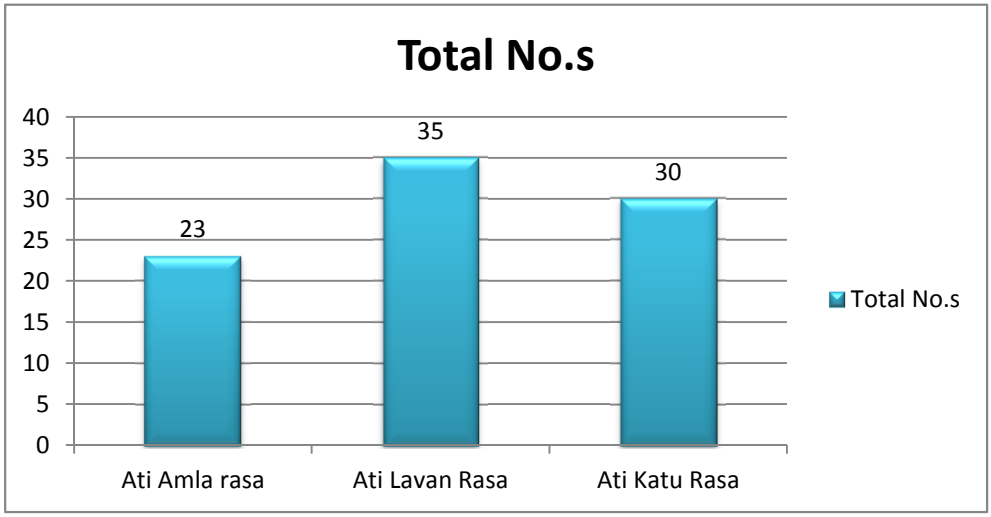


Figure No. 33. Consumption of Excessive *Rasa* : Drug Group

Table No. 34. Consumption of Excessive *Katu, Amla* and *Lavan Rasa* : Control Group

Rasa	Total No.s	%
Ati Amla rasa	23	23
Ati Lavan Rasa	35	35
Ati Katu Rasa	30	30
Total	88	**100**

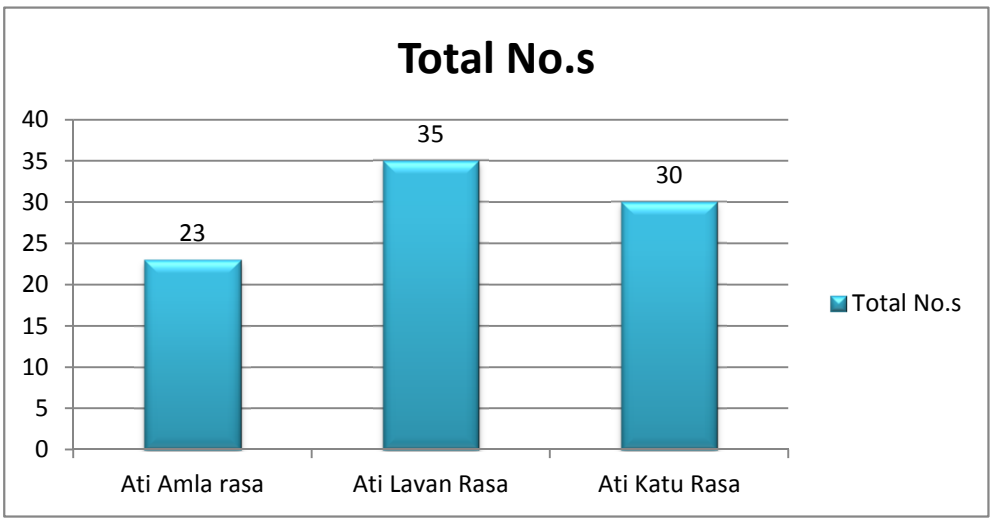


Figure No. 34. Consumption of excessive *Rasa* : Control Group

Table No. 35. Personality Trait : Drug Group

Trait	Total No.s	%
Krodh	**33**	**33**
Shokh	**35**	**35**
Total	**68**	**100**

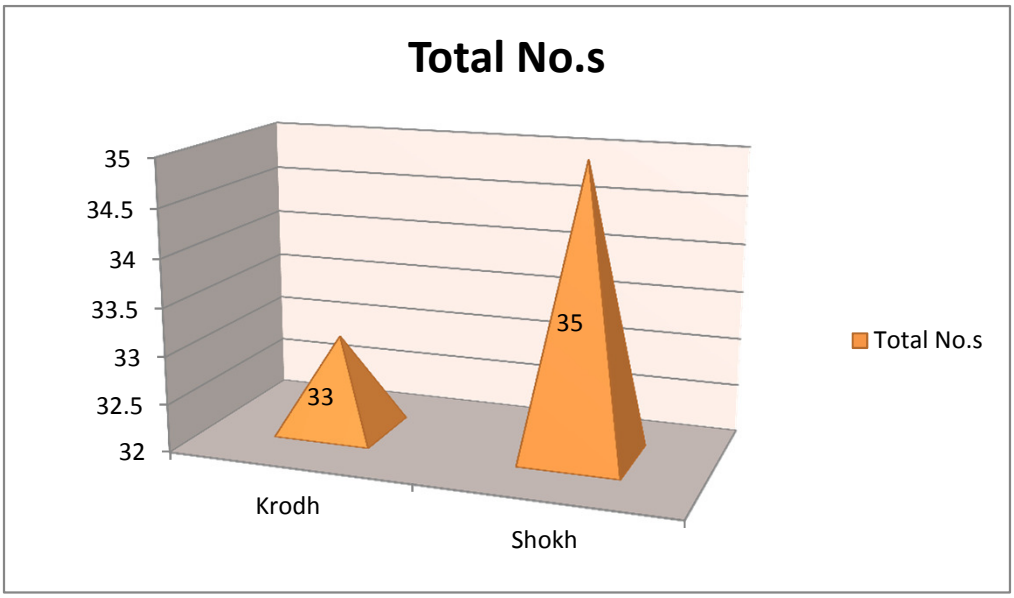


Figure No. 35. Personality Trait : Drug Group

Table No. 36. Personality Trait : Control Group

Trait	Total No.s	%
Krodh	**33**	**33**
Shokh	**35**	**35**
Total	**68**	**100**

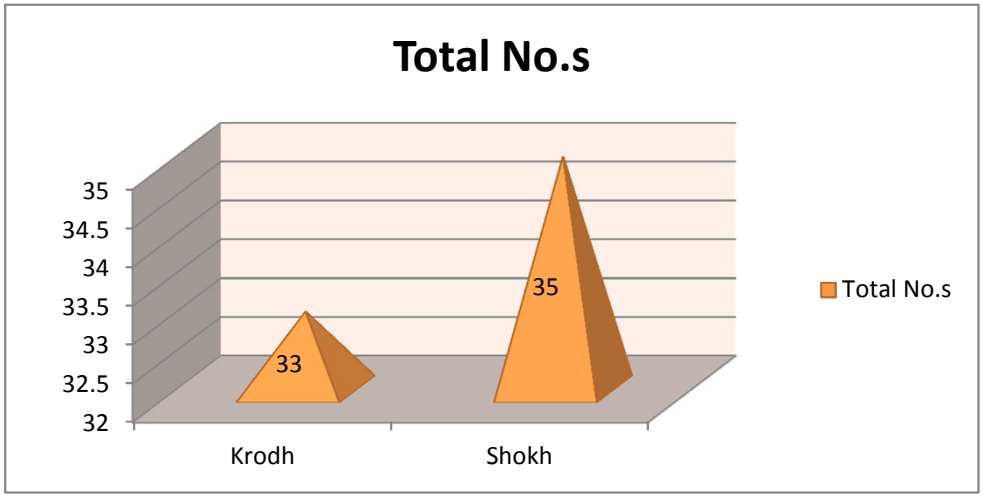


Figure No. 36. Personality Trait : Control Group

CATEGORY VI : Observations Noted After the clinical trial

Table No. 37. Adverse Events Noted : Drug Group

Events	Total No.	%
Pimples	1	1
Itching on face	2	2
Redness/Burning of eyes	1	1
Sweaty on exposure to sun	1	1
Stickyness/ Oilyness on face	3	3
Total	8	100

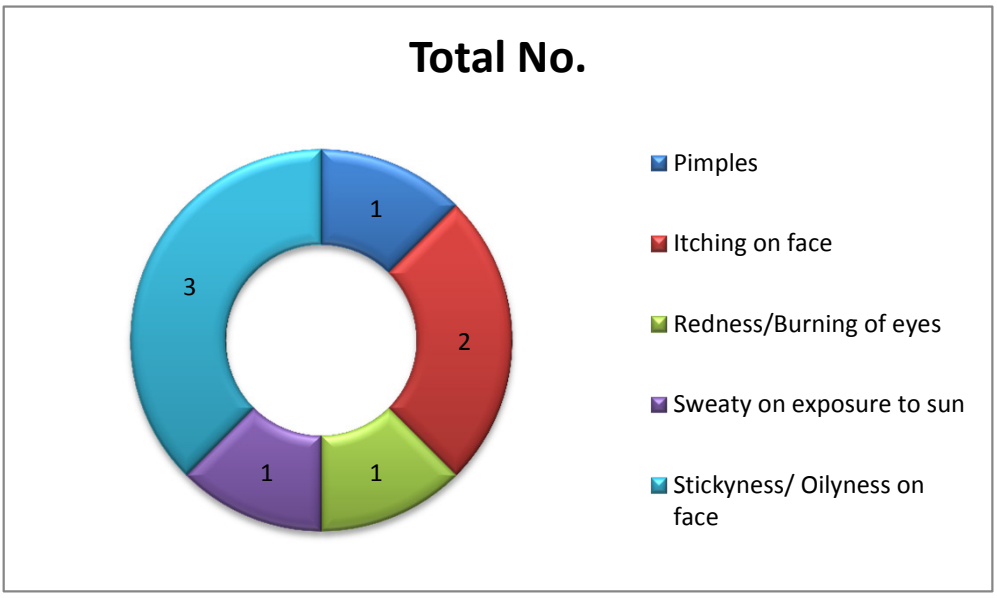


Figure No. 37. Adverse Events noted: Drug Group

Table No. 38. Adverse Events Noted : Control Group

Events	Total No.	%
Pimples	2	2
Itching on face	5	5
Redness/Burning of eyes	4	4
Sweaty on exposure to sun	1	1
Stickyness/ Oilyness on face	0	0
Total	12	100

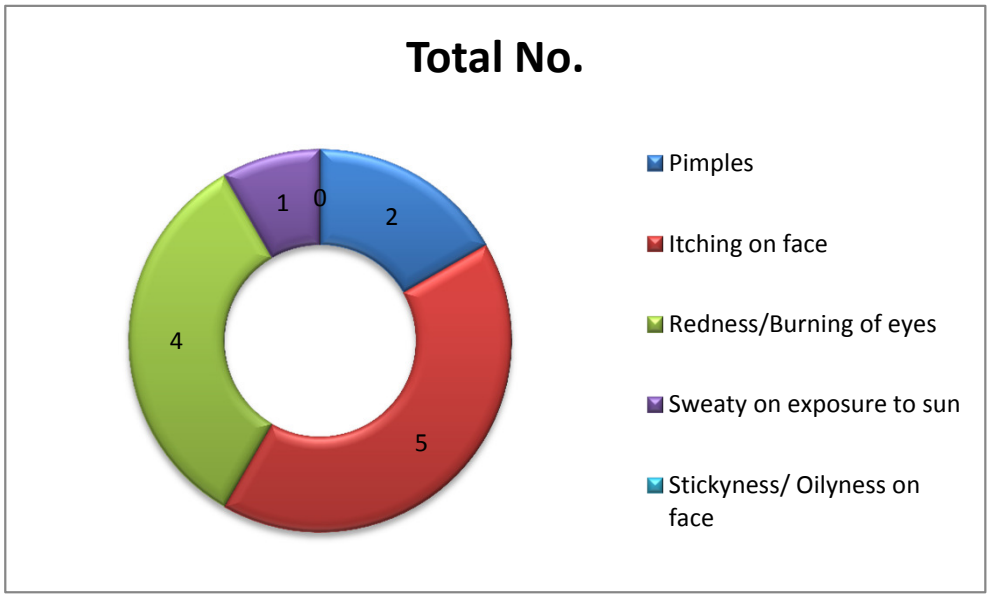


Figure No. 38. Adverse Events Noted : Control Group

Table No. 39. Quality of Life Score Before and After: Drug Group

Score Parameters	Score : Before	Score: After	
0 to 1	52	61	
2 to 5	35	38	
6 to 10	15	4	
11 to 20	1	0	
21 to 30	0	0	

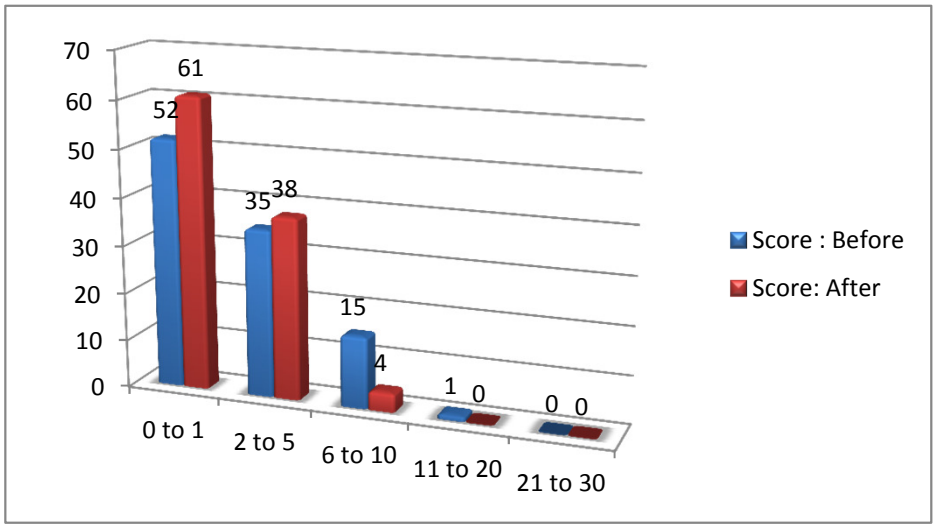


Figure No. 39. Quality of Life Score, Before and After: Drug Group

Table No. 40. Quality of Life Score Before and After: Control Group

Score Parameters	Score : Before	Score: After	
0 to 1	44	47	
2 to 5	38	42	
6 to 10	11	4	
11 to 20	0	0	
21 to 30	0	0	

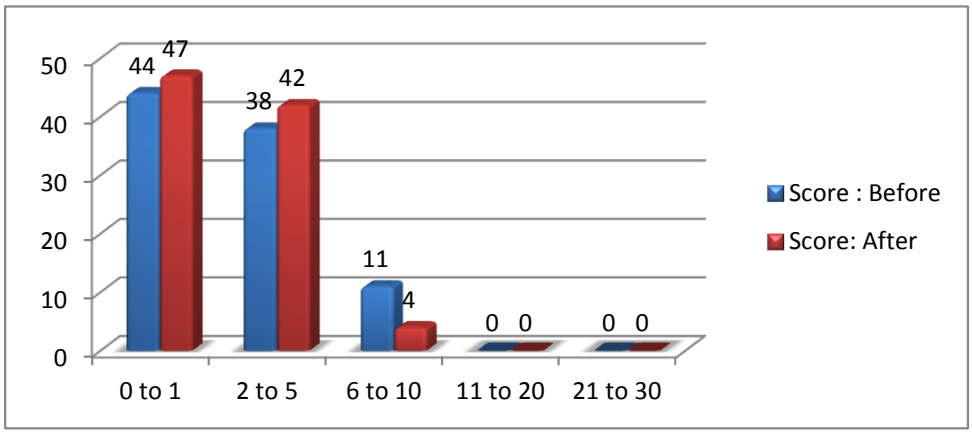


Figure No. 40. Quality of Life Score Before anf After : Control Group

0 to 1 = No effect on patient's life
2 to 5 = Small effect
6 to 10 = Moderate effect
11 to 20 = very large effect
21 to 30 = Extremely large effect.

STATISTICAL ANALYSIS OF THE STUDY

The clinical trial was assessed on the basis of following 6 scales

1. Fairness meter. Scale 1 to 7
2. Melasma Severity Scale 0 to 3
3. MASI Score: As per the calculation
4. Patient's Assessment Scale 1 to 4
5. Physician's Assessment Scale 0 to 6
6. Clinical Response to Treatment Scale 2 to □
7. Quality of Life Score.

The data that was collected according to the given scales was Non Parametric data and so for Intra Group ie. Assessment within a group during various visits was done by using Friedman test and Inter group assessment between both Trial and Control Group was done using Mann Whitney's Test. The result have been displayed below for all the respective scales in their respective Tables and Graphs

The result of clinical trial as per the 6 assessment scales is as follows:

1. **Fairness Meter Scale:**

Table 1. Friedman Test applied for Intra group assessment of Trial Group: Fairness Meter Scale

Trial Group	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100	100
Median	06	06	05	05	05	04	04
Range	04 - 07	04 - 07	03 – 07	03 – 07	02 - 07	02 – 07	02 – 07

Sum of Ranks	619.50	618.50	450.00***	349.50***	285.00***	240.50***	237.00***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)						
	Friedman Statistic Fr = 437.06 (corrected for ties)						
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**						

(***p < 0.001 compared to V1)

We can see the median changing from 6 at Visit 1 to 4 at Visit 6. There is no change in the median at Visit 7 as compared to Visit 6. Thus there is no relapse in Fairness Meter Scale, 1 month after stopping of medicine.

We can also see that there has been a significant change in fairness only from Visit 3 and not before that and the second jump is observed at Visit 6.

Table 2. Friedman Test applied for Intra group assessment of Control Group: Fairness Meter Scale

Control Group	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100	100
Median	06	06	05	05	05	05	05
Range	04 - 07	04 - 07	04 - 07	03 - 06	03 - 06	03 – 06	03 - 06
Sum of Ranks	590.50	589.50	432.50***	329.50***	296.00***	281.00***	281.00***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)						
	Friedman Statistic Fr = 397.85 (corrected for ties)						

	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**

Thus this table shows that on Fairness Meter Scale the drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 7.

(***p < 0.001 compared to V1)

We can see the median changing from 6 at Visit 1 to 5 at Visit 6. There is no change in the median at Visit 7 as compared to Visit 6. Thus there is no relapse in Fairness Meter Scale, 1 month after stopping of the control medicine.

We can also see that there has been a significant change in fairness only at Visit 3 and not before that.

Thus this table shows that on Fairness Meter Scale the control drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 7.

Table 3. Mann Whitney Test applied for Inter group assessment between Trial and Control Group: Fairness Meter Scale

Visit	Group	Median (Range)	Mann – Whitney U Statistic	U'	P Value, Inference
V1	Trial	06 (04 – 07)	4553.0	5447.0	0.2701, Not Significant
	Control	06 (04 – 07)			
V2	Trial	06 (04 – 07)	4552.5	5447.5	0.2696, Not Significant
	Control	06 (04 – 07)			
V3	Trial	05 (03 – 07)	4900.0	5100.0	0.8058, Not Significant
	Control	05 (04 – 07)			

V4	Trial	05 (03 – 07)	4781.0	5219.0	0.5891, Not Significant
	Control	05 (03 – 06)			
V5	Trial	05 (02 – 07)	4271.5	5728.5	0.0715, Not Quite Significant
	Control	05 (03 – 06)			
V6	Trial	04 (02 – 07)	3651.0	6349.0	0.0009, Extremely Significant
	Control	05 (03 – 06)			
V7	Trial	04 (02 – 07)	3638.0	6362.0	0.0008, Extremely Significant
	Control	05 (03 – 06)			

In the above table we can see that there is no significant difference in both the groups if we compare their medians from Visit 2 to Visit 5. However extremely significant difference has been noted at Visit 6 and Visit 7.

Graph 1. Intra Group and Inter Group Assessment of FMS (Median values) in both the groups.

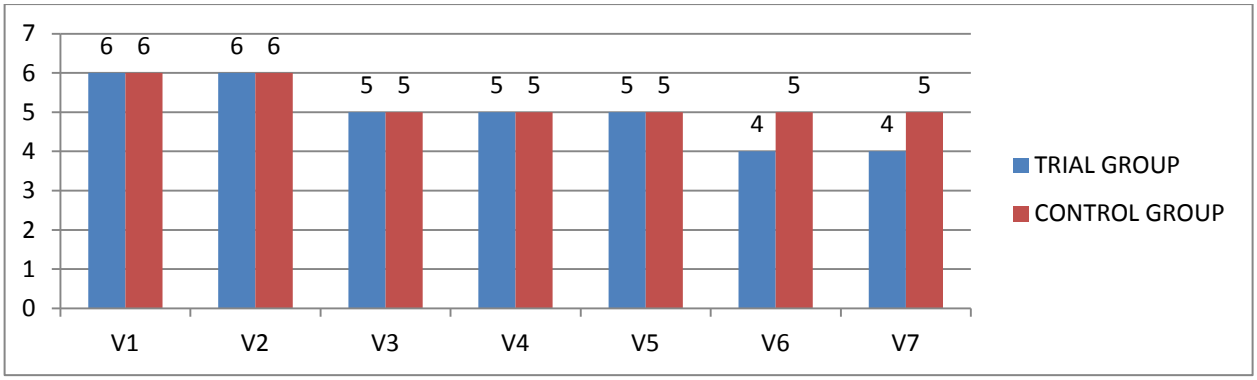
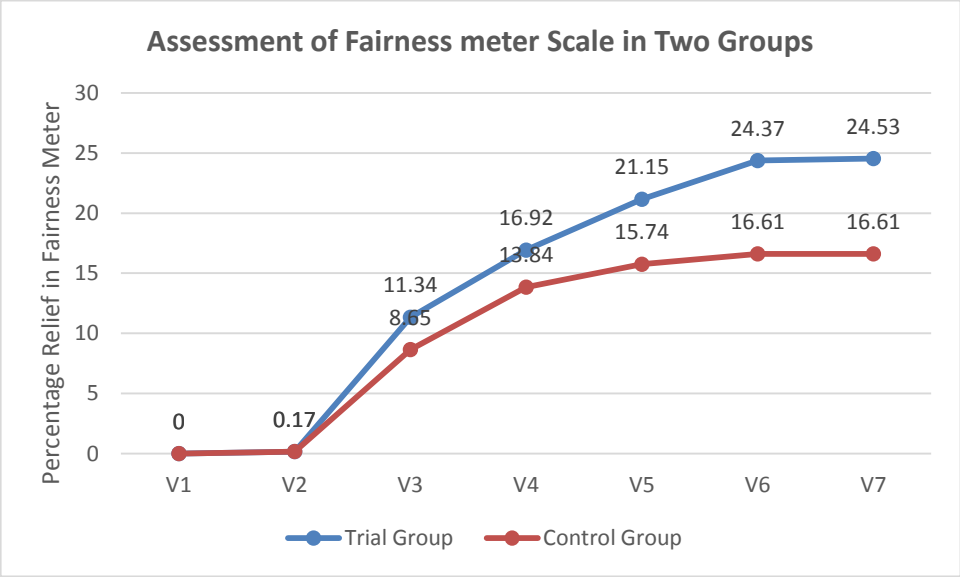


Table 4. Inter Group % Change: Fairness Meter Scale

	V1	V2	V3	V4	V5	V6	V7
Trial Group	591	590	524	491	466	447	446
Difference		1	67	100	125	144	145
% Change		**0.17**	**11.34**	**16.92**	**21.15**	**24.37**	**24.53**
Control Group	578	577	528	498	487	482	482
Difference		1	50	80	91	96	96
% Change		**0.17**	**8.65**	**13.84**	**15.74**	**16.61**	**16.61**

In the above table the change in the score as compared to Visit 1 was calculated for each visit for both the groups and it was found that the % of Change was more in Trial Group as compared to Control Group.

Graph 2. Inter Group % Change at every Visit: Fairness Meter Scale



The above Graph shows the representation of the % Change between Trial and Control Group at all visits as depicted in Table 4. And it can be seen that the Trial Group has performed better than the Control Group.

2. **Melasma Severity Scale**

Table 5. Friedman Test applied for Intra group assessment of Trial Group: Melasma Severity Scale

Trial Group	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**
Sample Size (n)	100	100	100	100	100	100
Median	02	02	02	02	01	01
Range	01 – 03	01 – 03	01 – 03	01 – 03	00 – 03	00 – 03
Sum of Ranks	450.00	450.00	406.50	329.50***	242.00***	222.00***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					
	Friedman Statistic Fr = 280.61 (corrected for ties)					
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**					

(***p < 0.001 compared to V1)

We can see the median changing from 2 at Visit 1 to 1 at Visit 5. We can also see that there has been a significant change in severity of Melasma only at visit 5 and not before that .

Thus this table shows that on Melasma Severity Scale the drug has proved to show significant changes as compared to Visit 1 from visit 4 to visit 6.

Table 6. Friedman Test applied for Intra group assessment of Control Group: Melasma Severity Scale

Control Group	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**
Sample Size (n)	100	100	100	100	100	100
Median	02	02	02	02	02	02

Range	01 – 03	01 – 03	01 – 03	01 – 03	00 – 03	00 – 03
Sum of Ranks	407.00	407.00	377.00	320.00*	296.00***	293.00***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					
	Friedman Statistic Fr = 141.79 (corrected for ties)					
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**					

(*p< 0.05, ***p < 0.001 compared to V1)

We can see that there is no change in the median when compared to Visit 1 throughout the trial.

Thus this table shows that on Melasma Severity Scale the Control drug has proved to show significant changes as compared to Visit 1 only at Visit 5 and Visit 6.

Table 7. Mann Whitney Test applied for Inter group assessment between Trial and Control Group: Melasma Severity Scale

Visit	Group	Median (Range)	Mann – Whitney U Statistic	U'	P Value, Inference
V1	Trial	02 (01 - 03)	4648.0	5352.0	0.3827, Not Significant
	Control	02 (01 - 03)			
V2	Trial	02 (01 - 03)	4648.0	5352.0	0.3827, Not Significant
	Control	02 (01 - 03)			
V3	Trial	02 (01 - 03)	4878.0	5122.0	0.7628, Not Significant
	Control	02 (01 - 03)			
V4	Trial	02 (01 - 03)	4778.0	5222.0	0.5806, Not Significant
	Control	02 (01 - 03)			
V5	Trial	01 (00 - 03)	3786.5	6213.5	0.0026, Very
	Control	02 (00 - 03)			

					Significant
V6	Trial	01 (00 - 03)	3544.0	6456.	0.0003, Extremely Significant
	Control	01 (00 - 03)			

In the above table we can see that there is no significant difference in both the groups if we compare their medians from Visit 2 to Visit 4. There is a difference in the medians at Vist 5 and Visit 6. However significant difference has been observed in both the groups from Visit 1 to Visit 4 and very significant and extremely significant difference can be noted at Visit 5 and Visit 6 respectively.

Graph 3 : Intra and Inter Group Assesment of MSS (Median values) in both the groups.

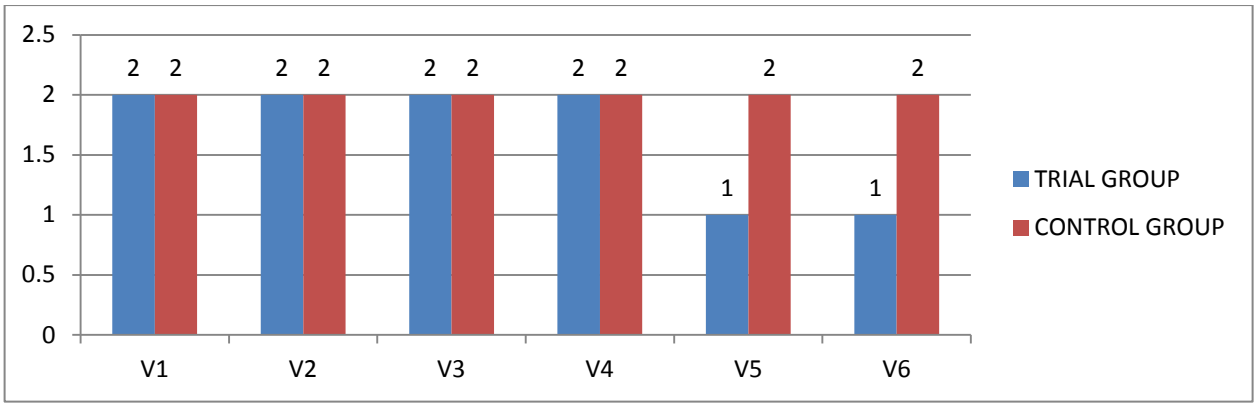
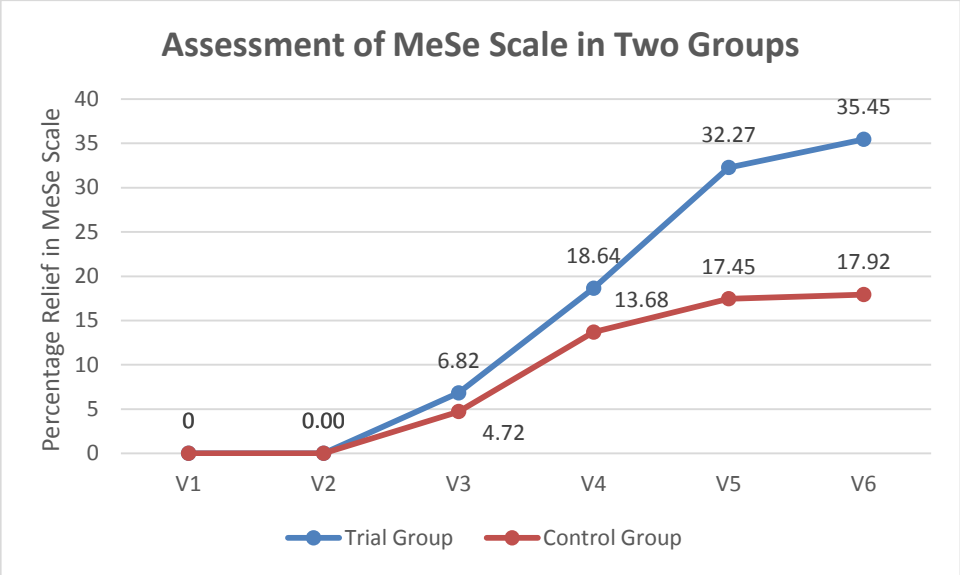


Table 8. Inter Group % Change: Melasma Severity Scale

	V1	**V2**	**V3**	**V4**	**V5**	**V6**
Trial Group	220	220	205	179	149	142
Difference		0	15	41	71	78
% Change		**0.00**	**6.82**	**18.64**	**32.27**	**35.45**
Control Group	212	212	202	183	175	174
Difference		0	10	29	37	38
% Change		**0.00**	**4.72**	**13.68**	**17.45**	**17.92**

In the above table the change in the score as compared to visit 1 was calculated for each visit for both the groups and it was found that the % of Change was more in Trial Group as compared to Control Group.

Graph 4. Inter Group % Change at every Visit: Melasma Severity Scale



The above Graph shows the representation of the % Change between Trial and Control Group at all visits as depicted in Table 8. It also shows that there has been no change at Visit 2. Significant changes can be noted from Visit 3 onwards.

And it can be seen that the Trial Group has performed better than the Control Group

3. MASI Score

Table 9. Friedman Test applied for Intra group assessment of Trial Group: MASI Score

Trial Group	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100	100
Mean ± SD	7.15 ± 4.26	7.19 ± 4.19	6.16 ± 3.61	5.41 ± 2.98	4.63 ± 2.52	4.18 ± 2.38	4.18 ± 2.38

Median	06	06	5.4	4.8	4.8	3.9	3.9
Range	1.2 – 25.2	1.2 – 25.2	0.6 – 21.6	0.6 – 15.0	00 – 9.9	00 – 9.9	00 – 9.9
Sum of Ranks	618.50	620.00	473.50***	387.50***	277.50***	211.50***	211.50***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)						
	Friedman Statistic Fr = 493.05 (corrected for ties)						
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**						

(***p < 0.001 compared to V1)

We can see the median changing from 6 at Visit 1 to 5.4 at visit 3, 4.8 at Visit 4 and Visit 5 and 3.9 at Visit 6 and Visit 7. So we can see that there has been a significant change in the MASI Score starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that the MASI score has not worsened after stopping the medicine at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per MASI score the drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 6.

Table 10. Friedman Test applied for Intra group assessment of Control Group: MASI Score

Control Group	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	97	97	97	97	97	97	97
Mean ± SD	6.79 ± 3.86	6.78 ± 3.74	6.08 ± 3.34	5.54 ± 3.12	5.16 ± 2.83	5.02 ± 2.78	5.02 ± 2.78
Median	06	06	5.1	4.8	4.8	4.8	4.8
Range	1.2 –	1.2 –	1.2 – 14.4	0.6 – 14.4	00 – 14.4	00 – 14.4	00 – 14.4

	19.2	19.2					
Sum of Ranks	580.50	584.50	447.50***	335.00***	275.50***	246.50***	246.50***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)						
	Friedman Statistic Fr = 415.37 (corrected for ties)						
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**						

(***p < 0.001 compared to V1)

We can see the median changing from 6 at Visit 1 to 5.1 at Visit 3and 4.8 at Visit 4, Visit 5, Visit 6 and Visit 7. So we can see that there has been a significant change in the MASI Score starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that the MASI score has not worsened after stopping the medicine at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per MASI score the control drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 6

Table 11. Mann Whitney Test applied for Inter group assessment between Trial and Control Group: MASI Score

Visit	Group	Median (Range)	Mann – Whitney U Statistic	U'	P Value, Inference
V1	Trial	06 (1.2 – 25.2)	4617.0	5083.0	0.5610, Not Significant
	Control	06 (1.2 – 19.2)			
V2	Trial	06 (1.2 – 25.2)	4606.0	5094.0	0.5426, Not Significant
	Control	06 (1.2 – 19.2)			
V3	Trial	5.4 (0.6 – 25.2)	4815.5	4884.5	0.9323, Not

	Control	5.1 (1.2 – 14.4)			Significant
V4	Trial	4.8 (0.6 – 15.0)	4766.5	4933.5	0.8356, Not Significant
	Control	4.8 (0.6 – 14.4)			
V5	Trial	4.8 (00 – 9.9)	4339.5	5360.5	0.2022, Not Significant
	Control	4.8 (00 – 14.4)			
V6	Trial	3.9 (00 – 9.9)	3962.0	5738.0	0.0265, Significant
	Control	4.8 (00 – 14.4)			
V7	Trial	3.9 (00 – 9.9)	3962.0	5738.0	0.0265, Significant
	Control	4.8 (00 – 14.4)			

In the above table we can see that there is no significant difference in both the groups if we compare their medians from Visit 2 to Visit 5. There is a difference in the medians at Vist 6 and Visit 7.Thus significant difference has been observed in both the group at Visit 6 and Visit 7..

Graph 5: Intra and Inter Group Assessment of MASI (Median values) in both the groups.

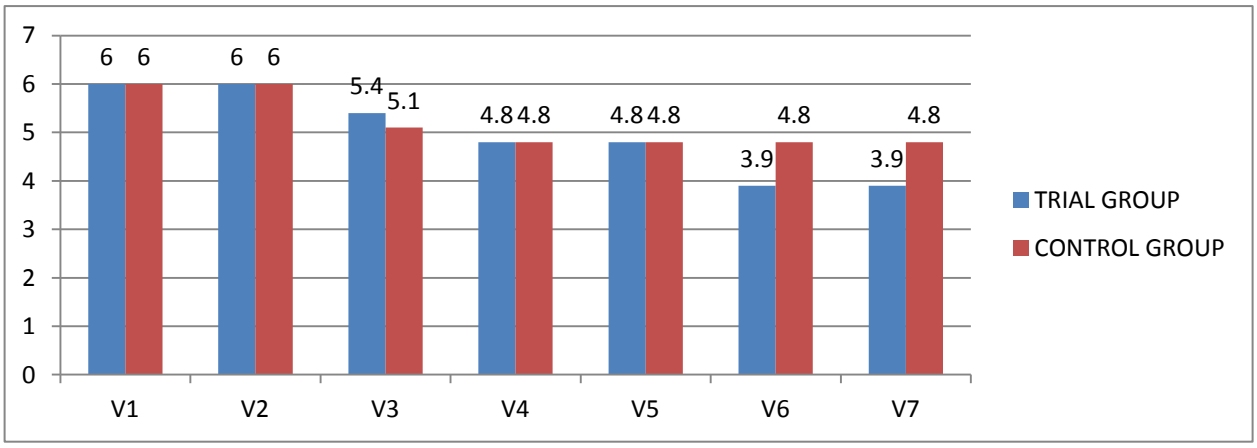
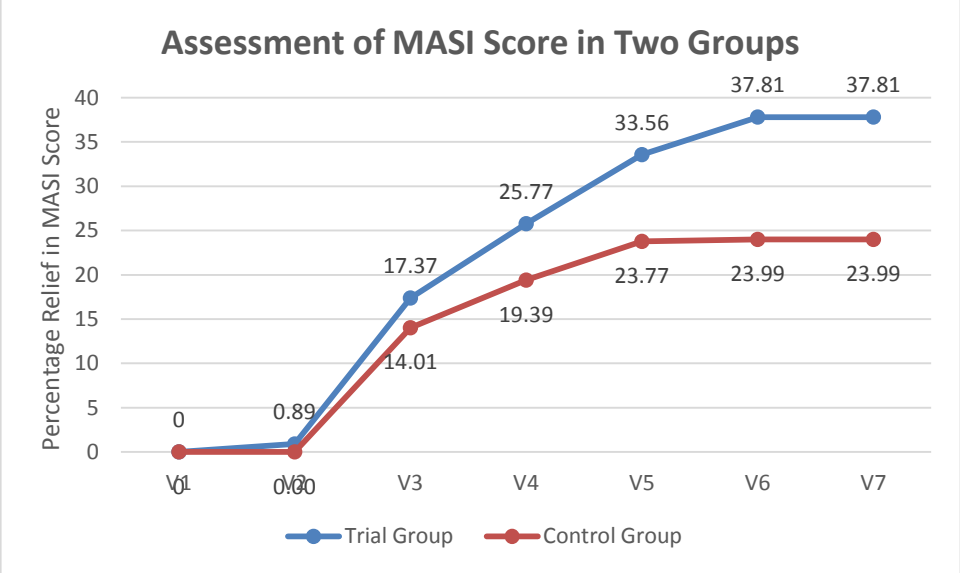


Table 12. Inter Group % Change: MASI SCORE

	V1	V2	V3	V4	V5	V6	V7
Trial Group	303.9	301.2	251.1	225.6	201.9	189	189
Difference		2.7	52.8	78.3	102	114.9	114.9
% Change		**0.89**	**17.37**	**25.77**	**33.56**	**37.81**	**37.81**
Control Group	267.6	267.6	230.1	215.7	204	203.4	203.4
Difference		0	37.5	51.9	63.6	64.2	64.2
% Change		**0.00**	**14.01**	**19.39**	**23.77**	**23.99**	**23.99**

In the above table the change in the score as compared to Visit 1 was calculated for each visit for both the groups and it was found that the % of Change was more in Trial Group as compared to Control Group.

Graph 6. Inter Group % Change at every Visit: MASI Score



The above Graph shows the representation of the % Change between Trial and Control Group at all visits as depicted in Table 12. It also shows that there has been no change at Visit 2. Significant changes can be noted from Visit 3 onwards.

And it can be seen that the Trial Group has performed better than the Control Group

4. **Patient's Assessment Scale:**

Table 13. Friedman Test applied for Intra group assessment of Trial Group: Patient's Assessment Scale

Trial Group	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100
Median	04	03	03	03	03	03
Range	03– 04	03 - 04	02 - 04	02 - 04	01 – 04	01 - 04
Sum of Ranks	576.50	405.00***	326.50***	283.50***	255.50***	253.00***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					
	Friedman Statistic Fr = 361.96 (corrected for ties)					
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expectedby chance.**					

(***p < 0.001 compared to V1)

We can see the median changing from 4 at Visit 2 to 3 at Visits 3, 4,5, 6 and 7. So we can say that there has been a significant change in the Patient's assessment scale starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that the Patient's assessment scale has not worsened after stopping the medicine at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per Patient's Assessment Scale the Trial drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 6.

Table 14. Friedman Test applied for Intra group assessment of Control Group: Patient's Assessment Scale

Control Group	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100
Median	04	03	03	03	03	03
Range	03– 04	03 - 04	02 - 04	01 - 04	01 – 04	01 - 04
Sum of Ranks	555.50	410.50***	314.50***	278.50***	270.50***	270.50***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					
	Friedman Statistic Fr = 341.78 (corrected for ties)					
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expectedby chance.**					

(***p < 0.001 compared to V1)

We can see the median changing from 4 at Visit 2 to 3 at Visits 3, 4,5, 6 and 7. So we can say that there has been a significant change in the Patient's assessment scale starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that the Patient's assessment scale has not worsened after stopping the medicine at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per Patient's Assessment Scale the drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 6.

Table 15. Mann Whitney Test applied for Inter group assessment between Trial and Control Group: Patient's Assessment Scale

Visit	Group	Median (Range)	Mann – Whitney U Statistic	U'	P Value, Inference
V2	Trial	04 (03 – 04)	5000.0	5000.0	0.9990, Not Significant
	Control	04 (03 – 04)			
V3	Trial	03 (03 – 04)	4050.0	5950.0	0.0183, Significant
	Control	03 (03 – 04)			
V4	Trial	03 (02 – 04)	4244.0	5756.0	0.0546, not quite significant
	Control	03 (02 – 04)			
V5	Trial	03 (02 – 04)	3994.5	6005.5	0.0109, significant
	Control	03 (01 – 04)			
V6	Trial	03 (01 – 04)	3616.0	6384.0	0.0005,extremely significant
	Control	03 (01 – 04)			
V7	Trial	03 (01 – 04)	3570.0	6430.0	0.0003, Extremely Significant
	Control	03 (01 – 04)			

In the above table we can see that there is no significant difference in both the groups if we compare their medians of Visit 2 and Visit 4. There is a difference in the medians at Vist 3,5,6 and Visit 7. There is a significant difference observed in both the group at Visit 6 and Visit 7.

Graph 7: Intra and Inter Group Assessment of Patient's Assessment Scale (Median Values) in both the groups.

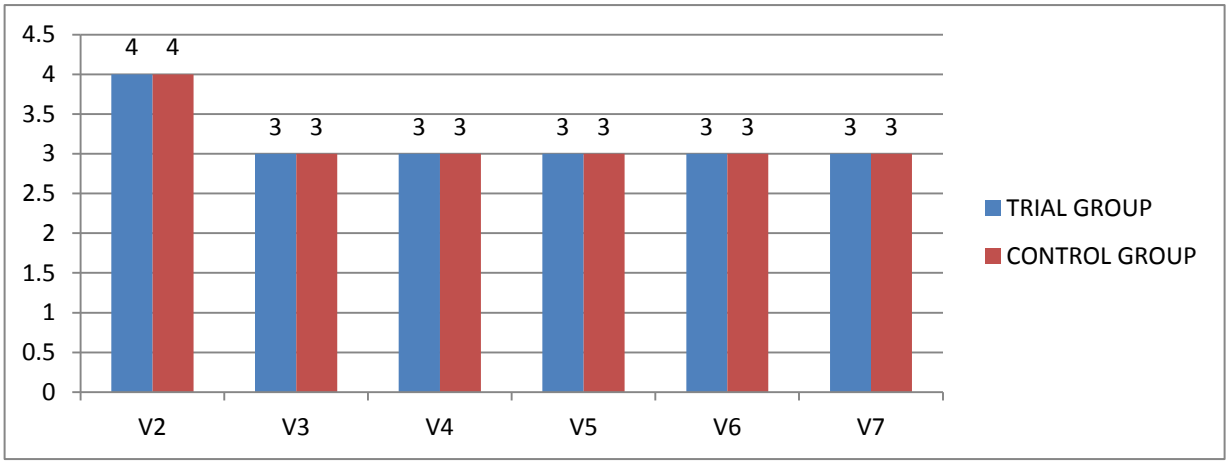
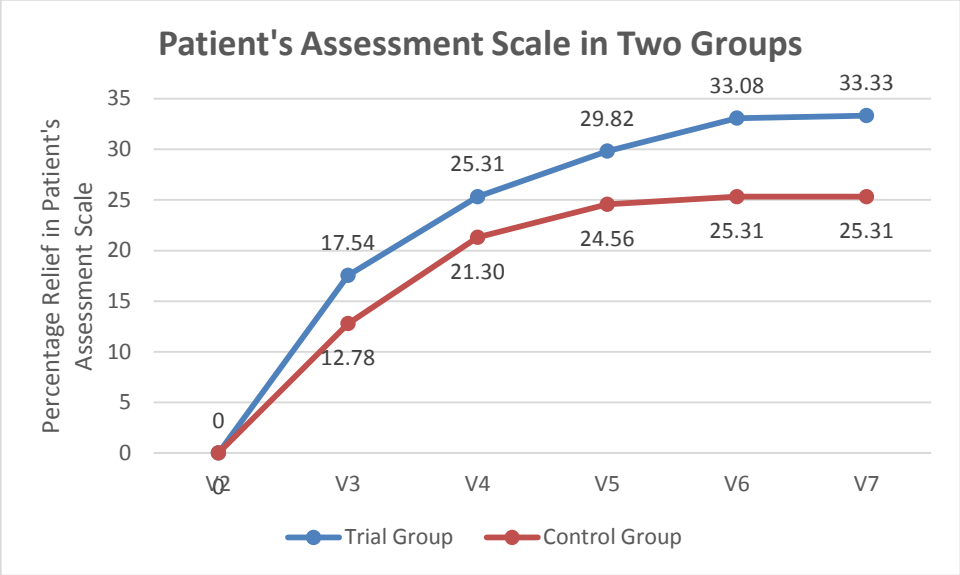


Table 16. Inter Group % Change: Patient's Assessment Scale

	V2	**V3**	**V4**	**V5**	**V6**	**V7**
Trial Group	399	329	298	280	267	266
Difference		70	101	119	132	133
% Change		**17.54**	**25.31**	**29.82**	**33.08**	**33.33**
Control Group	399	348	314	301	298	298
Difference		51	85	98	101	101
% Change		**12.78**	**21.30**	**24.56**	**25.31**	**25.31**

In the above table the change in the score as compared to visit 2 was calculated for each visit for both the groups and it was found that the % of Change was more in Trial Group as compared to Control Group.

Graph 8. Inter Group % Change at every Visit: Patient's Assessment Scale



The above Graph shows the representation of the % Change between Trial and Control Group at all visits as depicted in Table 16. It also shows that there has been no change at Visit 2. Significant changes can be noted from Visit 3 onwards. And it can be seen that the Trial Group has performed better than the Control Group

5. Physician's Assessment Scale

Table 17. Friedman Test applied for Intra group assessment of Trial Group: Physician's Assessment Scale

Trial Group	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100
Median	05	04	04	04	03	03
Range	04 – 05	03 - 05	03 - 05	02 - 05	01 – 05	01 - 05
Sum of Ranks	575.50	424.00***	356.00***	269.00***	236.50***	238.50***

Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)
	Friedman Statistic Fr = 375.48 (corrected for ties)
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**

(***p < 0.001 compared to V1)

We can see the median changing from 5 at Visit 2 to 4 at Visits 3 to Visit 5 and 3 at Visits 6 and Visit 7. So we can say that there has been a significant change in the Physician's assessment scale starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that as per the Physician's assessment scale the condition of Melasma has not worsened after stopping the medicine at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per Physician's Assessment Scale the drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 7.

Table 18. Friedman Test applied for Intra group assessment of Control Group: Physician's Assessment Scale

Control Group	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100
Median	05	04	04	04	04	04
Range	04 – 05	04 - 05	03 - 05	00 - 05	00 – 05	00 - 05
Sum of Ranks	557.50	408.00***	314.00***	279.50***	270.50***	270.50***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					
	Friedman Statistic Fr = 338.48 (corrected for ties)					

	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**

(***p < 0.001 compared to V1)

We can see the median changing from 5 at Visit 2 to 4 from Visit 3 to Visit 7. So we can say that there has been a significant change in the Patient's assessment scale starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that as per the Physician's assessment scale the condition of Melasma has not worsened after stopping the control drug at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per Physician's Assessment Scale the drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 7.

Table 19. Mann Whitney Test applied for Inter group assessment between Trial and Control Group: Physician's Assessment Scale

Visit	**Group**	**Median (Range)**	**Mann – Whitney U Statistic**	**U'**	**P Value, Inference**
V2	Trial	05 (04 – 05)	4850.0	5150.0	0.6976, Not Significant
	Control	05 (04 – 05)			
V3	Trial	04 (03 – 05)	3922.0	6078.0	0.0073, Very Significant
	Control	04 (04 – 05)			
V4	Trial	04 (03 – 05)	4165.5	5834.5	0.0340, Significant
	Control	04 (03 – 05)			
V5	Trial	04 (02 – 05)	3255.5	6744.5	< 0.0001, Extremely Significant
	Control	04 (00 – 05)			
V6	Trial	03 (02 – 05)	2855.5	7144.5	< 0.0001, Extremely Significant
	Control	04 (00 – 05)			
V7	Trial	03 (01 – 05)	2901.5	7098.5	< 0.0001, Extremely Significant
	Control	04 (00 – 05)			

In the above table we can see that there is no significant difference in both the groups if we compare their medians of Visit 2. But there is a significant difference in the medians at Vist 3 and Visit 4. Also there is an extremely significant difference observed in both the groups at Visits 5, 6 and Visit 7.

Graph 9: Intra and Inter Group Assessment of Physician's Assessment Scale (Median values) in both the groups.

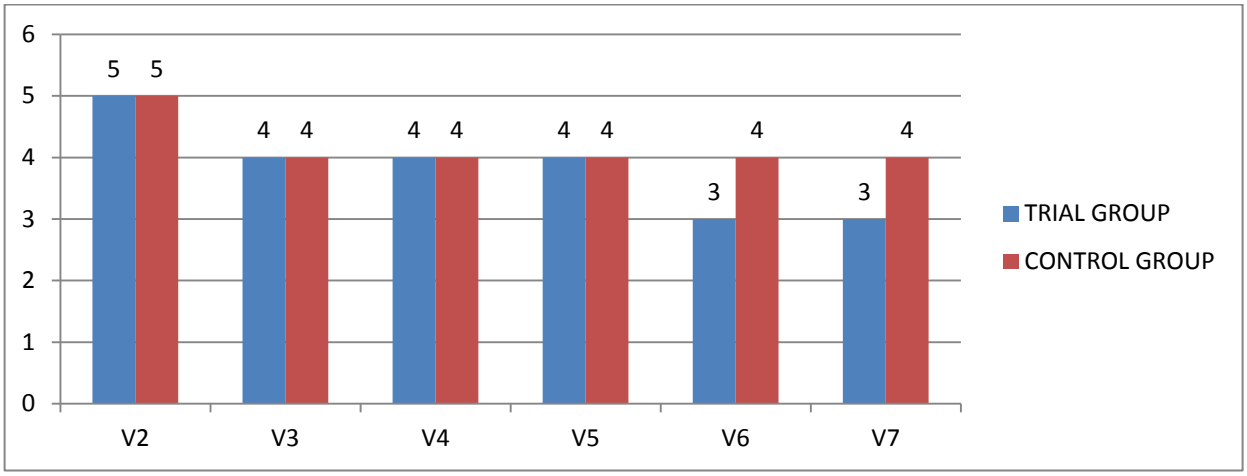
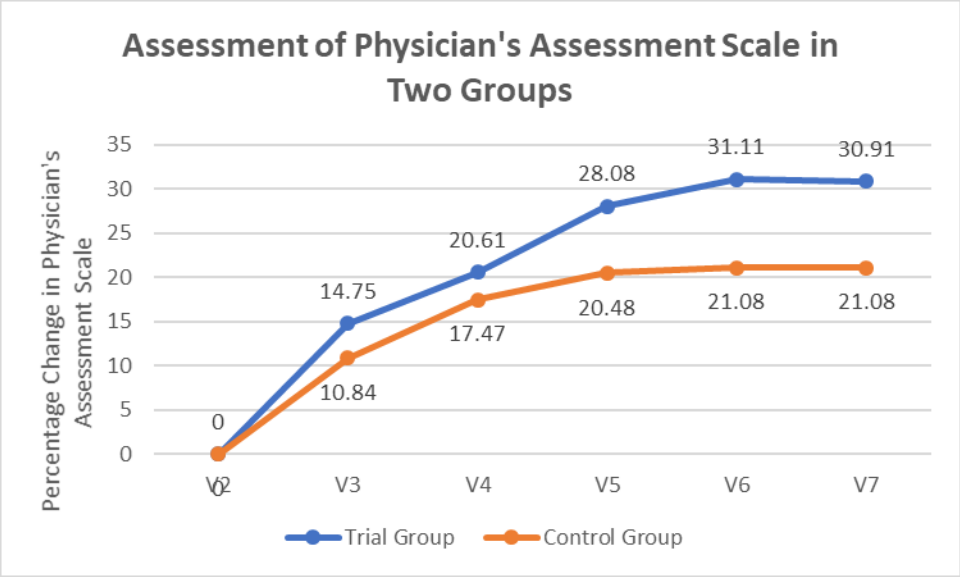


Table 20. Inter Group % Change: Physician's Assessment Scale

	V2	**V3**	**V4**	**V5**	**V6**	**V7**
Trial Group	495	422	393	356	341	342
Difference		73	102	139	154	153
% Change		**14.75**	**20.61**	**28.08**	**31.11**	**30.91**
Control Group	498	444	411	396	393	393
Difference		54	87	102	105	105
% Change		**10.84**	**17.47**	**20.48**	**21.08**	**21.08**

In the above table the change in the score as compared to Visit 2 was calculated for each visit for both the groups and it was found that the % of Change was more in Trial Group as compared to Control Group.

Graph 10. Inter Group % Change at every Visit: Physician's Assessment Scale



The above Graph shows the representation of the % Change between Trial and Control Group at all visits as depicted in Table 20. It also shows that there has been no change at Visit 2. Significant changes can be noted from Visit 3 onwards. And it can be seen that the Trial Group has performed better than the Control Group.

6. **Clinical Response to Treatment Scale**

Table 21. Friedman Test applied for Intra group assessment of Trial Group: Clinical Response to Treatment Scale

Trial Group	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100
Median	00	01	01	01	01	01
Range	00 – 01	00 – 01	00 – 02	00 – 02	00 – 02	00 – 02
Sum of Ranks	129.50	294.00***	366.00***	410.50***	450.00***	450.00***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					

	Friedman Statistic Fr = 357.79 (corrected for ties)
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**

(***p < 0.001 compared to V1)

We can see the median changing from 0 at Visit 2 to 1 from Visits 3 to Visit 7. So we can say that there has been a significant change in the Patient's assessment scale starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that as per the Clinical Response to Treatment Scale the condition of Melasma has not worsened after stopping the trial drug at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per Clinical Response to Treatment Scale the drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 7.

Table 22. Friedman Test applied for Intra group assessment of Control Group: Clinical Response to Treatment Scale

Control Group	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Sample Size (n)	100	100	100	100	100	100
Median	00	01	01	01	01	01
Range	00 – 01	00 – 01	00 – 01	00 – 02	00 – 02	00 – 02
Sum of Ranks	151.50	298.50***	37.00***	422.00***	428.00***	425.50***
Test of Significance	Friedman Test (Nonparametric Repeated Measures ANOVA)					
	Friedman Statistic Fr = 323.94 (corrected for ties)					
	The P value is < 0.0001, considered extremely significant. **Variation among column medians is significantly greater than expected by chance.**					

(***p < 0.001 compared to V1)

We can see the median changing from 0 at Visit 2 to 1 from Visits 3 to Visit 7. So we can say that there has been a significant change in the Patient's assessment scale starting from Visit 3.

There is no change in the Median value at Visit 6 and Visit 7 which shows that as per the Clinical Response to Treatment Scale the condition of Melasma has not worsened after stopping the control drug at Visit 6 so there was no relapse noticed at Visit 7.

Thus this table shows that as per Clinical Response to Treatment Scale the control drug has proved to show significant changes as compared to Visit 1 from Visit 3 to Visit 7.

Table 23. Mann Whitney Test applied for Inter group assessment between Trial and Control Group: Clinical Response to Treatment Scale

Visit	Group	Median (Range)	Mann – Whitney U Statistic	U'	P Value, Inference
V2	Trial	00 (00 – 01)	4950.0	5050.0	0.8977, Not Significant
	Control	00 (00 – 01)			
V3	Trial	00 (00 – 01)	4200.0	5800.0	0.0467, Very Significant
	Control	00 (00 – 01)			
V4	Trial	01 (00 – 02)	4269.0	5731.0	0.0632, Not Quite Significant
	Control	01 (00 – 01)			
V5	Trial	01 (00 – 02)	4311.5	5688.5	0.0808, Not Quite Significant
	Control	01 (00 – 02)			
V6	Trial	01 (00 – 02)	3651.5	6348.5	0.0007, Extremely Significant
	Control	01 (00 – 02)			
V7	Trial	01 (00 – 02)	3617.5	6382.5	0.0005, Extremely Significant
	Control	01 (00 – 02)			

In the above table we can see that there is no significant difference in both the groups if we compare their medians of Visits 2, 4 and 5. But there is a Very significant difference at Visit 3 and Extremely significant difference in the medians at Vist 6 and Visit 7 respectively.

Graph 11. Intra and Inter Group Assessment of CRT Scale (Median values) in both the groups

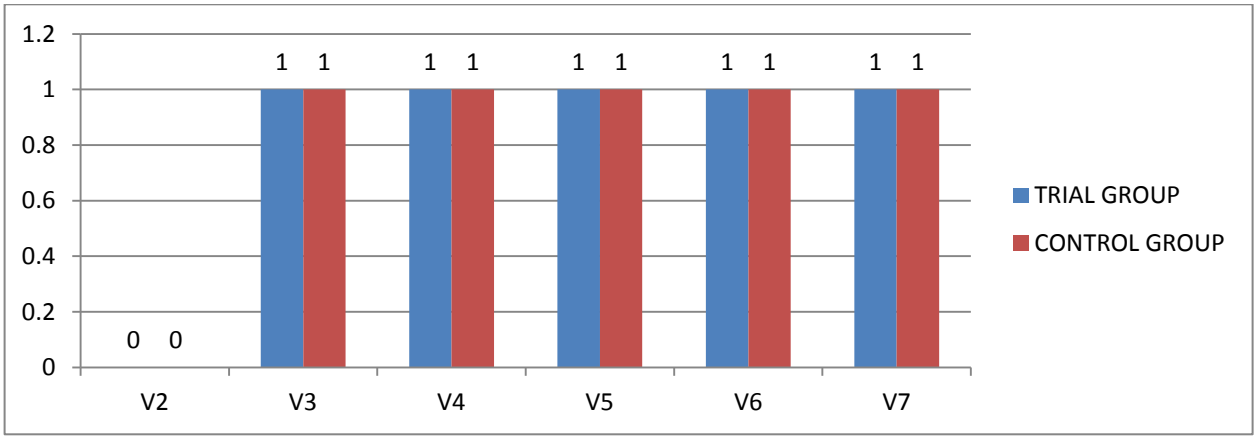
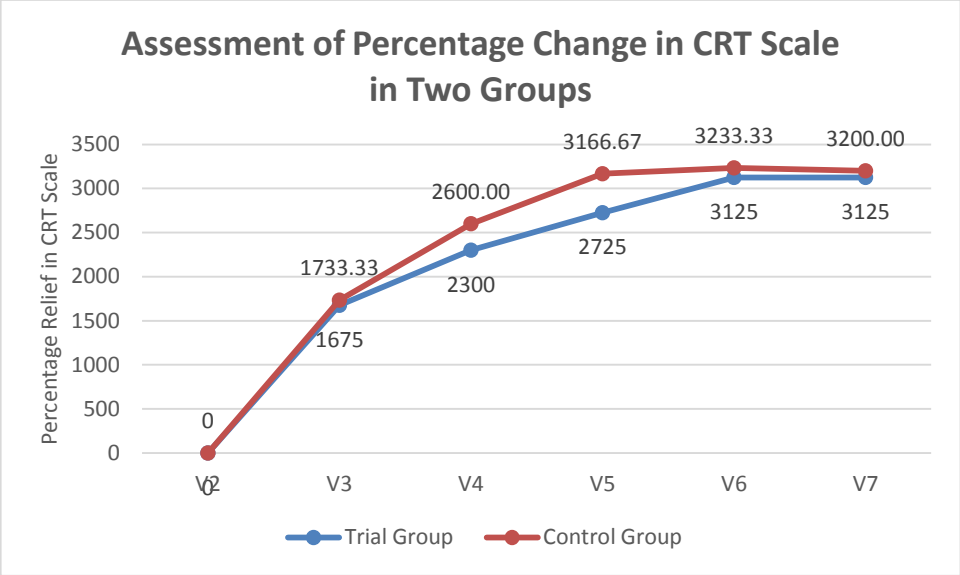


Table 24. Inter Group % Change: Clinical Response to Treatment Scale

	V2	**V3**	**V4**	**V5**	**V6**	**V7**
Trial Group	4	71	96	113	129	129
Difference		67	92	109	125	125
% Change		**1675**	**2300**	**2725**	**3125**	**3125**
Control Group	3	55	81	98	100	99
Difference		52	78	95	97	96
% Change		**1733.333**	**2600**	**3166.667**	**3233.333**	**3200**

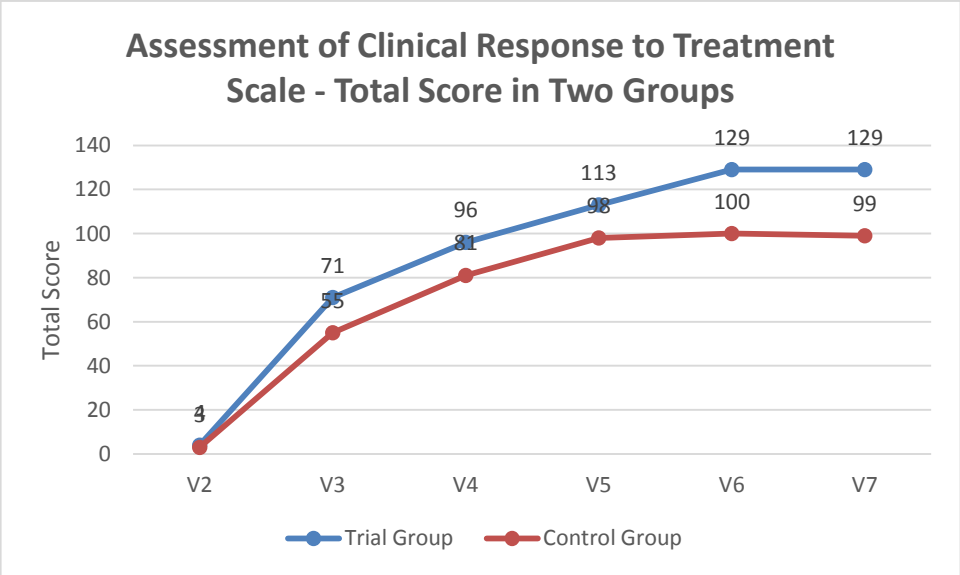
In the above table the change in the score as compared to visit 2 was calculated for each visit for both the groups and it was found that the % of Change was more in Control Group as compared to Trial Group.

Graph 12. Inter Group % Change at every Visit: Clinical Response to Treatment Scale



The above Graph shows the representation of the % Change between Trial and Control Group at all visits as depicted in Table 20. It also shows that there has been no change at Visit 2. Significant changes can be noted from Visit 3 onwards.

Graph 13. Inter Group Total Score at every Visit: Clinical Response to Treatment Scale



The above Graph shows the representation of the total Score between Trial and Control Group at all Visits. It also shows that there has been no change at Visit 2. Significant changes can be noted from Visit 3 onwards. And in this Graph we can see that Trial Group shows higher scores as compared to Control Group. Which means Trial Group has performed better than the Control Group.

Also to conclude the final results of the effect of our treatment, to find out how many had improved or how many had no change at all, following chart was prepared.
In none of the patients the condition worsened (-1, -2) so only 3 grades were considered, 0, 1, and 2.

Table No. 25. Result of CRT Scale

CRT SCALE	Trial Group (100)	Control Group (100)
0. No Change	3	8
1. Improved (Upto 50% relief)	65	85
2. Much improved (> 50% relief))	32	7

From the above table we can see that although improvement is seen in both the groups , number of patients showing much improvement ie. more than 50 % improvement is seen more in Drug Group/Trial Group.

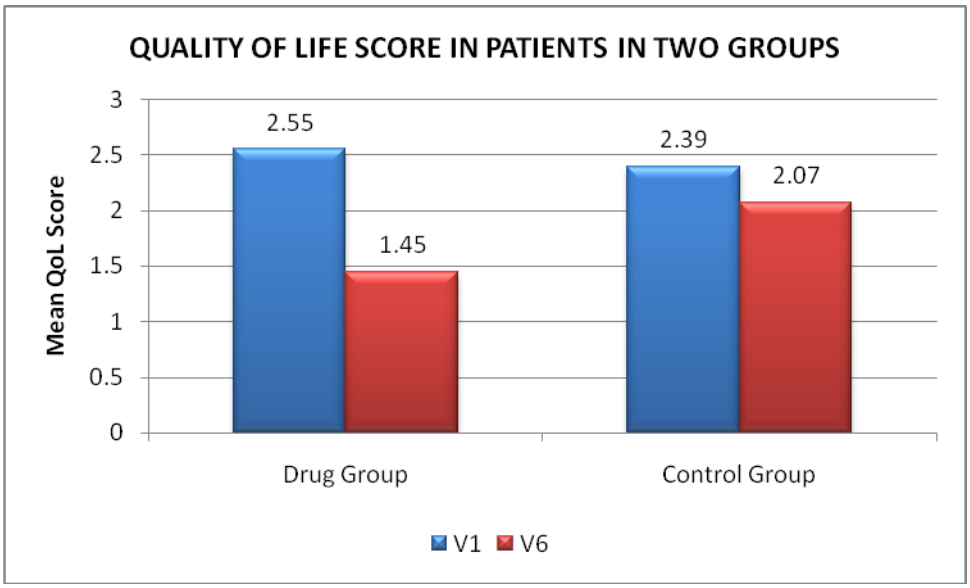
7. Quality of Life Score

Table No. 26. Quality of Life score of both the groups

	Drug Group QOL Score		Control Group QOL Score	
	V1	**V6**	**V1**	**V6**
Sample Size (n)	100	100	100	100
Mean ± SD	2.55 ± 3.08	1.45 ± 1.87	2.39 ± 2.36	2.07 ± 2.05
SE	0.31	0.31	0.24	0.24
Median	02	00	02	02
Range	00 - 15	00 - 08	00 - 08	00 - 08
Passed Normality Test?	No	No	No	No
Intra-Group Comparison				
Test of Significance	Wilcoxon matched-pairs signed-ranks test		Wilcoxon matched-pairs signed-ranks test	
Statistics	Sum of all signed ranks (W) = 528.00 Number of pairs = 32		Sum of all signed ranks (W) = 135.00 Number of pairs = 18	
P Value	The two-tailed P value is > 0.0001, considered extremely significant.		The two-tailed P value is 0.0019, considered very significant.	

From the above Chart it can be seen that there is an Extremely significant and Very significant changes seen in the Quality of Life Scores of both Drug Group and Control Group from Visit 1 to Visit 6.

Graph 8. Inter Group and Intra Group assessment of Quality of Life Score



In the above bar diagram we can see the difference in the mean scores at Visit 1 and Visit 6 of both the groups and we can also see that in Drug Group the difference seems more, citing better performance. Because lesser the Score better the effect.

INFERENCES

1. Melasma occurs more in Females than Males.
2. Age group 41 to 50 yrs are more affected by this disease.
3. *Pitta* and *Pitta Kapha Prakriti* persons were more prone to *Vyanga*.
4. Fair skinned patients were most affected by *Vyanga*.
5. *Vyanga* occurs mainly in Malar region.
6. It was found that in nearly 60.5% patients no Cause and Effect relation could be established
7. Most of *Vyanga* Patients were found to be consuming excessive *Amla*, *Katu* and *Lavan Rasa* in food.
8. Other Traits such as Disturbed Sleep, Anger and Depression could be the causes of *Vyanga*.
9. Hormonal changes as a cause such as Menopause, Pregnancy induced Melasma, Irregular Menses and Consumption of Oral Contraceptives was also seen in number of Female patients.
10. The patients of *Lakshadi Malhar* and Control *Malhar* both showed significant improvement in improving the darkness, area of distribution and Homogeneity of Melasma.
11. On comparing the results of both groups, *Lakshadi Malhar* Group showed better results than Control *Malhar* group.
12. On assessing the Quality of Life Score of *Vyanga* patients before and after the treatment, the quality of life showed marked improvement.

DISCUSSION

Analysis of the Drug.

In the analytical report of *Lakshadi Malhar* it was observed that the colour of Batch 1 and Batch 2 is Light Brown whereas of Batch 3 it is Dark Brown. The colour of the *Malhar* was due to the ingredients used especially *Laksha. Laksha* is red in colour and therefore the *kwatha* prepared becomes dark brown in colour. After adding the rest of the ingredients to prepare the *Malhar* the final product becomes brown in colour. The ingredients and the ratio of these ingredients was the same for all the 3 batches. And yet if the colour parameter seemed different, it could be due to the reason that the assessment of colour is a subjective parameter and can vary from person to person assessing the product. Also since these batches were prepared at different intervals this could have led to some colour changes in the raw materials. But at the same time it must be kept in mind that it was ensured each time that the raw material used were of good condition.

For standardization of any sample we need at least 3 batches to come to a final conclusion and therefore keeping this in mind although 4 batches each of control and *Lakshadi Malhar* were prepared analysis of only first 3 batches were considered to be reported.

Reason for Dropouts

During the course of study I encountered many dropouts. 68 patients from 270 recruited dropped out of the trial which is nearly 25% dropout rate. There were many reasons for the same.

1. Total duration of the study was 135days. To hold a patient for this long in a trial was a difficult task and thus this duration was the major reason for dropout.
2. *Vyanga* hampers the looks and thus for those suffering from it want immediate relief. If they didn't find that relief within 15 days or even less than that, they would not turn out for the second follow up thus adding to the drop out.
3. In the initial phase of the clinical trial I failed to call the patients often to remind them of their upcoming visits and this way they were lost to follow up. After realizing this later I

maintained a chart of their upcoming visits and would call them frequently reminding the same. So not keeping track of your patients wellbeing in time can cause dropouts.

The data of the patients recruited in this study revealed a lot of information.

The **Sex Ratio** for both the groups together revealed 66% Females as against 34% Males. This supports the previous studies which proved that Melasma occurrence is seen more in Females than Males.[3]

The **Age Group** Distribution showed 13% of 20 to 30 yr, 36% of 31 to 40 yrs and 51% of 41 to 50 yrs age groups respectively. Although previous studies have shown that the occurrence is common in age group of 31 to 40 yrs,[4] I found it to be more in age group 41 to 50yrs.

Prakriti assessment was done of all the patients to find a relation between *Prakriti* and occurrence of *Vyanga*. It was found that 34.5 % were of *Pitta Kapha Prakriti*, 22% of *Pitta Prakriti*, 17% of *Kapha Pitta Prakriti*, 6.5% of *Pitta Vaat Prakriti* and 4.5% of *Vaat Pitta Prakriti* and Others 15.5%.

This disease as per Bruhatrayee is *Vaat* and *Pitta* predominant disease. But as far as *Prakriti* was concerned this disease was predominant in *Pitta Kapha* and *Pitta Prakriti.*

As far as the **Diet** was concerned the Patients were 68% Nonvegetarian and 32% Vegetarian. It could be a mere coincidence or Diet had definitely some role to play with *Vyanga* occurrence. But if we see the survey done on Vegetarian crowd in Maharshtra it was found that 40.2% of the population in Maharashtra are Vegetarian and the rest Non vegetarian.[5]

It was also found that from the 132 Females in both the group 25% were in Menopause Phase. Menopause is one of the probable causes of *Vyanga* in Women.

52% of Patients having Moist skin had *Vyanga*(Melasma) as against 23% who had Dry skin and 25% who had Oily skin. As for the **colour of skin**, Melasma occurred in 54% of Fair skinned patients, 36.5 % of wheatish/brown skinned patients and 9.5% of Dark skinned Patients. According to previous studies though, occurrence of Melasma is common is brown skin coloured people than Fair skinned or Dark skinned Persons.[6]

As for the **Addiction** history, only 10.5% were addicted to Tea, 4.5 % had other addictions such as Smoking, Alcohol and Tobacco consumption. Rest 85% were not addicted.

Age of Melasma of the patients was calculated too. About 37.5% patients had it for >1 yr to 3 yrs, 25.5% were having it for >3 yrs to 5 yrs, 19.5% Upto a year and others above 5 years.

Distribution of *Vyanga*(Melasma) was observed, 79% had it on Malar region, 7% had a Malar + Forhead and Malar + Nose presentation each respectively. 5.5 % had a Malar + Forhead + Nose presentation and others such as only Chin, Forhead or Nose 2.5%. As per the previous studies Centerofacial presentation is most common.

Family history revealed occurrence of Melasma in Family in about 7.5% which is non significant as against 92.5% who had no family history.

Mode of onset of Melasma was either Sudden found in 46.5% patients or Gradual in 53.5% patients.

Of the patients who were recruited in the trial, nearly 61.5 % had not taken any **treatment** previously, 19.5% had taken Allopathy treatment, 17% Ayurvedic treatment and 2% Homeopathy treatment. Many patients often do not treat Melasma as they do not give it much importance especially the elderly crowd. The middle age crowd is though conscious and are quick in taking medication for the symptoms.

When the Causes or Etiology history was taken of the patients it was found that in about 65.5% there were seen no cause for occurrence whereas in 27% Sunexposure on daily basis was seen as a probable cause. Of the 66% Females of the study, 12.8% had Melasma since Pregnancy, 18% had it since Menopause and 1.5% was on Oral Contraceptive Pills.

Along with the above known Etiology few other parameters were also considered, to see if they had any contribution in occurrence of Melasma. It was found that 20.5% patients had Disturbed sleep, 3% had Irregular Menstrual flow, 2.5% had excessive exposure to Computer/ Print. 1% had history of Trauma at the site of occurrence.

On detailed study of the type of food it was explored that 35% consumed excessive amount of *Lavan*(Salty) *Rasa*, 30% consumed excessive amount of *Katu*(Spicy) and 23% consumed excessive

amount of *Amla*(Sour) *Rasa*. All these 3 rasas are responsible for increasing *Pitta Dosha* which is a major contributing factor in causing Melasma.

On enquiring about their Personality traits it was discovered that 35% of the Patients had the habit of Overthinking and feeling Low about any events that occurred. And 33% of the Patients had high Temper(Anger). These 2 symptoms could be probable causes of Melasma as how we feel reflects on our skin. Our mind is related to the health of our skin.

Few Adverse Events were noted in the Trial as well Control group. In Trial Group 8 % and in Control group 12% complained of symptoms such as Itching over the face, Burning or Redness of eyes, Stickyness on exposure to Sun and Pimples. These symptoms were mild and disappeared without any medication and persisted only during 1^{st} or 2^{nd} time of application of cream and thus although noted the patients were continued in the trial.

Quality of Life Score was marked by the patient at Visit 1 and Visit 6. There was seen a great drop of negative score from Visit 1 to Visit 6. The score in 0 to 1 category(No effect on Patient's life) which was 52 and 44 at Visit 1 increased to 61 and 47, in 2 to 5 category (Small effect) which was 35 and 38 increased to 38 and 42, whereas in 6 to 10 category (Moderate effect) which was 15 and 11 reduced to 4 each during Visit 6 in Drug and Control Group respectively. This means the score decreased from Visit 1 to Visit 6 implying improvement in Quality of Life.

Pathya Apathya

On Visit 1 the detailed case record form was filled of the patient. In this the tentative cause for the occurrence of *Vyanga* was assessed. In the etiology section the type of food consumed, the type o work and daily routine was enquired. As a remedy the patient was advised to avoid spicy, oily and salty food. Pittakar aahaar like poha, toor daal, bakery items, etc were told to be reduced. They were encouraged to eat aamla, gulkand, moong daal, fresh food, fruits and vegetables. If the patient had anger issues, pranayam was advised. The patients were also told to perform some kind of exercise daily, like yoga, or walk, or gym exercises. To avoid exposure to sun tying a scarf around the face was suggested.

Assessment Criterias of *Vyanga*

Vyanga has been assessed using the 6 assessment scales already mentioned in Chapter 3. These scales have been widely used for study of *Vyanga*. In our texts *Vyanga* has been described as *Shyaava/Shyamal*(darkened colour/brown/black) circular patches on face which are *Aruja*(painless) and *Tanu*(thin/unelevated). The patients were selected as per these criteria. All the assessment was done using the scores of each scale. Each scale has scores which are well defined and the patients were thus given scores as per these definations. For measuring *Shyaavata/Shyamalta*(darkness of patches), Fairness meter scale, Melasma Severity Scale and MASI Score was used. For Area of the patches MASI Score was used. The patches were measured to score the Homogenity in MASI Score. This was done with the help of a thread and then measured on a scale. Patient scored themselves(for percentage of relief acquired from *vyanga* symptoms) with the help of Patient's Assessment Scale. Physician's Assessment scale and Clinical Response to Treatment Scale were used by the Physician to study the final effect of the treatment. The scores were given based on the observation of Fairness Meter Scale, Melasma Severity Scale and MASI Score. And finally during the last visit the patient was categorized into Much Worse, Worse, No change, Improved, Much improved as per the Clinical Response to treatment Scale.

In Ayurveda texts no assessment criteria as such has been mentioned but it is understood from the line of treatment that *Vaat Pittashamak* and *Varnya* treatment is given both orally and locally, more the later and also *Raktamokshan* (blood letting procedure) is been indicated to treat *Vyanga.* And thus the criteria could be to see the reduction of the dark coloured patches. This could be more subjective. The Scales however helps us to give a score to check the effect of a treatment and is thus less subjective.

Adverse events noted

During the study few adverse events were noted in both drug group and control group. In Drug group 1 patient complained of occurrence of pimples after application of cream after 2 visits, she was later discontinued from the trial, 2 patients complained of itching on face after first application which vanished after further applications, one patient complained of redness and burning of eyes who was discontinued from the trial, one patient complained of feeling sweaty on exposure to sun after the application, he was advised to not apply the cream and go out instead to apply it in the

morning after bath and wash the face before going out in the sun, 3 patients experienced stickyness/oilyness on face after cream application. This was due to the presence of teel oil in the cream and since the patients had oily skin may be this was felt by them the most. These events noted were manageable and not serious barring the burning of eyes and the occurring of pimples who were discontinued from the study for their well being. Also the percentage of the event occurrence was negligible.

Result of the Clinical Study

On basis of all the Scales both the groups Trial as well Control Group showed significant results with **p value < 0.001,** yet on comparing the results of both the group the overall performance of the Trial Group has been better than the Control Group. This can be well seen in the representive Graphs in The Result section.

The chief symptoms of *Vyanga* are *Shyava* (Black), Painless, Circular or any shape lesions on the face. The improvement on Fairness meter Scale and Melasma Severity scale showed the effect of medicine in reducing the darkness ie. *Shyavta* of *Vyanga*. Improvement on MASI Score showed the effect of Medicine on reducing the Darkness, Area of Distribution and Homogeneity of *Vyanga* (Melasma) lesions.

The Patient's Assessment Scale, Physician,s Assessment Scale and the Clinical Response to Treatment Scale too showed an improvement in the condition of *Vyanga*.

Although the Control *Malhar* did not contain the medicine it contained *Teel* oil in addition to Emulsifiers, Stabilisers, Preservatives and essence. So we can say from the significant results that we found in Control Group that *Teel* Oil which is a very good moisturizer plays an important role in curing *Vyanga* too. And we can say that it even helps in reducing the darkness of the *Vyanga* lesions.

The Trial starts at Visit 1 ie. Day 0 and ends at Visit 7 Day 135. Although the medicine starts at Day 1, there seems to have been no impact of the treatment on Visit 2 ie. Day 21. The changes are noticed only at Visit 3 ie. Day 42. So we can say that the changes start somewhere between Visit 2 and Visit 3.

After the treatment stops at Visit 6 ie Day 105, there has been no changes in the symptoms at Visit 7 ie. Day 135. The Visit 7 was kept to see if there is any noticeable relapse observed in patients after stopping the medicines which is generally seen with other medicines.

But in this study no relapse was noticed in any patients after stopping both Trial and Control Cream.

Applying the cream was very comfortable for the patient as it could be carried along with them wherever they went. Could be applied anywhere as it would get absorbed in the skin easily.

One of the complains of the cream was although it was Oil in Water emulsion wherein, quantity of water was more than of oil, the use of *Teel* oil made the cream a bit oily. So in few patients when their skin was exposed to Sun the skin would feel sticky or oily. It didn't feel so at home in the shade but only on exposure to Su

Action of the Drug

Lakshadi Malhar contained decoction of Mango seeds, *Jamun* seeds, Pomogranate peels, *Yashtimadhu* roots, *Bala* roots and *Laksha*, Teel oil, emulsifiers, stabilizers, preservatives and essence.

Mango seeds are known to be an excellent moisturiser. It ensure healthy skin. It's the best for dry skin, especially for the delicate areas like eyes and cheeks It contains a very gentle ingredient and acts as a barrier to prevent skin drying.[7] *Vyanga* is *Vaat*, *Pitta* predominant disease and Mango seed is *Pitta shamak, Sheet virya, Kashay, Madhur rasa* and *Madhur Vipaaki.* It has been indicated in *Vyanga* in Chikitsa Prabhakar.

Jamun seeds have an astringent effect and so it is useful in oily skin to keep the oil levels in check. It is also helpful in clearing dark spots and acne if used over a period of time and makes the skin clean and clear.[8] They are *Madhur, Kahsay, Sheet Viryatmak* and *Pitta shamak*. Also they are indicated in *Vyanga* to be used externally as lepa as per Chikitsaprabhakar.

Pomogranate peels has healing properties, they can effectively fight acne, pimples and rashes. It is great for your skin, hydrates and protects your skin from pollutants and other environmental toxins. It helps to maintain the pH balance of the skin. The ellagic acid present in the peels moisturize the skin and keeps it soft and supple.[9] These peels have *Madhur,Kashay Rasa, Madhur Vipaak,*

Anushna Virya and are *Pitta shamak* and it is also indicated in *Vyanga* as *Varnya* in Chikitsa Prabhakar.

Yashtimadhu root contains a compound glycyrrhizin, which is used to treat skin conditions like eczema and acne. It is also a rich source of antioxidants, and offers skin lightening and anti-aging benefits.

Yashtimadhu root fights the free radicals (responsible for generating excessive melanin) by inhibiting their production and preventing excess melanin from being produced. It helps in removing the dark spots, lightens them and gives a clean and clear skin.[10]

As per Ayurveda *Yashtimadhu* has *Madhur Rasa, Madhur Vipaak* and *Sheet Virya*. It is both *Vaat* and *Pitta Shamak.* It is *Varnya* and *Rakta prasadak* hence indicated *Vyanga* in many texts.

Bala roots have lots of antioxidants and many other nutrients that promote glowing skin, whether used internally or externally it provides the nourishment needed for a good complexion.[11]

It has *Madhur Rasa, Madhur Vipaak* and *Sheet Virya*. It is *Vaat, Pitta shamak*. It is *Raktaprasadak* and thus indicated in *Vyanga* in number of texts.

Laksha resin has an astringent effect so it is useful in oily skin.[12]

It has *Kashay Rasa, Katu Vipaak* and *Sheet Virya*. It is *Pittashamak.* It is both *Varnya* and *Vyanga nashak*

Teel oil contains vitamin E, which can help protect skin cells from the damage caused by environmental factors, pollution, and toxins. It contains several phenolic compounds, which give it its antioxidant property. It helps prevent sun damage on skin. It may be especially beneficial for acne-prone skin and acne scars.[13]

Teel oil has *Madhur Rasa, Madhur Vipaak.* It is *Vaatshamak*. It is a natural moisturizer.

Seeeing all the properties of the drugs given above we know how *Lakshadi Malhar* benefitted the patients of *Vyanga*. Also due to benefits of *Teel* oil the patients of Control Group too had positive responses.

We can also say from the above description that if medicinal drugs having *Kashay*, *Madhur Rasa* such as *Jamun, Aamra, Laksha* are given to patients having *Vyanga* both internally and for External application they might give tremendous results in curing the symptoms of *Vyanga* in the long run.

***Samprapti* and *Samprapti bhanga* of *Vyanga*.**

When we sum up the *samprapti* described in the Bruhatrayi[Ch.2:4,5,6] we can conclude that due to causes such as *Krodh, Aayasa* and *Shoka, Vaat prakop* occurs. Now this *Vaat* is *Vyan Vaayu* as it circulates throughout the body and is also present in the skin. This *Prakupit Vaat* or we can call it *Vikrut Vaat* cannot perform its normal function such as *Bala, Varna, Sukha* and *Ayushya Nirmaan* but it destroys all of the above.[14] This leads to loss of *Prakrut Varna* as in *Vyanga* disease. Also this *Prakupit Vaat* combines with *Prakrut Pitta*, in this case the *Brajak Pitta* which is present in the skin and locate themselves *Mukhagat*(face) and thus hampers the normal function of *Pitta*. The important function of *Prakrut Pitta* to be considered here is enhancement of *Pakrut Varna*[15]. In absence of which *Vikrut Varna*(*Shyava/Shyamal*) occurs.Therefore patches of darkened coloured skin appear on the face. This is how *Vyanga Samprapti* happens. All this occurs in the second layer of skin ie *Lohita*. The *Vikrut Varna* could be *Shyava*(Dark coloured/Brown) or *Shaamal*(Dark coloured/Black).

Samprapti* of *Vyanga

Krodh/Shoka/Aayasa

⇩

Vaat (Vyaan Vaayu)Prakop

⇩

Bala Varna Haani

⇩

Prakupit Vaat + Pitta(Bhrajak Pitta)

⇩

Mukhagat Twacha Stansanshray(Lohita)

⇩

Prakupit Vaat obstructs the normal functioning of Pitta

⇩

Pitta is unable to enhance Prakrut Varna

⇩

Shyaav/Shyaam, painless,Circular patches

Appear on the face

⇩

Vyanga

Samprapti Bhanga* of *Vyanga* by using *Lakshadi Malhar

Now if we combine the properties of all the *dravya* used in *Lakshadi Malhar* we can conclude that it is *Madhur, Kashay Ras Pradhan. Sheeta Virya. Snigdha, Sookshma* and *Varnya* property.

Now if we study the action caused by each property individually on the skin locally we can see the following reflexes.

Madhur Rasa is *Vaat* and *Pitta shamak* both[16]. It acts on the skin locally and reduces the *Prakupit Vaat*, which then reduces *Rukshata* and Darkness caused by *Prakupit Vaat* on the face. Also *Pitta* which has been together with *Prakupit Vaat* starts performing its normal function of skin *Varna* enhancement.

Kashay Rasa is *Pittashamak,*[17] When applied on the skin it works on *Bhrajak Pitta*(present in the skin) and thus enhances the proper function of *Pitta* ie. *Varna* enhancement. *Kashay Rasa* also has astringent effect ie. cleaning effect. And so it can clears and leans the skin of any *doshas*.

Due to *Snigdha* and *Sookshma* guna the medicine penetrates the skin and moisturizes the skin. It also reduces *Prakupit Vaat*, reducing *Ruksha guna* of *Vaat*, which in turn helps in proper functioning of *Pitta* and *Vaat* also.

All the *dravya* have *Sheeta Virya.* Now *Sheeta Virya* is *Pittashamak*. According to Charak, any action that occurs is due to *Virya* and no action can occur without *Virya*.[18] Considering this as a fact we can say that our medicine acts as per its *Virya* too and thus enhances proper action of *Pitta* locally which is destroying *Vikrut Varna* and enhancing *Prakrut Varna.*

शीतोष्णमिती वीर्यं तु कियते येन या किया ।

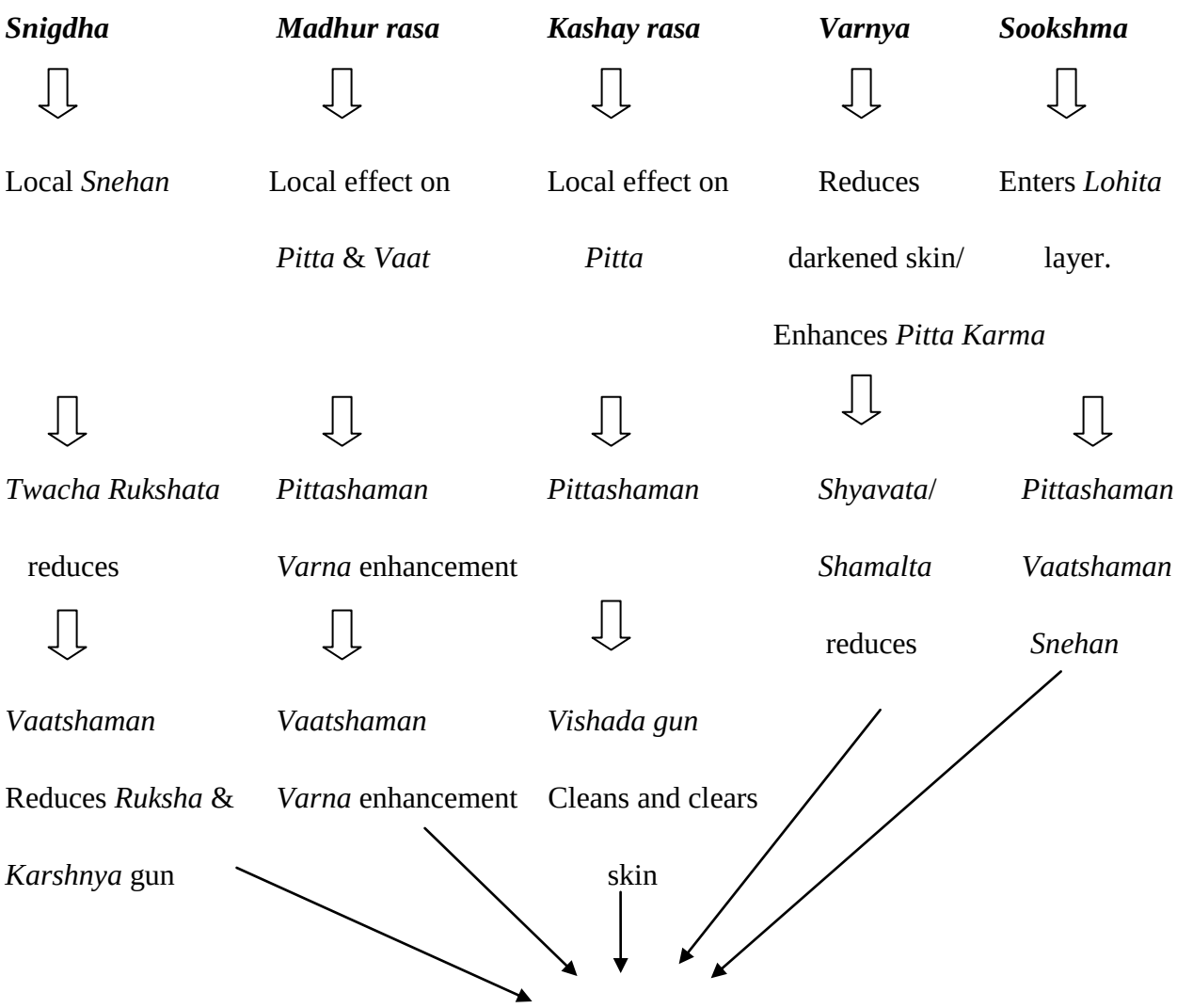
नीवीर्यं कुरूते किंचित सर्वा वीर्य कृता किया ॥

Ch. Su.26/64-65

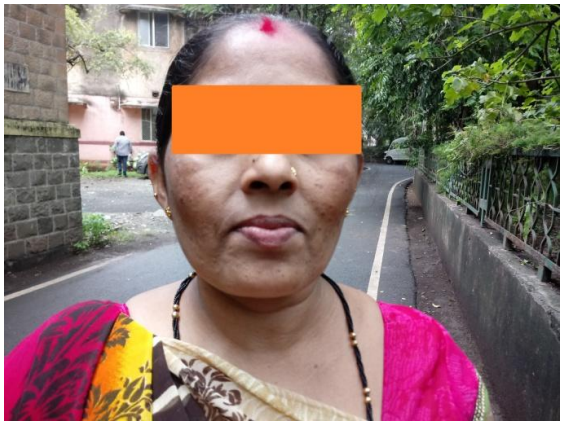
Lastly all the *dravya* are said to have *Varnya* property and are especially indicated for *Vyanga*. The *Varnya* property helps to induce skin lightening effect ie. it reduces darkened skin and helps to get back the normal skin colour.

The *Samprapti Bhanga* flow chart is given below

Samprapti Bhanga* of *Lakshadi Malhar

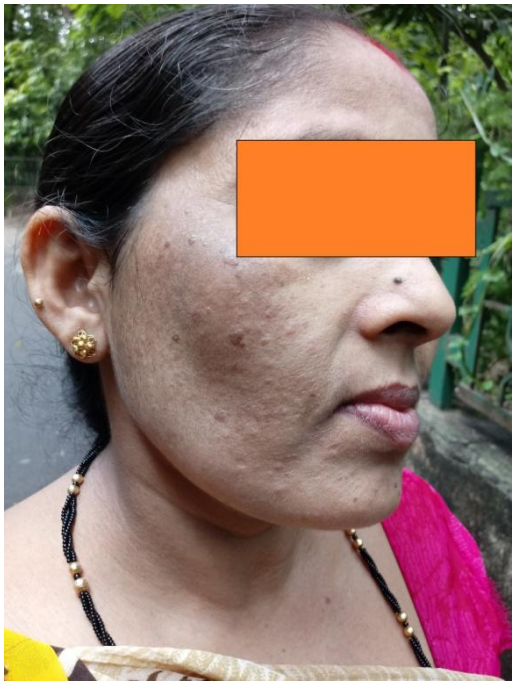


CONTROL GROUP PATIENT"S PICTURES

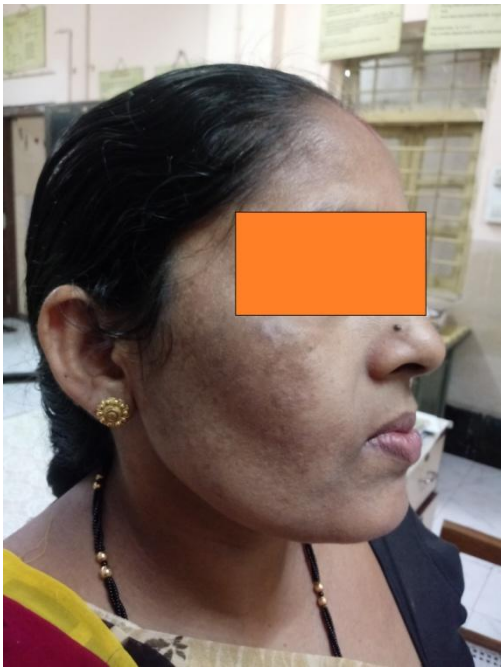


Pt. 1. Front view Visit 1

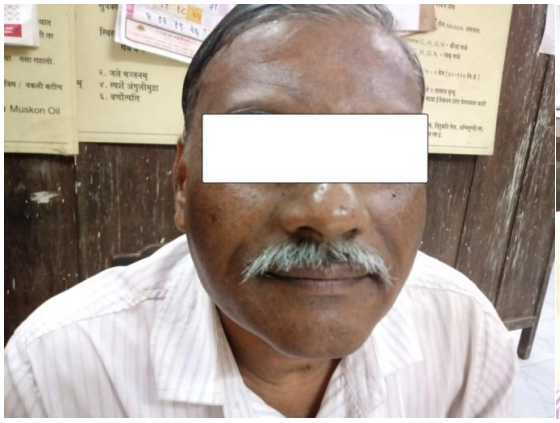
Pt. 1. Front view Visit 6



Pt. 1. Right cheek view. Visit 1

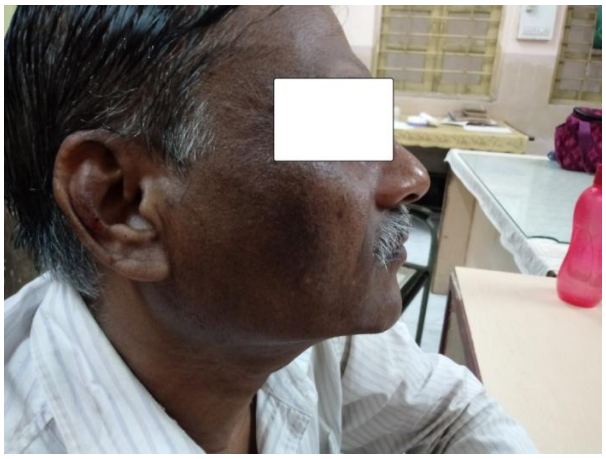


Pt. 1. Right cheek view. Visit 6.

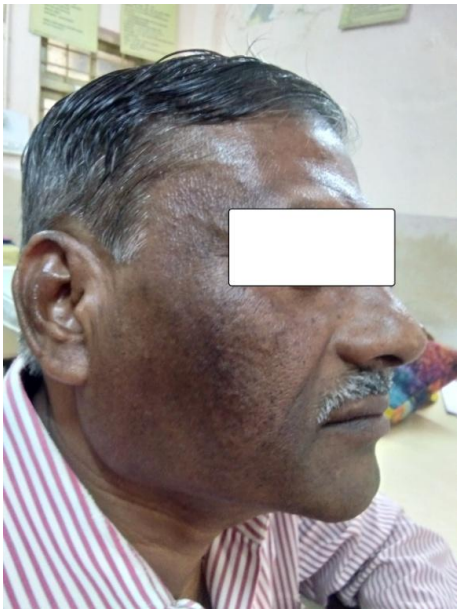


Pt. 2 Front view. Visit 1

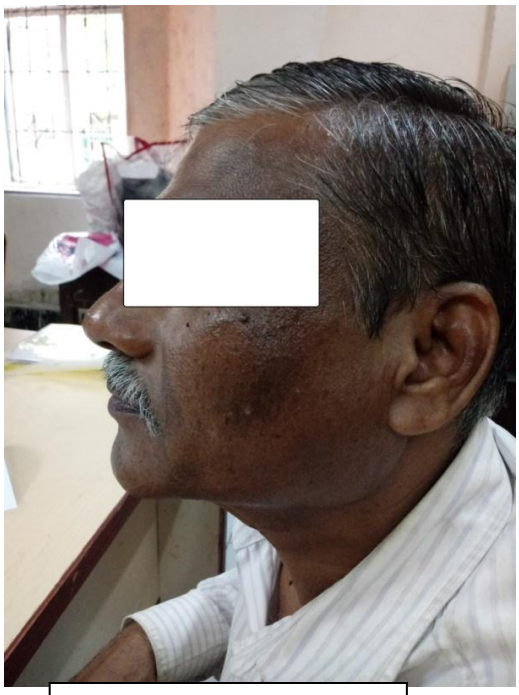
Pt.2 Front view Visit 6



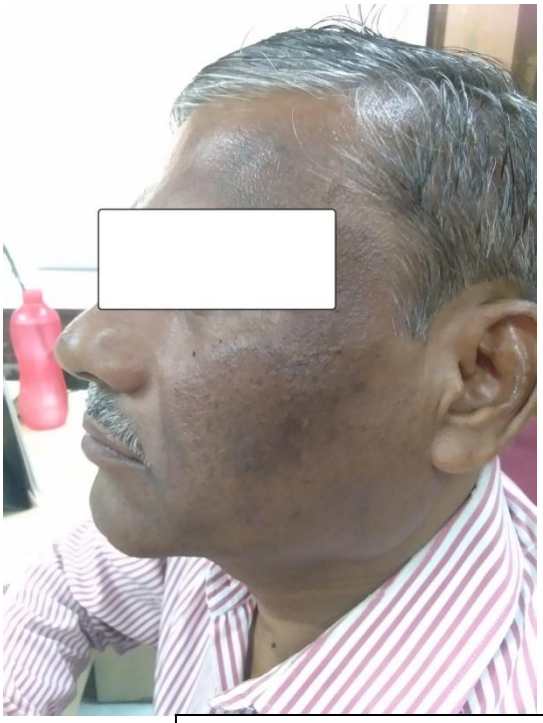
Pt. 2 Right cheek Visit 1



Pt. 2. Right cheek Visit 6



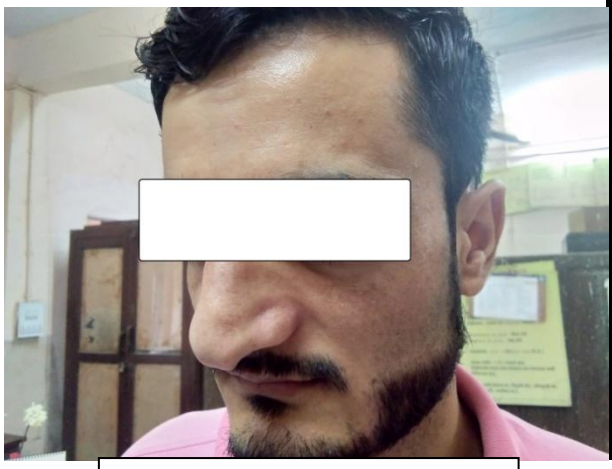
Pt. 2. Left cheek Visit 1



Pt. 2. Left cheek Visit 6

Pt. 3 Front view Visit 1

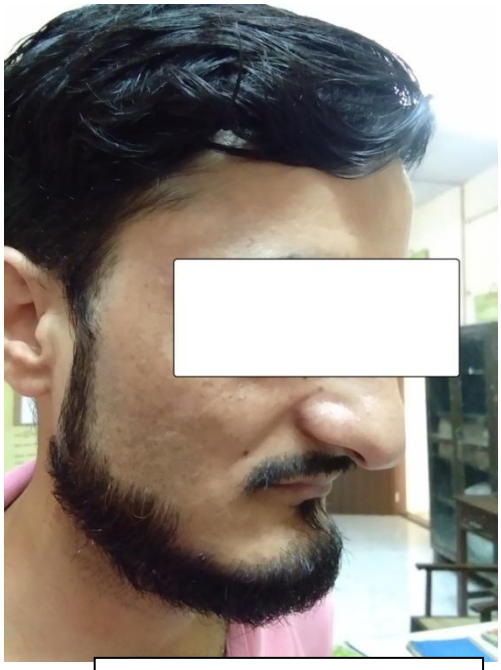
Pt. 3. Front view Visit 6



Pt. 3. Left cheek. Visit 1

Pt. 3. Left cheek. Visit 6

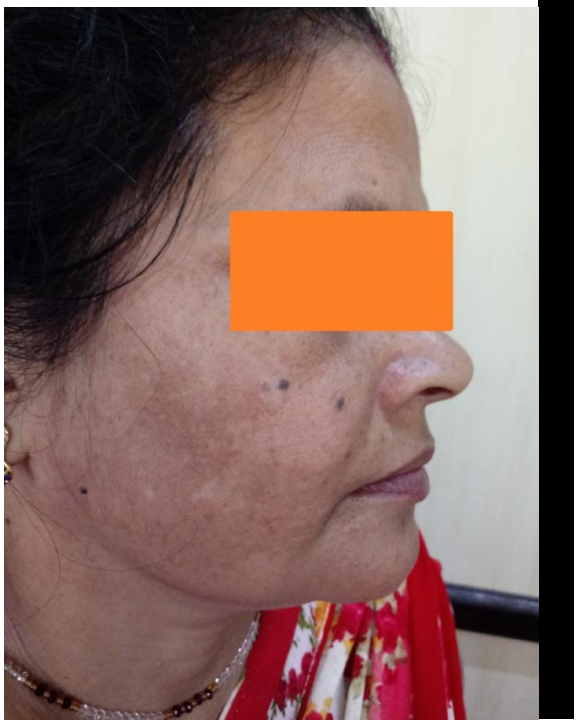
Pt. 3. Right cheek Visit 1



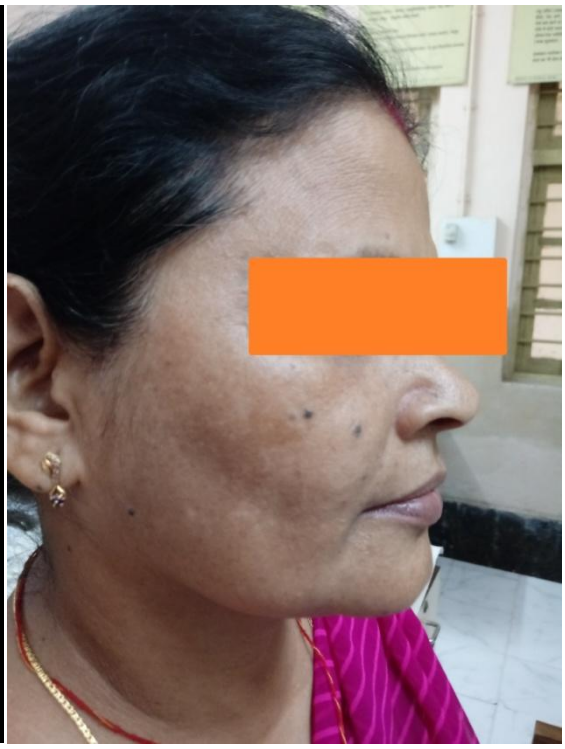
Pt. 3. Right cheek Visit 6

Pt. 4. Left cheek. Visit 1

Pt. 4. Left cheek. Visit 6

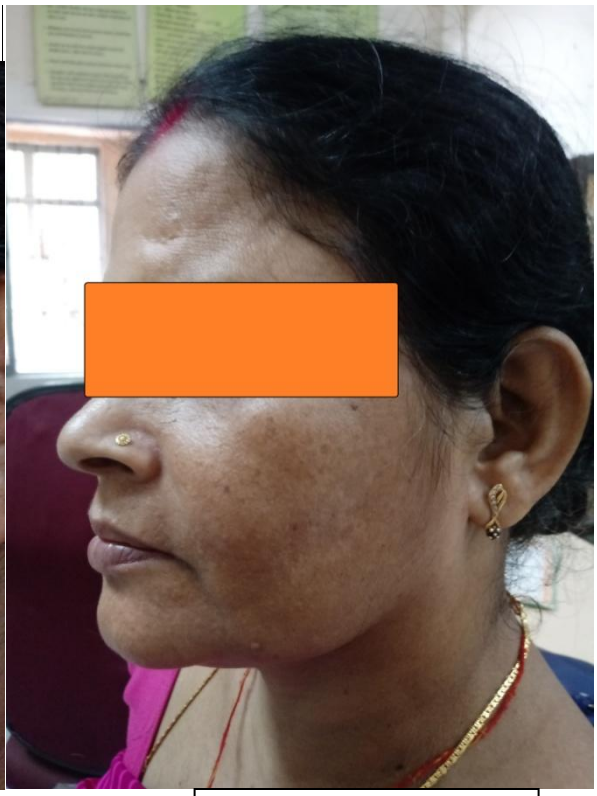


Pt. 5 Right cheek Visit 1



Pt. 5 Right cheek Visit 6

Pt. 5 Left cheek Visit 1

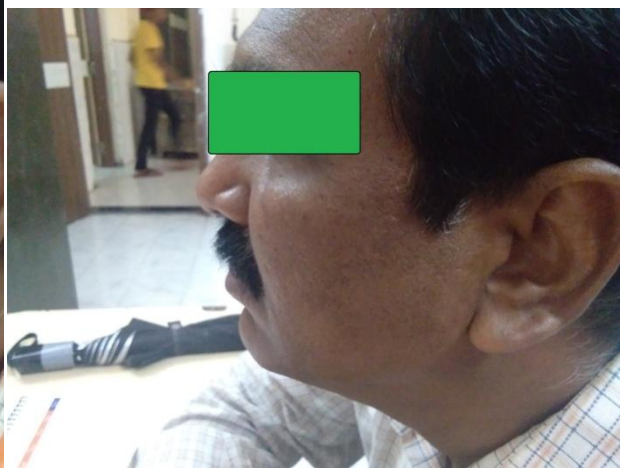


Pt. 5 Left cheek Visit 6

Pt. 6. Rt. Cheek Visit 1

Pt. 6. Rt. Cheek Visit 6

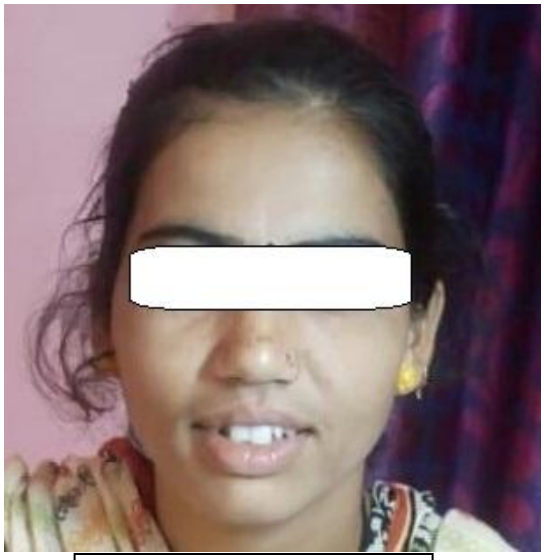
Pt. 6. Lt. Cheek Visit 1



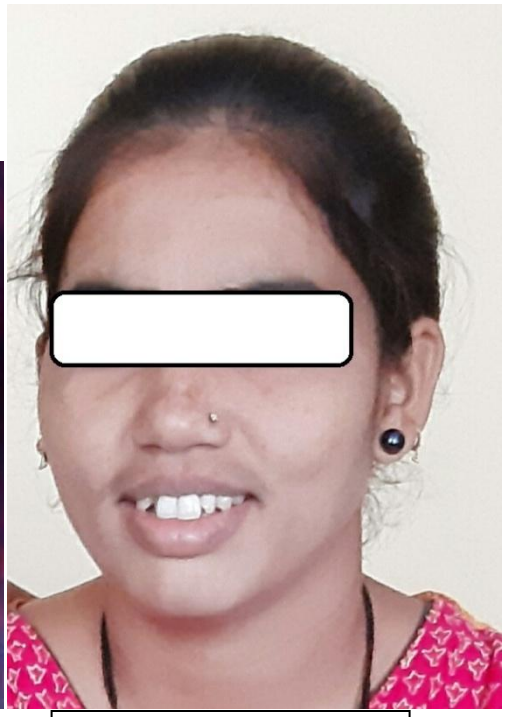
Pt. 6. Lt. Cheek Visit 6

Pt. 6. Front view Visit 1

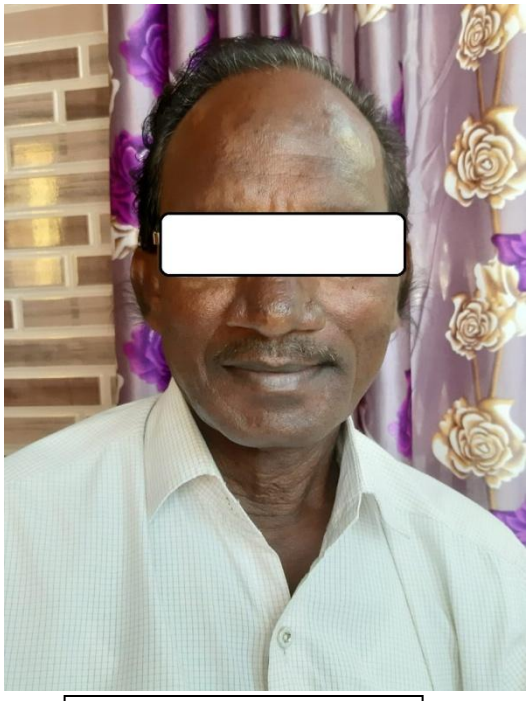
Pt. 6. Front view Visit 6



Pt. 7. Front view. Visit 1

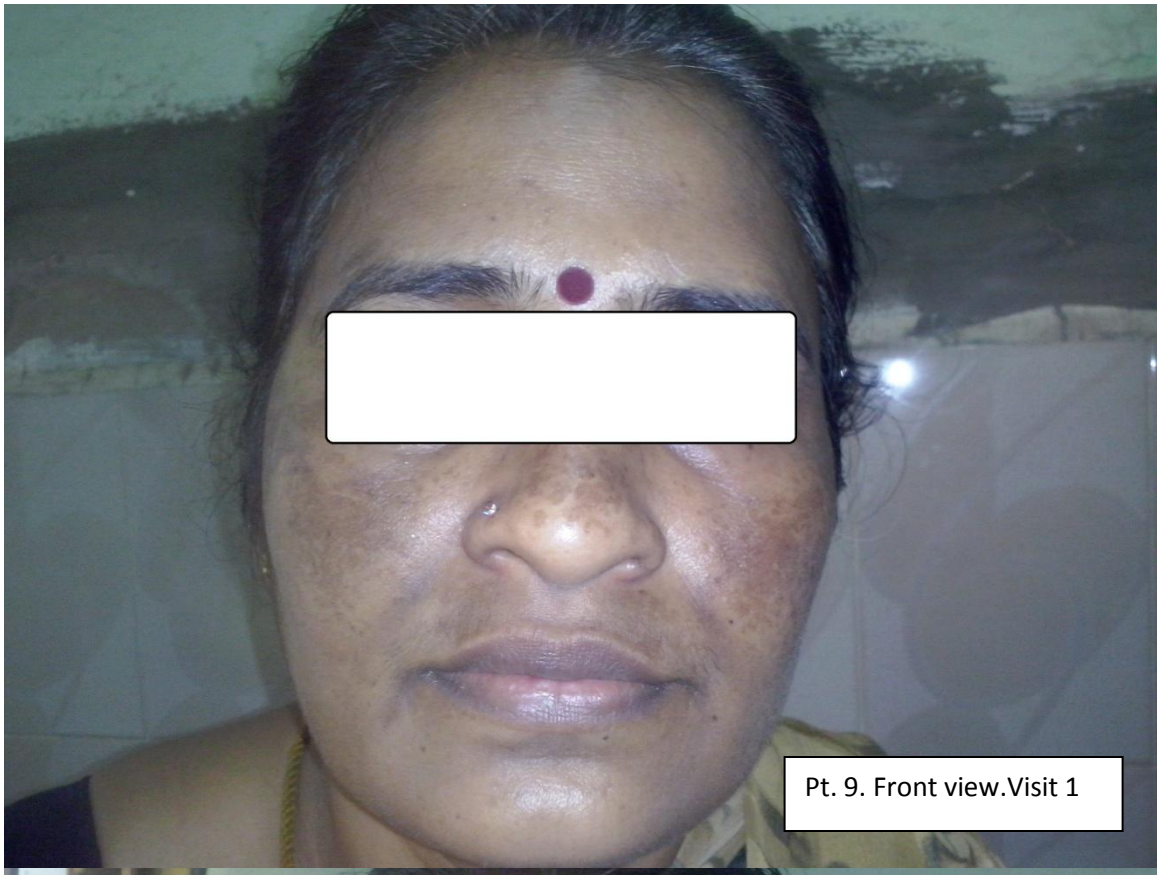


Pt. 7. Front view. Visit 6

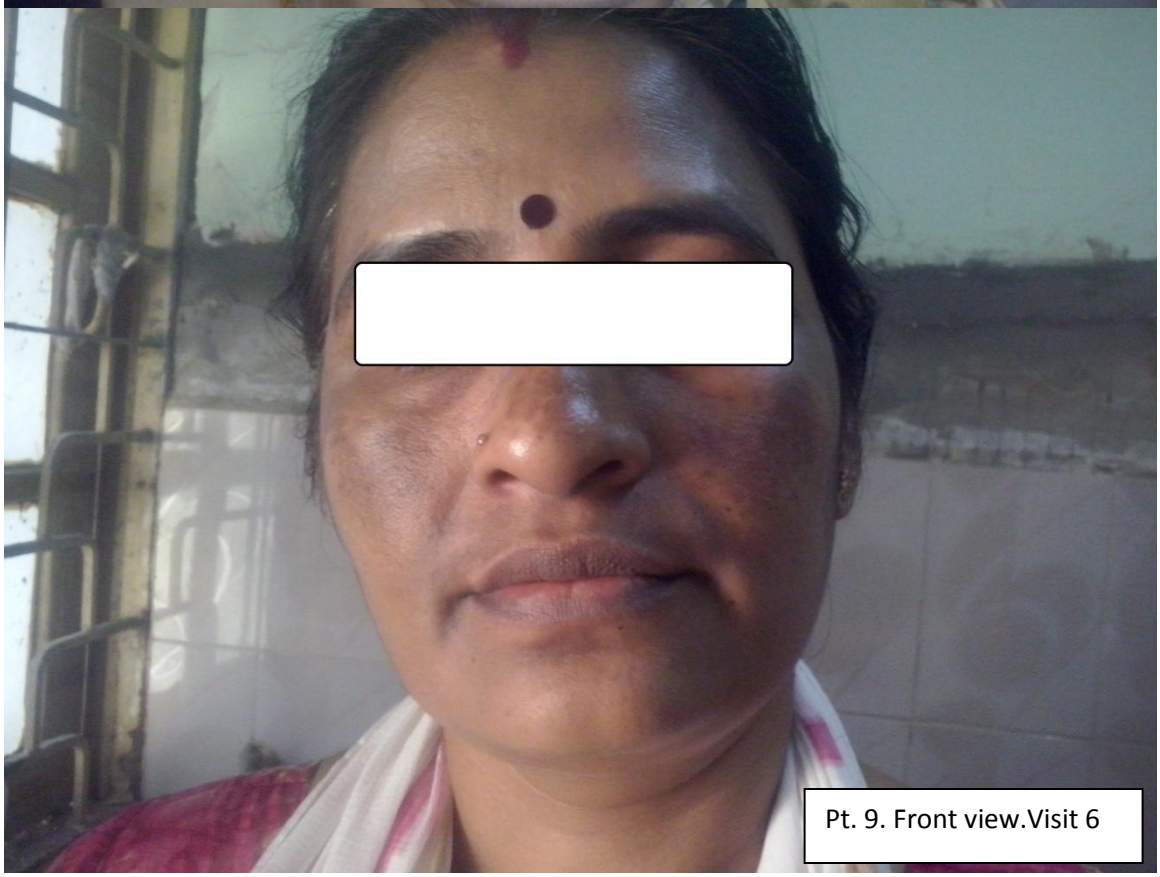


Pt. 8. Front view. Visit 1

Pt. 8. Front view. Visit 6

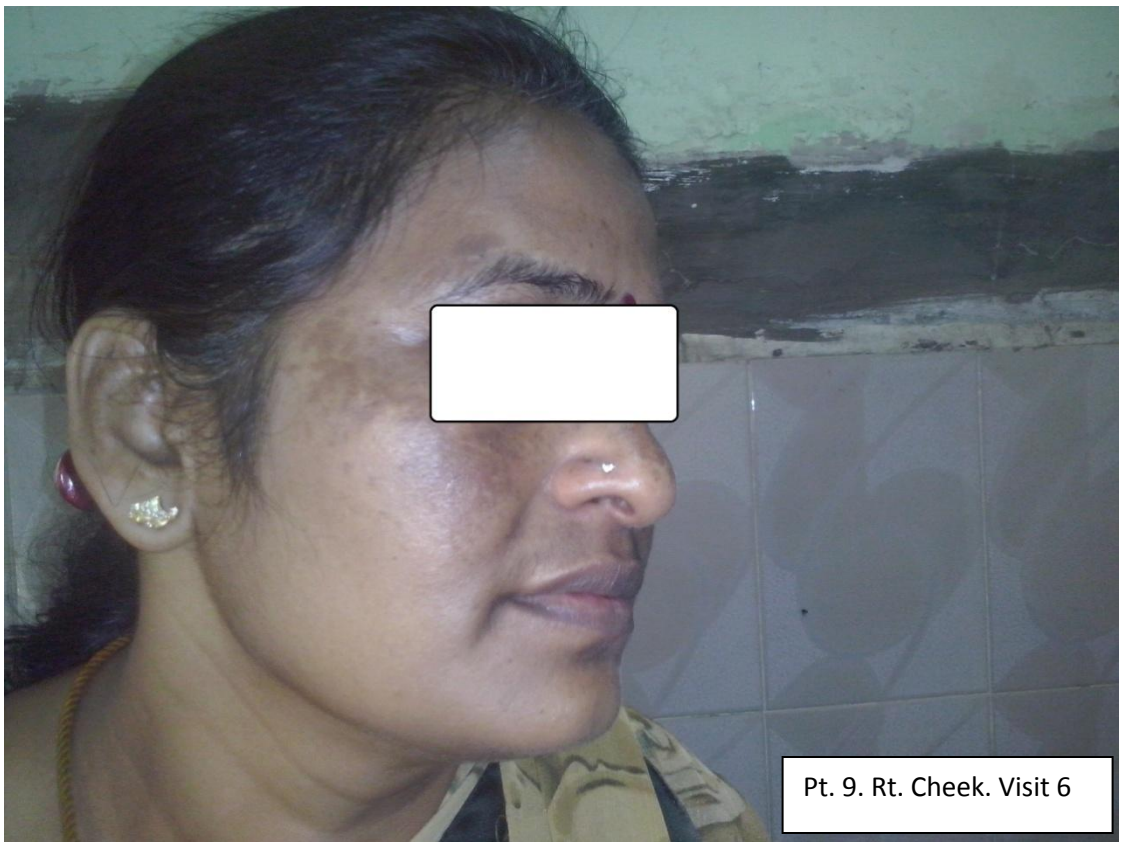


Pt. 9. Front view.Visit 1

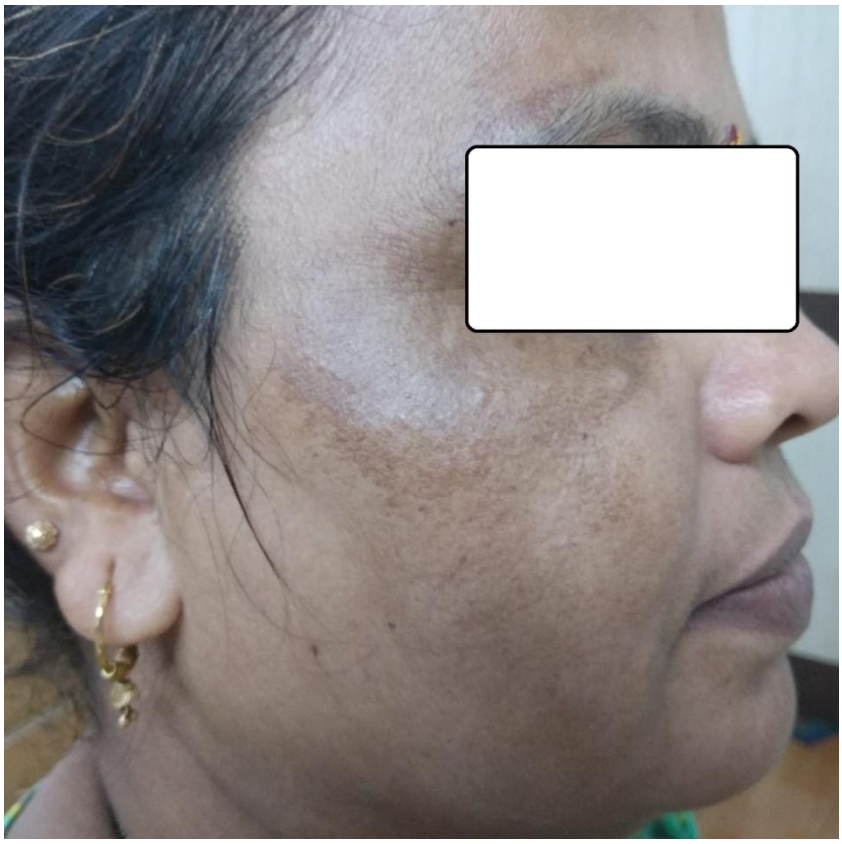


Pt. 9. Front view.Visit 6

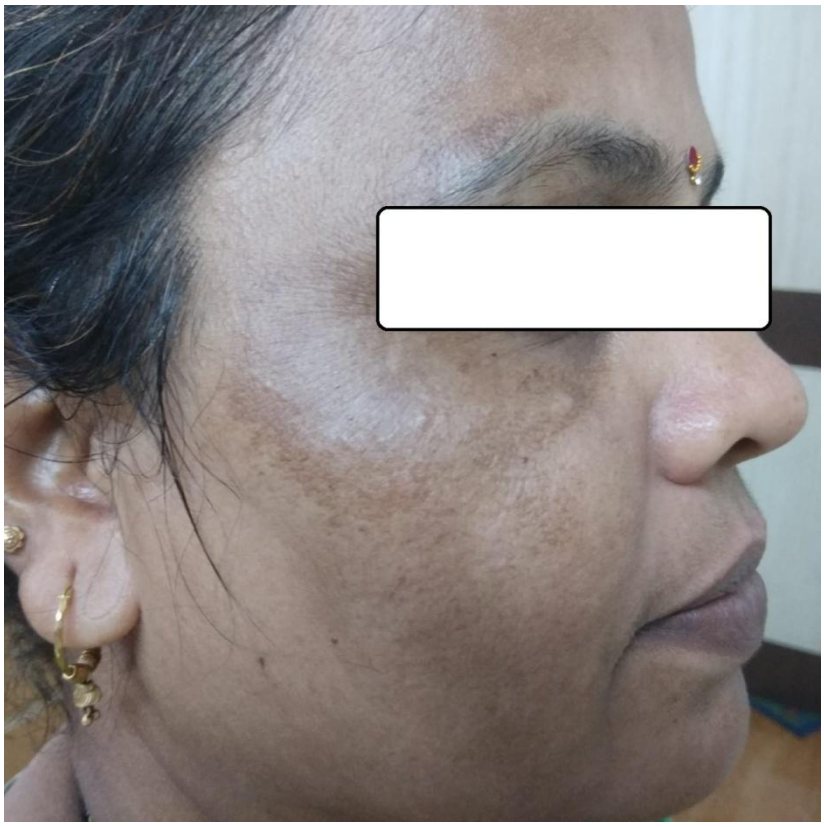
Pt. 9. Rt. Cheek. Visit 1



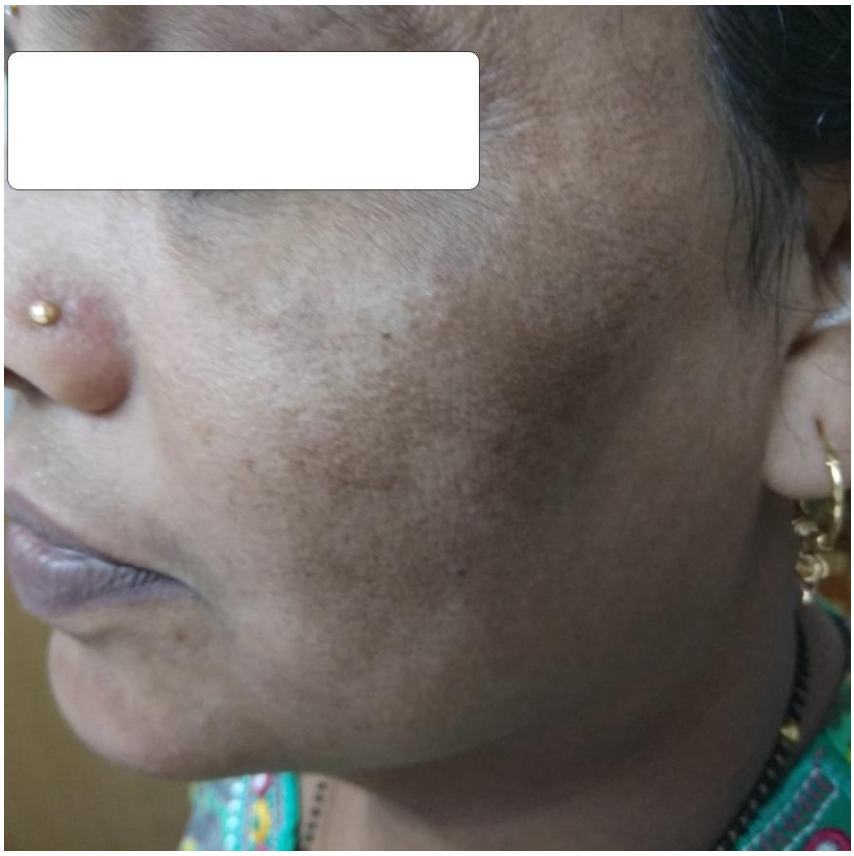
Pt. 9. Rt. Cheek. Visit 6



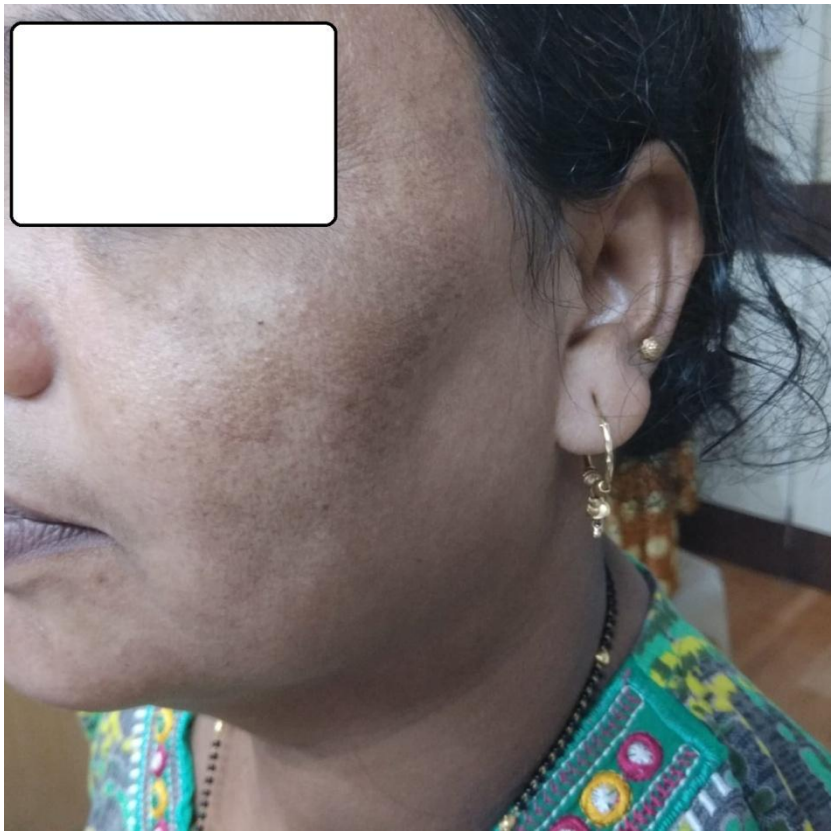
Pt. 10. Rt.Cheek. Visit 1



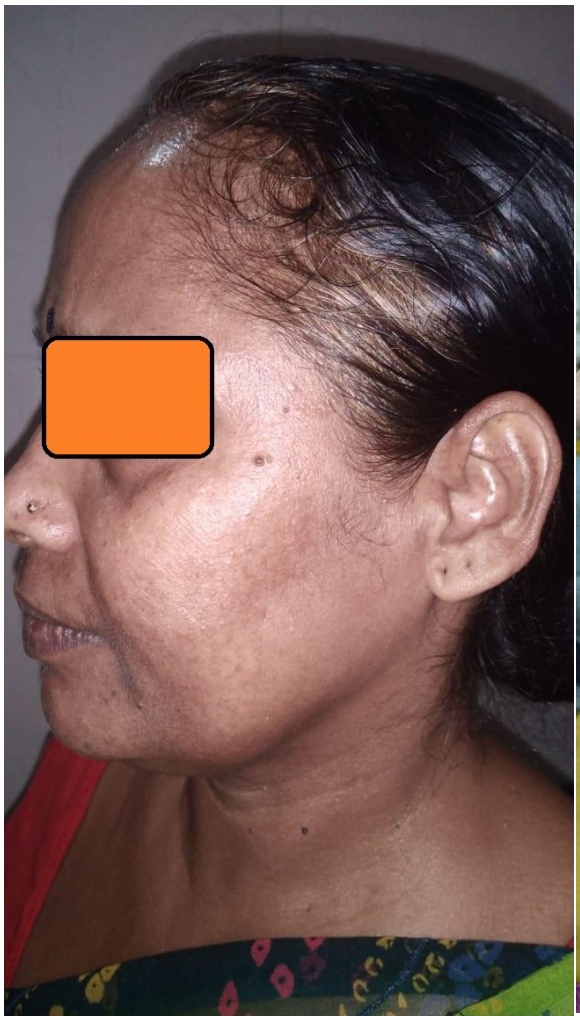
Pt. 10. Rt.Cheek. Visit 6



Pt. 10. Lt. Cheek. Visit 1

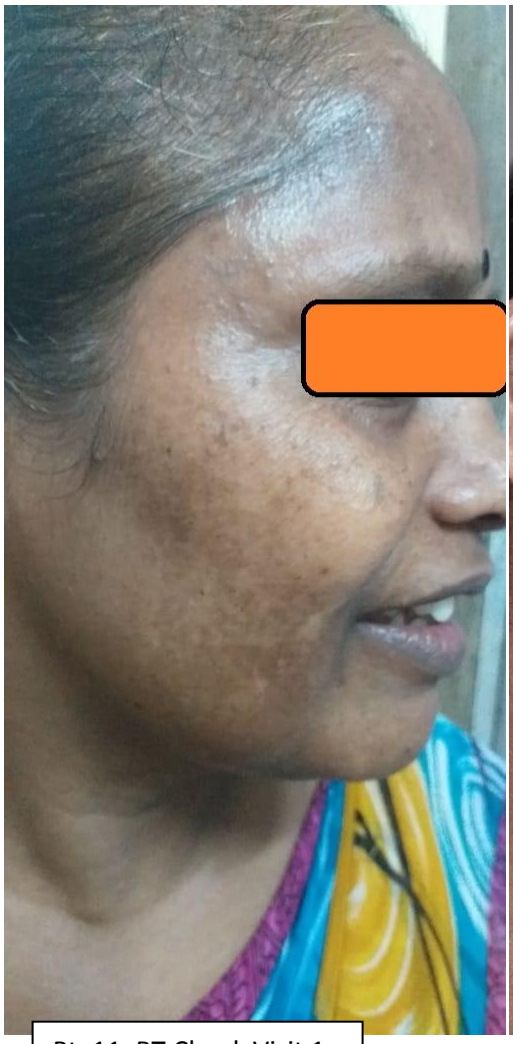


Pt. 10. Lt. Cheek. Visit 6

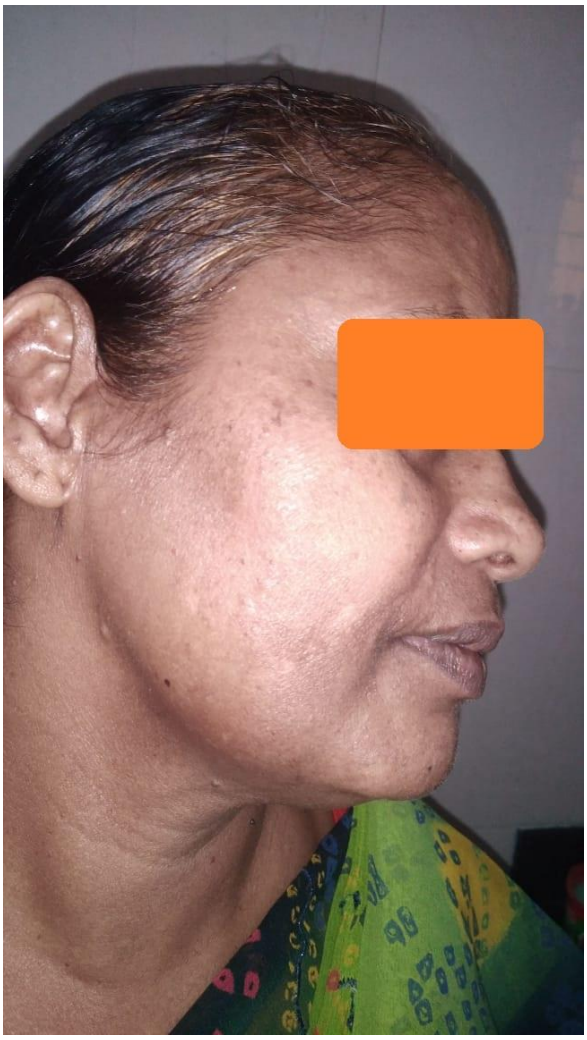


Pt. 11. Lt. cheek. Visit 6

Pt. 11. Lt. cheek. Visit 1



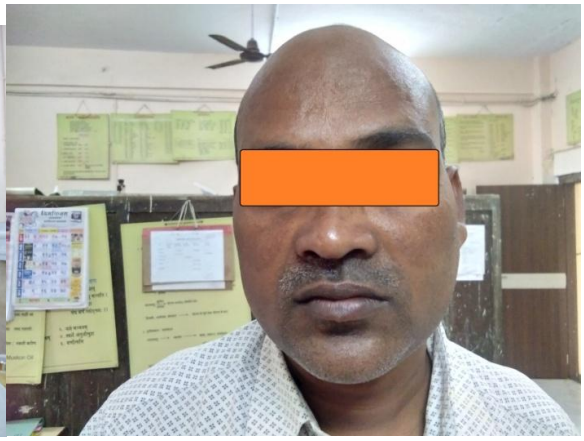
Pt. 11. RT Cheek Visit 1



Pt. 11. RT Cheek Visit 6

LAKSHADI MALHAR PATIENT'S PICTURES

Pt. 1. Front View. Visit 1

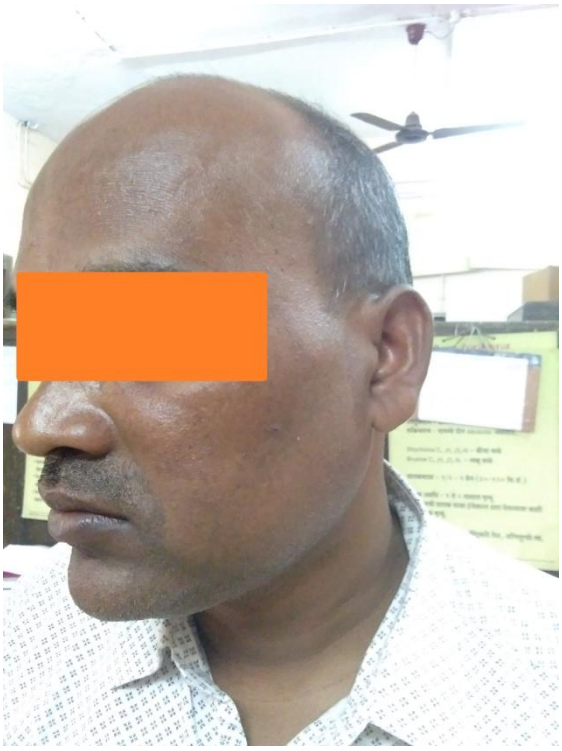


Pt. 1. Front View. Visit 6

Pt. 1. Right Cheek. Visit 1

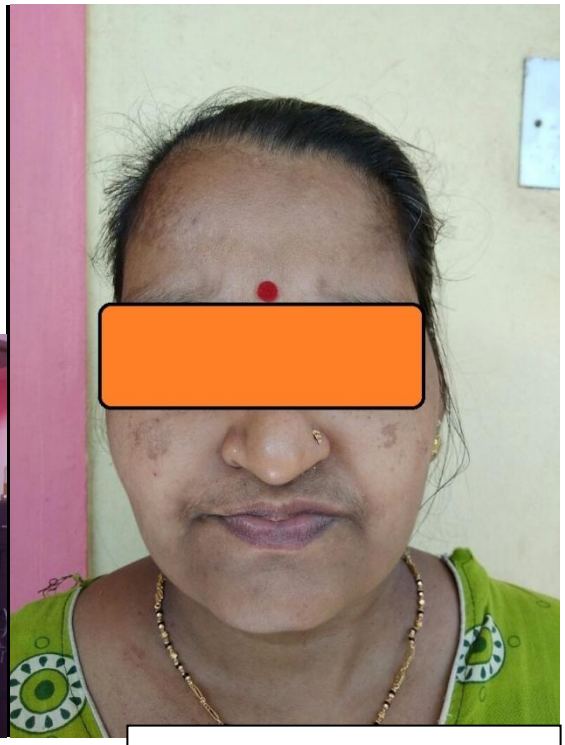
Pt. 1. Right cheek. Visit 6

Pt. 1. Left Cheek. Visit 1

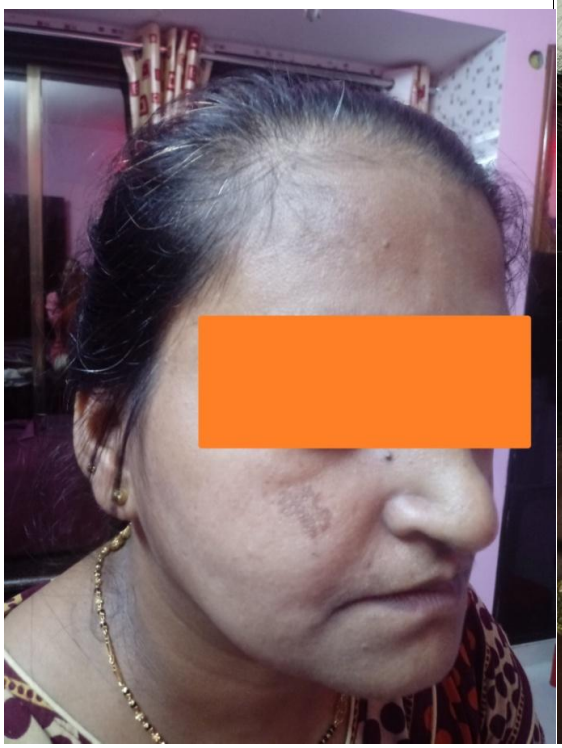


Pt. 1. Left cheek. Visit 6

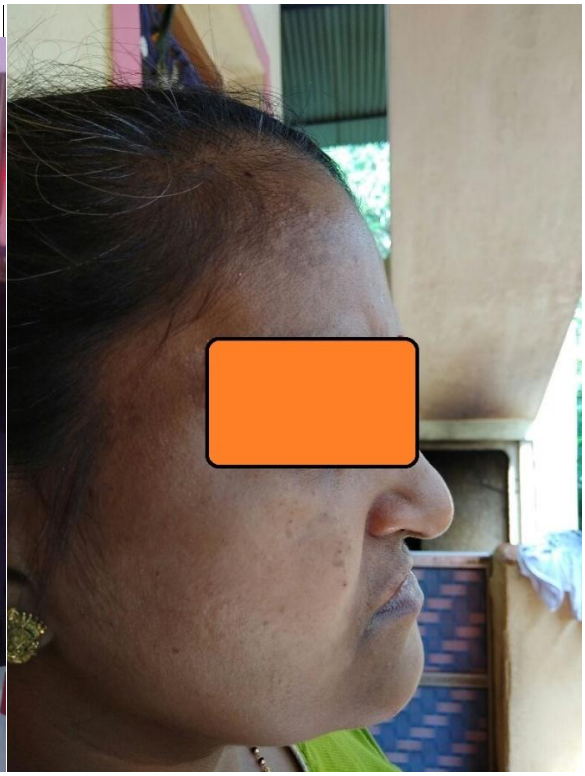
Pt. 2. Front view. Visit 1



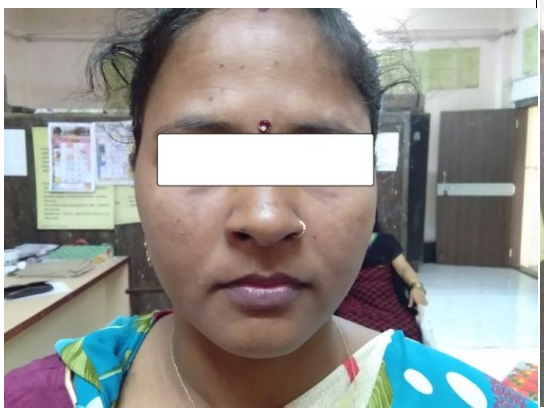
Pt. 2. Front view. Visit 6



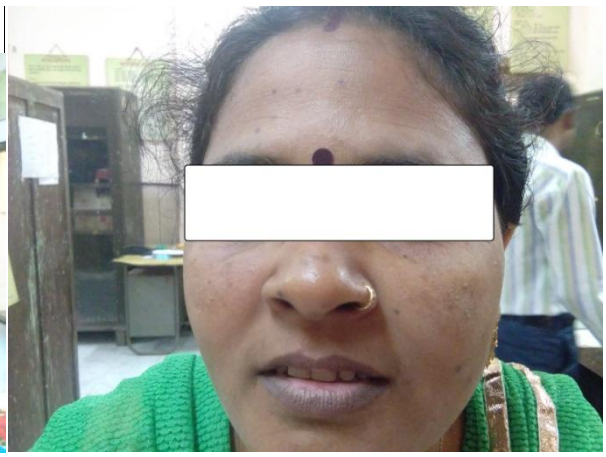
Pt. 2. Right cheek. Visit 1



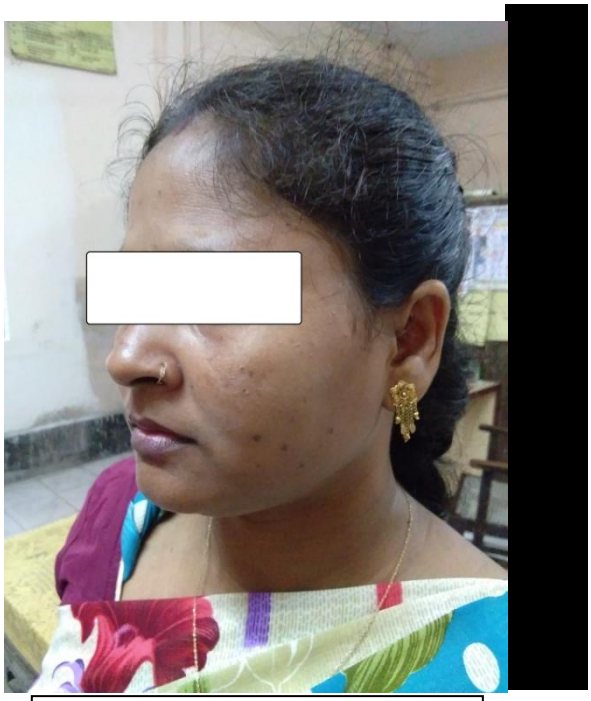
Pt. 2. Right cheek. Visit 6



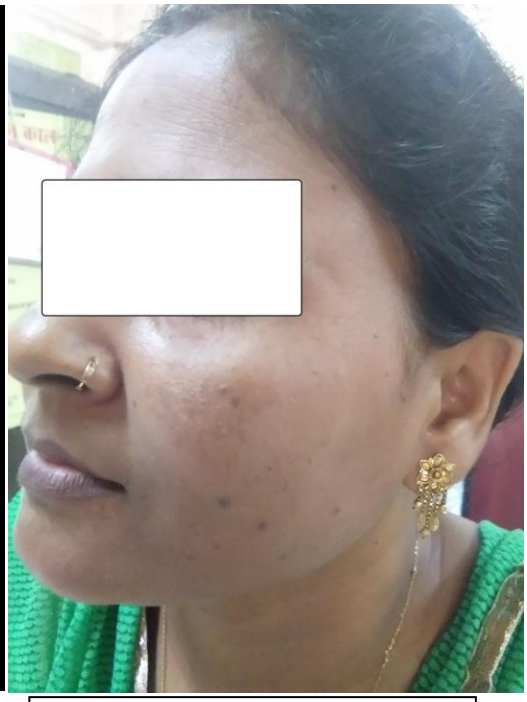
Pt. 3. Front View Visit 1



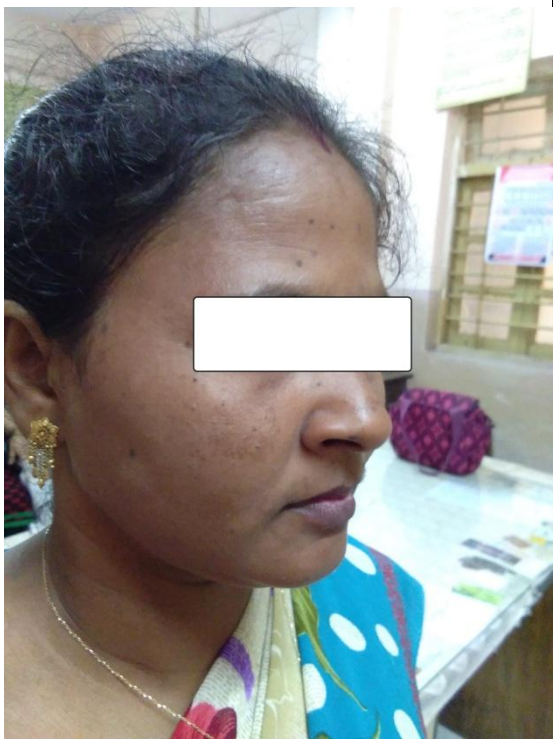
Pt. 3. Front view Visit 6



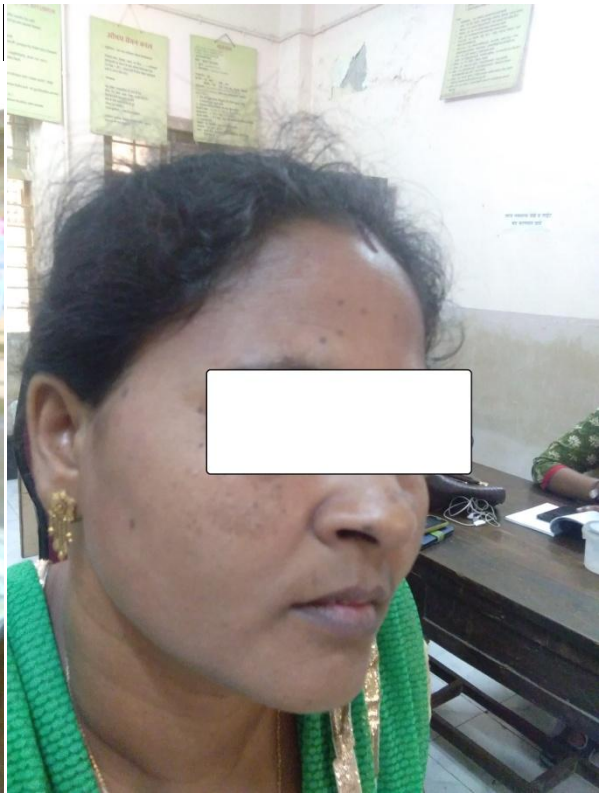
Pt. 3. Left cheek Visit 1



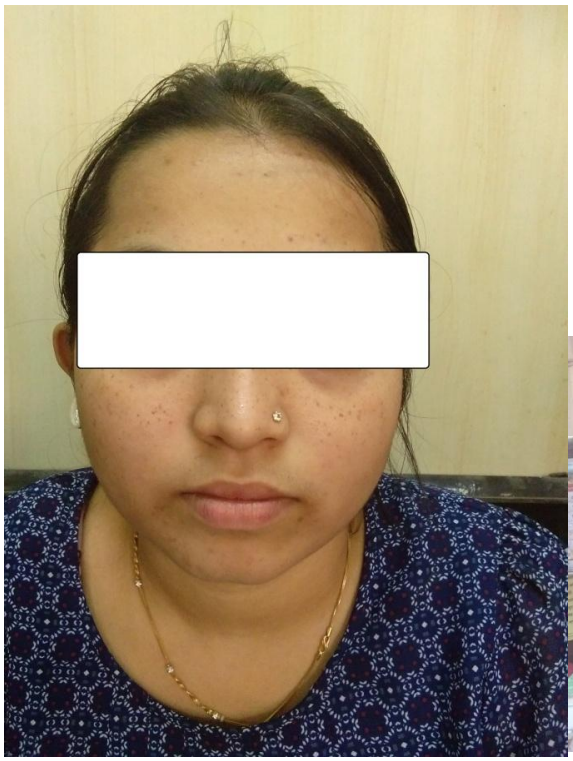
Pt. 3. Left cheek. Visit 6

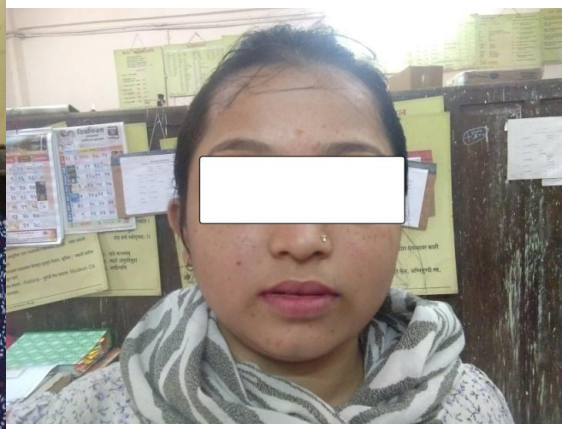


Pt. 3. Right cheek Visit 1



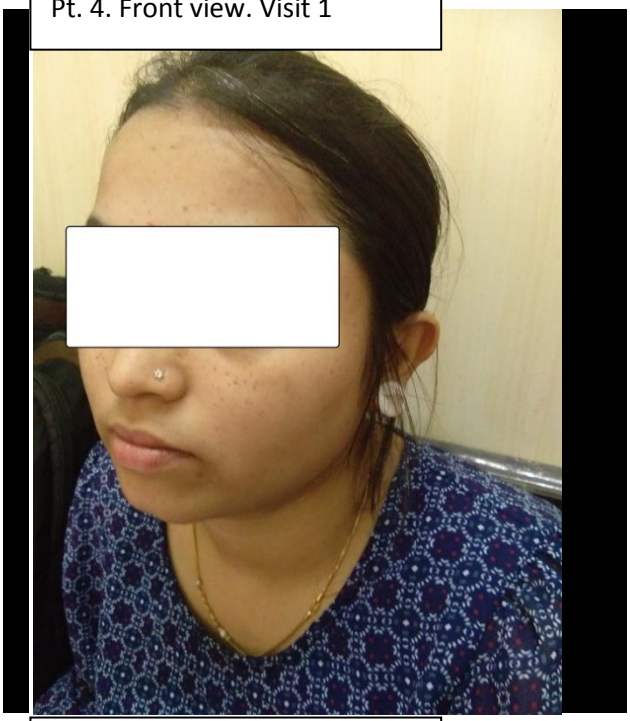
Pt. 3. Right cheek Visit 6

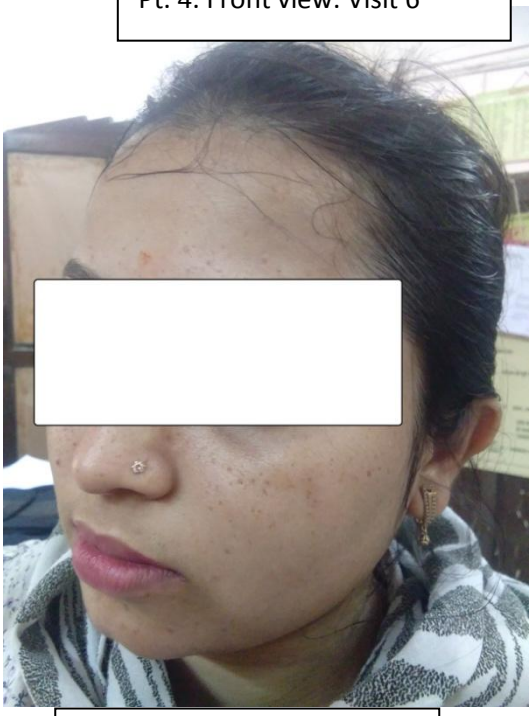




Pt. 4. Front view. Visit 1

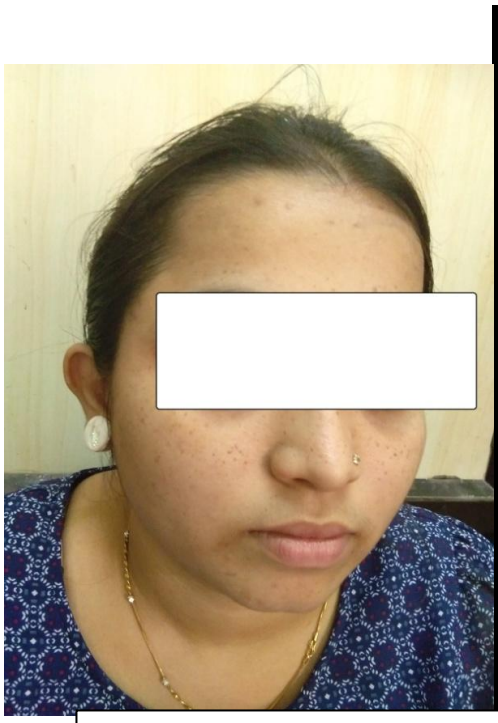
Pt. 4. Front view. Visit 6



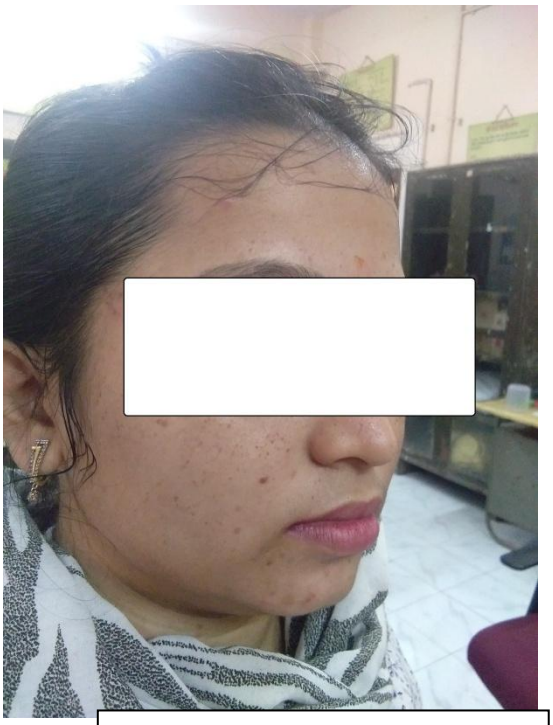


Pt. 4. Left cheek Visit 1

Pt. 4. Left cheek Visit 6

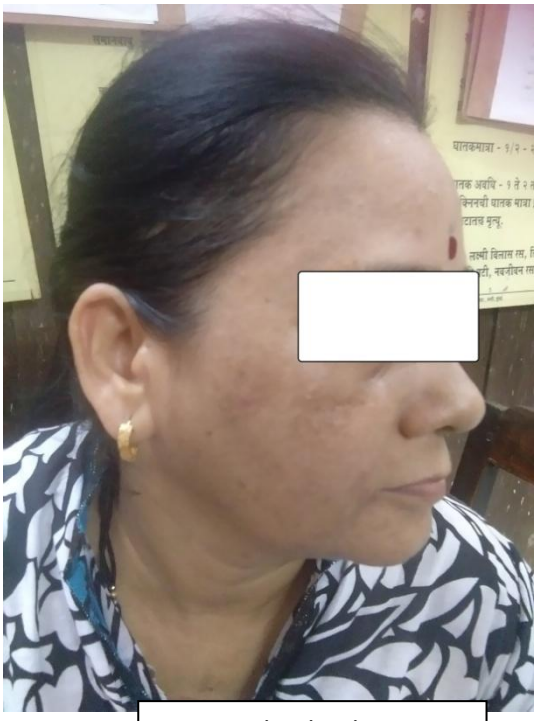


Pt. 4. Right cheek Visit 1

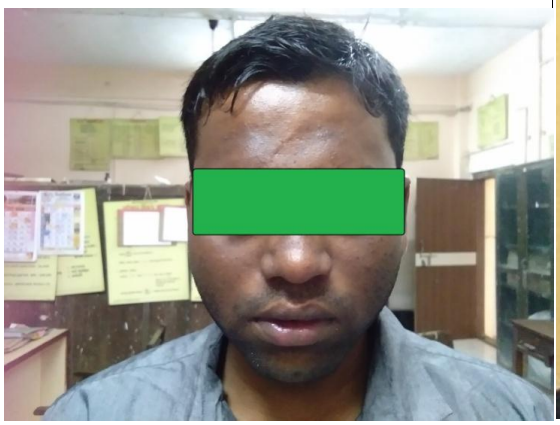


Pt. 4. Right cheek Visit 6

Pt. 5. Right cheek Visit 1



Pt. 5. Right cheek Visit 6



Pt. 6. Front view. Visit 1

Pt. 6. Front view. Visit 6

Pt. 6. Left cheek. Visit 1

Pt. 6. Left cheek. Visit 6

Pt. 6 Right cheek. Visit

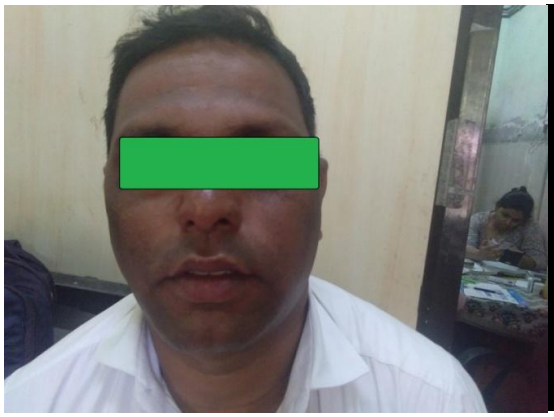
Pt. 6. Right chek. Visit 6

Pt. 7. Right cheek. Visit 1

Pt. 7. Right cheek. Visit 6

Pt. 7 Left cheek Visit 1

Pt. 7 Left cheek Visit 6



Pt. 8 Front view Visit 1

Pt. 8 Front view Visit 6

Pt. 8. Left cheek Visit 1

Pt. 8. Left cheek Visit 6

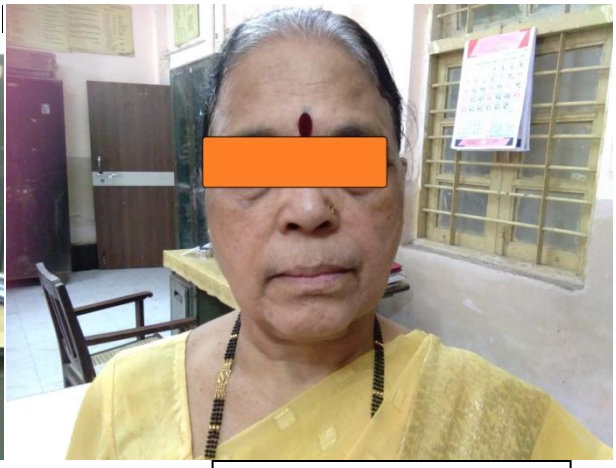
Pt. 9. Left cheek Visit 1

Pt. 9. Left cheek Visit 6

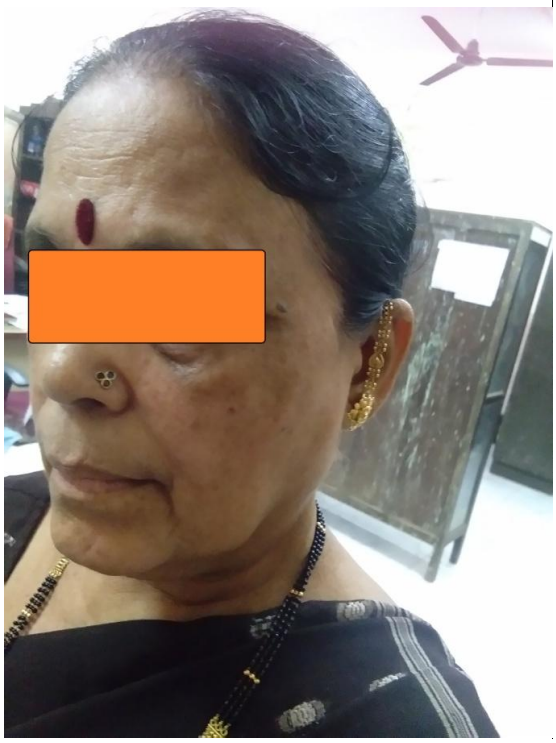
Pt. 9 Right cheek Visit 1

Pt. 9 Right cheek Visit 6

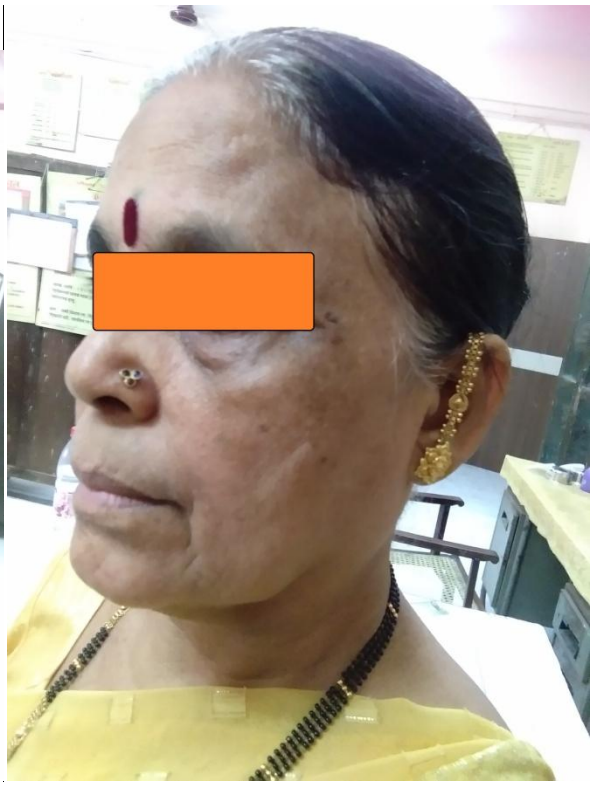
Pt. 10 Front View. Visit 1



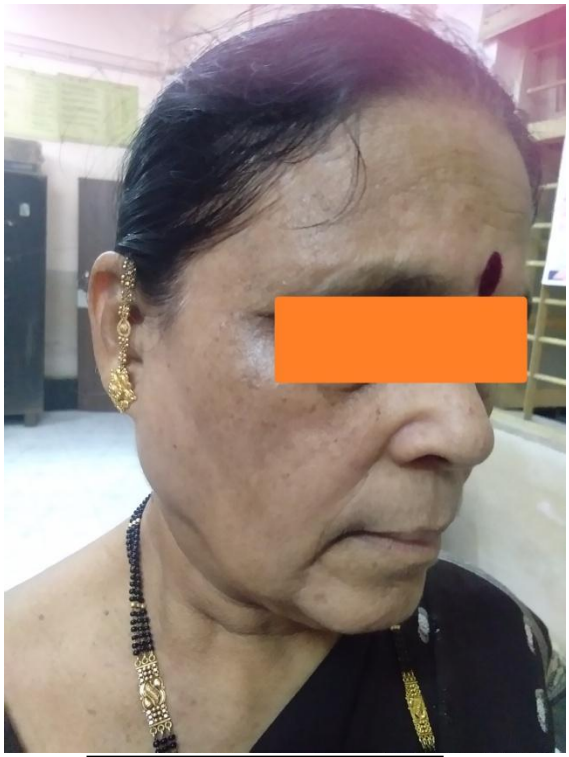
Pt. 10 Front View. Visit 6



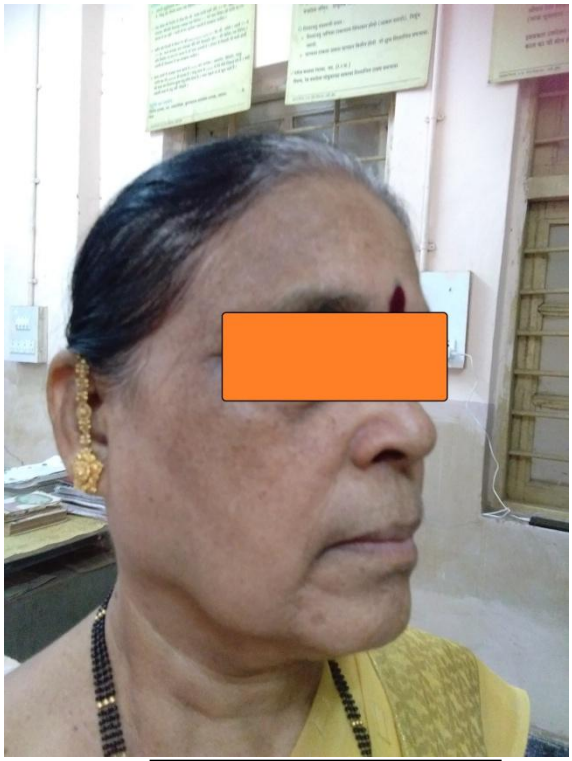
Pt. 10. Left cheek Visit 1



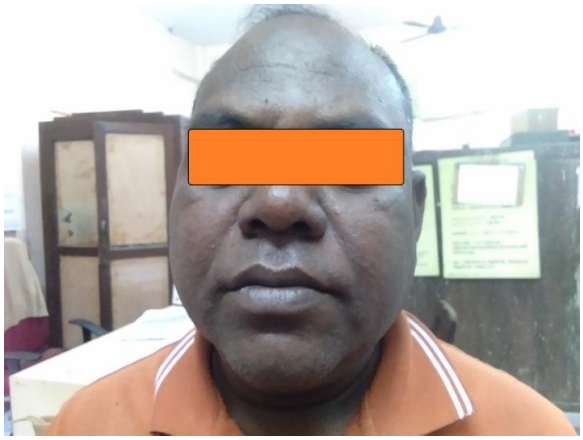
Pt. 10. Left cheek Visit 6



Pt. 10 Right cheek Visit 1



Pt. 10 Right cheek Visit 6



Pt. 11 Front view Visit 1

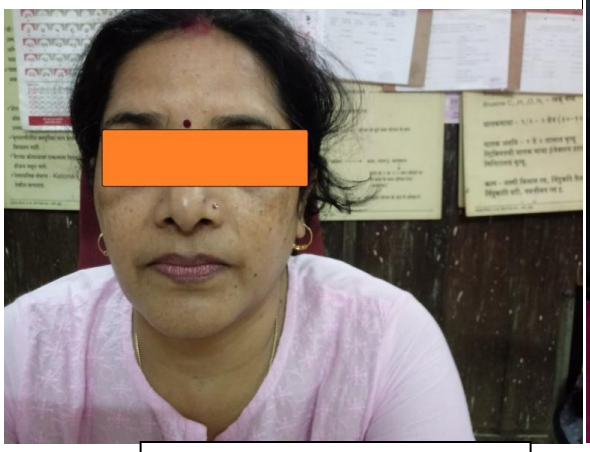
Pt. 11 Front view Visit 6

Pt. 11 Right cheek Visit 1

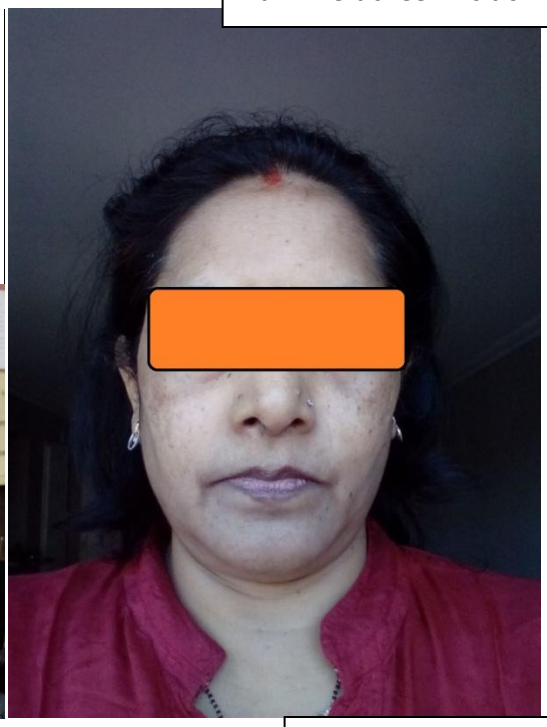
Pt. 11 Right cheek Visit 6

Pt. 11 Left cheek Visit 1

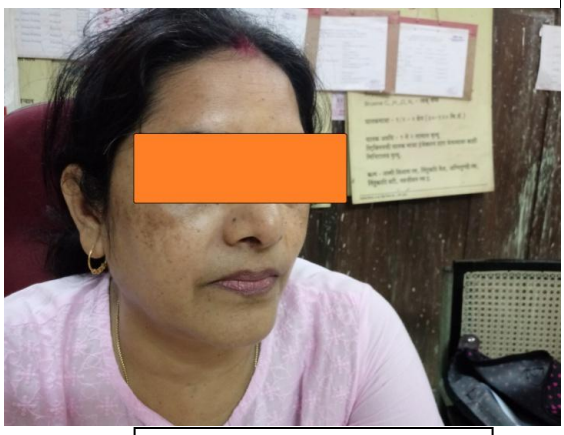
Pt. 11 Left cheek Visit 6



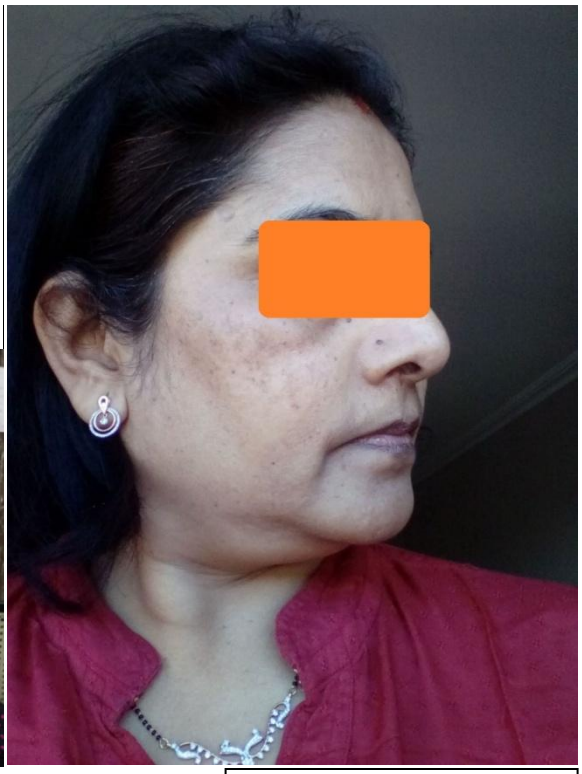
Pt. 12 Front view Visit 1



Pt. 12 Front view Visit 6



Pt. 12 Right cheek Visit 1



Pt. 12 Right cheek Visit 6

CONCLUSION AND SUMMARY

SUMMARY

The study, "A randomized, controlled clinical trial to evaluate the efficacy of *Lakshadi Malhar in Vyanga"* aimed to find a remedy in the form of local application to cure *Vyanga* (Melasma)

Although there had been previous trials with various *Lepas* in *Vyanga*, this study especially aimed at preparing a formulation which would be easy to apply, less greasy, could be readily applied anyplace and easy to carry wherever one went.

The raw material Mango seed, *Jamun* seed, *Dadim* peels, *Yashtimadhu* root, *Bala* root and *Laksha* to study their efficacy in *Vyanga* were selected from Chikitsa Prabhakar and other texts. It was also ensured that no previous work was done on the above ingredients. In this text these materials were indicated to be used as *Lepa*. But for ease of use and to enhance longer duration of effect we decided to make a cream of these ingredients.

This cream was named as *Lakshadi Malhar*. As many other ingredients such as emulsifiers, stabilizers, preservatives are also needed to prepare a cream. It was decided to have a separate Control *Malhar* group which will comprise of the ingredients except the 6 raw materials used in *Lakshadi Malhar*.

The drugs were analyzed for their authenticity and purity before the preparation of the cream. And the final product, both *Lakshadi* and the Control *Malhar* were analyzed too.

Ensuring proper blinding and randomization total 200 patients (100 in each group) were recruited in the clinical trial to study the efficacy of *Lakshadi Malhar* in *Vyanga* and also to compare its results with the efficacy of Control cream in *Vyanga* patients.

The trial was of 7 visits ie. 135 days. Visit 1 ie. Day 0 was Screening visit, after working out the criteria, the patient were either recruited in the trial or excluded. Each follow up was after 21days. On each visit the patient's symptoms were assessed as per the assessment scales and medicine were given (allotted to them as per randomization). On

Visit 6 the medicine was stopped. The last Visit ie. Visit 7 was after 30 days, it was to see whether relapse occurred in patients after stopping of treatment.

The statistics showed significant results in both the groups. The impact of the medicine could only be noticed after Visit 2 in both the groups.

On Intra Group assessment of the creams in both the Groups it was seen that the drug performed better at every visit as compared to Visit 1. Significant results were however seen from Visit 3.

On Inter assessment between the groups there was seen a significant change in their performance. Where the *Lakshadi Malhar* Group performed better than the Control *Malhar* Group.

On studying the data of the patient various factors were discovered. Fair skinned patients, *Pitta*, and *Pitta Kapha Prakruti* people were more prone to have *Vyanga*. 41 to 50 yrs is the age group most affected. Disturbed sleep, Excessive intake of *Amla ras*, *Lavan rasa* and *Katu rasa*, Tea addiction, Anger, Depression could be the causes of *Vyanga* as these factors were noticed in these patients.

Overall the study proved that the drug selected was efficacious in *Vyanga* patients, ie. the *Shyavata*(darkened skin colour), area of the patches and its distribution reduced but not completely eradicated except in few patients. But it was also noticed that with few changes in the Diet, Habits and *Nidanparivarjan* (Eradication of Etiology) the treatment can prove to be more beneficial than without the above mentioned changes.

Thus in *Vyanga*, or for that matter any disease it is very necessary to find the probable cause of that disease and along with medication try to work towards eradicating the cause and miraculous results will occur.

Also according to Ayurveda, *Vyanga* occurs due to *Vaat* and *Pitta dosha* and so although external application is the necessary mode of treatment to treat *Vyanga*, to give Oral medication to correct this *dushta Vaat* and *Pitta* is also needed.

CONCLUSION

The Aim of our study was to study the efficacy of *Lakshadi Malhar* on *Vyanga* and from the statistics of the clinical data we found that our drug *Lakshadi Malhar* did prove to be efficacious in *Vyanga.*

Our study also had many objectives; first one was to correlate *Vyanga* with Melasma. We found that there were many similarities between the above diseases regarding their presentation, colour and distribution and thus we had considered them as the same. Therefore for sample calculation, percentage of occurrence of melasma was taken into consideration. Ayurved has considered *Vaat* and *Pitta dushti* as the chief cause of *Vyanga* but the modern science has many underlying causes and yet have no definite etiology for this disease.

Lakshadi Cream was prepared and standardized as per the API standards. As 3 samples are required to standardise any new drug here too 3 batches of drug group were analysed.

The drug was assessed to evaluate the efficacy of drug on signs and symptoms of *Vyanga* using 6 assessment scales used globally for assessment of Melasma. The drug was found efficient on all the 6 scales.

We also wanted to see the effects of the drug on the Quality of Life of the patient and it was observed that with the improvement in the signs and symtoms of *Vyanga* the Quality of Life improved too. For assessment of this, The Dermatology Life Quality Index (DLQI) was used and the score calculated on Visit 1 and Visit 6 were compared.

We even wanted to study the *Prakruti* of the patients suffering from *Vyanga*. To assess the *Prakruti* TNMC *Prakruti* 2004 Questionnaire was used an *Prakruti*. The *Prakruti* was assesses on Visit 1. The data collected from the questionnaire showed that nearly 34% had *Pitta Kapha Prakruti* and 17% each were of *Pitta* and *Kapha Pitta Prakruti*. Which means nearly 68% of the total 200 patients recruited in the trial were of *Pitta* predominant *Prakruti*.

Since *Vyanga* had *Vaat* and *Pitta dushti* as its predominant cause and also since we found so many *Pitta Prakruti* predominant patients in the study we advised the patients to avoid *Pitta kar aahar vihaar*. They patients were to avoid excessive spicy, salty and oily food. The patients with anger issue were advised to conduct *Pranayam* daily. All the patients were advised to conduct some sort of physical exercise daily.

Thus the aim of our study to find the efficacy of *Lakshadi Malhar* was successfully fulfilled. We also found that if the medicine is collaborated with diet changes or restrictions and daily exercise it could give better results. One needs to study this scientifically and with proper planning to see the definite results.

From the Statistic Results we have rejected Null Hypothesis and accepted Alternate Hypothesis. Although both *Lakshadi Malhar* and Control *Malhar* have shown significant results in treating *Vyanga* however *Lakshadi Malhar* showed better results than the Control Group.

REFERENCES

CHAPTER 1. INTRODUCTION

1. https://rgcell.com/skin care improves your self confidence/Dated: Oct 2018
2. Shree Madhavkar, Madhavnidan, 27th ed. 1997. Varanasi. Chaukhambha Sanskrit Bhawan. Pg.210.
3. https://synapse.koremed.org/Dolx.php?.id=10.5021/ad.2010.22.4.373 & vmode=FULL.
4. Dogra S.Sarangal R. Pigmentary disorders: An insight Pigment International 2014, 1:5 to 7.
5. Pasricha JS Binod K.Khaitan, Sushrute Pash.Pigmentary disorders in India Dermatologic clinic. Vol 25: 3: 343 to 352.
6. Sclessinger Joel. Melasma facts. www.medicinenet.com
7. Gertrude Emilia Costin, Stanca Ariana Birlea. What is the mechanism for melasma that so commonly accompanies human pregnancy. IUBMB Life,58(1):55-57,Jan 2006
8. www. Dermascope.com/treatments/new advances in treating hyperpigmentation#vbGdRv66bMI
9. "Clinical Evaluation of Varnya Gana lepa in Vyanga". AYU 2015, April¹June, Ver.36(2), 151¹156.
10. "Management of Vyanga with Arjun twak lepa and Panchanimba choorna". AYU 2014, Jan¹Mar, Ver 35(1), 50¹53.
11. "A randomized comparative clinical study to evaluate the effect of topical formulations in Vyanga"Rajiv Gandhi University of Health Sciences, Bengaluru. 2012..
12. "Clinical evaluation of efficacy of Vatankuradi lepa in the management of Vanga w.s.r to Melasma". WJPMR 2019, Ver.5(7), 310¹314.
13. "Comparative study of Ingudi Phalamajja lepa and Anantamool Ghana in the management of Vyanga." IJAM. Vol.11(2). 2020. April¹June.
14. "An Ambroxia for complexion care : Varnya lepa." IJAR. Vol. 9(12). December 2019.

15. " Management of Vyanga with herbal formulation¹A clinical study". IJRAP. Vol. 7(5). September ¹October 2016.
16. " A comparative Pharmaco¹Clinical study of Arjuna and Manjishta w.s.r to Vyanga". JAIMS Vol. 4(4). July¹August 2019.
17. "To evaluate the combined effect of Arjun and Manjishta lepa on Vyanga w.s.r to Melasma." WJPR. Vol.6(5). April 2017. 1000¹1010.
18. " To evaluate the efficacy of Mukhakantikar cream and Microderma abrasion with Aluminium oxide crystal externally in patients of Vyanga". IJISET. Vol. 6(6). June 2019.
19. "Effect of Varun twak lepa in management of Vyanga". IJAM Vol.11(2). April¹June 2020.
20. An open labeled single armed, prospective, phase I, Clinical study to evaluate efficacy of Mukhakanti lepa in Vyanga". Ayurline. Vol.1(1) Jan¹Mar 2017.

CHAPTER 2. LITERATURE REVIEW

1. Shree Madhavkar, Madhavnidan, 27th ed. 1997. Varanasi. Chaurhambha Sanskrit Sansthan. Pg.193 to 194.
2. Shree Madhavkar, Madhavnidan, 27th ed. 1997. Varanasi. Chaurhambha Sanskrit Sansthan. Pg.210.
3. Prabhakar Ogala, Chikitsa Prabhakar, Revised edn. 1986. Pune. Continental Book Service. Pg. 700.
4. Agnivesha, Charak Samhita, Reprint 1998. Varanasi. Chaukhamba Bharati Academy. Pg. 379
5. Maharshi Sushrut(Prof. K.R.Srikantha Muthy), Sushrut Samhita Vol. 1, Reprint edn. 2010. Varanasi. Chaukhambha Orientalia. Nidan sthan. Pg. 552
6. Dr. Ganesh Garde, Sartha Vagbhat, edn. 8th. 1996. Pune. Raghuvanshi Prakashan. Uttarsthan. pg. 448
7. Vrudha Vagbhat, Ashtanga Sangraha with Sashilekha commentory, ed. 1. 2006. Varanasi. Chowkhamba Sanskrit Series Office. Uttarsthan. Pg. 817 to 818.
8. Maharshi Sushrut(Prof. K.R.Srikantha Muthy), Sushrut Samhita Vol. 1, Reprint edn. 2010. Varanasi. Chaukhambha Orientalia. Sharir sthan. Pg. 50 to 53

9. Agnivesha, Charak Samhita with Vidyotini commentary Vol. 1, Edition Reprint 2011. Varanasi. Chaukhamba Sanskrit Sansthan. Pg. 167
10. Maharshi Sushrut, Sushrut Samhita : Ayurved tatva Sandipika. Part. 1, Reprint edn. 2012. Varanasi. Chaukhambha Sanskrit Sansthan. Nidansthan. Pg. 372 to 373
11. Maharshi Sushrut, Sushrut Samhita : Ayurved tatva Sandipika. Part. 1, Reprint edn. 2012. Varanasi. Chaukhambha Sanskrit Sansthan.Chikitsa sthan. Pg. 118
12. Vrudha Vagbhat, Ashtanga Sangraha with Sashilekha commentory, ed. 1. 2006. Varanasi. Chowkhamba Sanskrit Series Office. Uttarsthan. Pg. 821 to 822.
13. Bhavmishra, Bhavprakash Samhita Vol. 2, edn. 1 2010. Varanasi. Chaukhambha Orientalia. Pg. 578 to 579
14. Bhishagratna Bhrahmashankar shastri, Yogratnakar. Edn.Reprint 2012, Varanasi. Chaukhamba Prakshan. Pg. 268 to 286.

14a. Maharshi Sushrut, Dr. Ambikadatta Shastri, Sushrut Sanhita, Sharir Sthan ,Part I,

2002,Varanasi,Chaukhambha Sanskrit Sansthan. Pg. 29 to 31.

14b https://www.aad.org/public/diseases/color-problems/melasma

14c Ref: https://link.springer.com/article/10.1007/s10227-004-0158-9

14d https://www.cochrane.org.skin

14e https://www.webmd.com/skin-problems-and-treatments/picture-of-the-skin#1

15. Prof. Krushnachanda Chunekar. Bhavprakash Nighantu. Edn: 2010.Varanasi. Chaukhambha Bharati Academy. Pg. 110
16. Bhavmishra, Bhavprakash Sanhita Vol.I. edn. 1 2010. Varanasi. Chaukhambha Orientalia. pg.384
17. Prof. Krushnachanda Chunekar. Bhavprakash Nighantu. Edn: 2010.Varanasi. Chaukhambha Bharati Academy. Pg. 571
18. Vd. V.M.Gogte. Ayurvedic Pharmacology & Therapeutic uses of Medicinal Plants.Edn.: Reprint 2009. New Delhi, Chaukhambha Publications. pg. 380,381.

19. Prof.Javalgekar. Dravyagunvidnyan. Edn: 5th 1999. Pune. Anmol Prakashan. Pg.469
20. Prof. Krushnachanda Chunekar. Bhavprakash Nighantu. Edn: 2010.Varanasi. Chaukhambha Bharati Academy. Pg. 540.
21. Vd. V.M.Gogte. Ayurvedic Pharmacology & Therapeutic uses of Medicinal Plants.Edn.: Reprint 2009. New Delhi, Chaukhambha Publications. pg. 542,543..
22. Prof. Krushnachanda Chunekar. Bhavprakash Nighantu. Edn: 2010.Varanasi. Chaukhambha Bharati Academy. Pg. 352 to 353.
23. Prof. Krushnachanda Chunekar. Bhavprakash Nighantu. Edn: 2010.Varanasi. Chaukhambha Bharati Academy. Pg. 62 to 63.
24. Prof. Krushnachanda Chunekar. Bhavprakash Nighantu. Edn: 2010.Varanasi. Chaukhambha Bharati Academy. Pg. 638 to 639.
25. 10 Science backed benefits of sesame oil. Written on July 18, 2019. Healthline.com
26. En.m.wikepedia.org. Emulsifying wax.
27. EDTA: https://inside¹our¹products.loreal.com
28. https://www.truthinaging.com
29. www.cir¹safety.org.
30. https://www.healthline.com
31. healthline.com. How to improve the health of your skin with lavender oil. Dec.17, 2018.
32. Dr. Manisha Joshi, Bhaishajya kalpan vidnyan, Edn.1 2014, Ayurvedokta Prakashan, Solapur. Pg. 358 to 362.
33. Anonymous, editor, Rasatantrasarasidhayogasangraha, 1st edn, Rajasthan: Krishna gopal Ayurveda Bhawan; 2010; pg.434-440
34. Pd.Kashinath shastri, Rastarangini, Edn.11th,2014,Motilal Banarasidas. Bangalore.
35. Notes provided during Ayurvedic Cosmetology Course at R.A.Podar Medical College.2017.
36. Maharshi Sushrut, Sushrut Sanhita Part I, Ayurved Tatva Sandipika,Edn. Reprint 2012. Chaukhambha Publicaions. Varansi. Pg. 364-374.

37. Vrudha Vagbhat, Ashtanga Sangraha with Sashilekha commentory, ed. 1. 2006. Varanasi. Chowkhamba Sanskrit Series Office. Uttarsthan. Pg. 813 to 818.
38. Vagbhat, Dr. Ganesh Krushna Garde. Sartha Vagbhat.Edn. 8. 1996. Raghuvanshi Prakashan. Pg. 446-448
39. Shree Madhav. Madhav Nidan. Vidyotini Hindi commentary. Chaukhambha Sanskrit Sansthan. Varanasi. Edn. 31. 2002. Pg 193-199
40. Vd. Laxmipati shastri, Yogratnakar with Vidyotini Hindi commentary. Chaukhambha Prakashan, Varanasi. Edn. Reprint 2012. Pg. 268-275.

CHAPTER 3. MATERIALS AND METHODS

1. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.113
2. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.113 & 114.
3. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.114
4. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.114 & 115.
5. Pharmacognistical & Phytochemical studies of Magnifera indica seed kernel. Suyambu Rajan et.al/ Journal of Pharmacy Research 2011. Vol. 4(11).
6. Ayurvedic Pharmacopoeia of India Part 1 Volume IV. 1st Edition. Govt. of India Ministry of Health and Family Welfare. Dept. of ISM & H, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.8.
7. Physicochemical & Nutritional Characterisation of Jamun. Food and Nutrition Journal. Vol.5(1). 2017
8. Ayurvedic Pharmacopoeia of India Part 1 Volume II. 1st Edition. Govt. of India Ministry of Health and Family Welfare. Dept. of AYUSH,

Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.58.

9. Ayurvedic Pharmacopoeia of India Part 1 Volume IV. 1st Edition. Govt. of India Ministry of Health and Family Welfare. Dept. of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.23.
10. Ayurvedic Pharmacopoeia of India Part 1 Volume I. 1st Edition. Govt. of India Ministry of Health and Family Welfare. Dept. of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.169.
11. Standardisation of Bala mula choorna. Int J Curr Pharm Res Vol.11(5). 2019. 27¹30.
12. C.K. Kokate, A.P. Purohit, S.B. Gokhale; Pharmacognosy, 50th edition, Nirali prakashan, pune, 2014; 14.151.
13. Researchgate.net.How_high_moisture_content_is_acceptable_for_the_plant_powder_used_for_Soxhlet_extraction. B.R.Rajeshwara Rao, Central Institute of Medicinal and Aromatic Plants. 23 April 2015.
14. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.117,122,123.
15. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.127,128
16. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.117.
17. http://www.uspbpep.com/usp31/v31261/usp31nf26s1_841. Specific gravity.
18. https://www.suezwaterhandbook.com/water-and-generalities/water-analysis-and-treatability/sludge-examination/total-solids-content-dry-matter-DM.
19. https://www.beautyglimpse.com/check-ph-balance-cosmetic-products/
20. https://www.paulaschoice.com/expert-advice/skincare-advice/myths/the-ultimate-guide-to-ph-and-your-skin.html
21. Protocol for testing Ayurvedic, Siddha and Unani drugs.Govt. of India, Gaziabad. pg.126

22. Protocol for testing Ayurvedic, Siddha and Unani drugs.Govt. of India, Gaziabad. pg. 127
23. Ayurvedic Pharmacopoeia of India Part 1 volume IX.Govt. of India, Ministry of AYUSH 2016. Gaziabad. pg.129,130
24. https://fssai.gov.in/upload/uploadfiles/files/Revised-method-acid-value_Oils_Fats_20_02_2018.pdf
25. https://en.wikipedia.org/wiki/Peroxide_value#:~:text=Peroxide%20values%20of%20fresh%20oils,a%20rancid%20taste%20is%20noticeable.
26. https://www.jstage.jst.go.jp/article/cpb/67/9/67_c18-00746/_html/-char/en
27. Ayurvedic Pharmacopoeia of India Part 1 Volume IX. 1st Edition. Govt. of India Ministry of AYUSH, Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad. pg.129.
28. https://litfl.com/randomisation/May 2019
29. https://www.verywellmind.com/what-is-a-double-blind-study-2795103. April 2020.

CHAPTER 4. STATISTICAL ANALYSIS, INFERENCES AND DISCUSSION

1. https://www.paulaschoice.com/expert-advice/skincare-advice/myths/the-ultimate-guide-to-ph-and-your-skin.html
2. https://en.wikipedia.org/wiki/Aflatoxin
3. https://www.medscape.com/answers/1068640-159330/what-are-the-sexual-predispositions-of-melasma
4. Clinico-epidemiological study and quality of life assessment in melasma. E IJD, Vol.60. Issue 5. 2015. Pg. 519.
5. https://en.wikipedia.org/wiki/Vegetarianism_by_country#:~:text=According%20to%20a%202018%20survey,Jammu%20%26%20Kashmir%20(31.45%25)%2C.
6. https://dermnetnz.org/topics/melasma/#:~:text=Melasma%20is%20more%20common%20in%20people%20that%20tan%20well%20or,skin%20types%205%20or%206).
7. https://www.stylecraze.com/articles/amazing-benefits-of-mango-seeds-for-skin-hair-and-health/
8. https://www.chiara.in/jamun-seeds-for-skin-4-skin-benefits-of-jamun-seeds/

9. https://www.thehealthsite.com/diseases-conditions/health-and-beauty-benefits-of-pomegranate-peel-you-never-knew-da0115-260086/
10. https://skinkraft.com/blogs/articles/licorice-root-for-your-skin
11. https://www.indigo-herbs.co.uk/natural-health-guide/benefits/bala
12. https://www.ayurtimes.com/lac-laccifer-lacca-health-benefits-uses-side-effects/
13. https://www.healthline.com/health/beauty-skin-care/sesame-oil-for-skin#nutrients
14. Chakrapanidutta, Charak Samhita, Vidyotini Tika Ist Part. Reprint 2007. Varanasi. Chaukhamba Sanskrit Sansthan. Sutrasthan 12/7 Pg. 174
15. Chakrapanidutta, Charak Samhita, Vidyotini Tika Ist Part. Reprint 2007. Varanasi. Chaukhamba Sanskrit Sansthan. Sutrasthan 12/11 Pg. 177
16. Chakrapanidutta, Charak Samhita, Vidyotini Tika Ist Part. Reprint 2007. Varanasi. Chaukhamba Sanskrit Sansthan. Sutrasthan 26/42:1 Pg. 345
17. Chakrapanidutta, Charak Samhita, Vidyotini Tika Ist Part. Reprint 2007. Varanasi. Chaukhamba Sanskrit Sansthan. Sutrasthan 12/42:6 Pg. 348
18. Agnivesh, Charak Samhita with Vidyotini Tika, Part I. Reprint 1998. Varanasi. Chaukhambha Bharati Academy. Sutrasthan 26/64,65. Pg. 513.

BIBLIOGRAPHY

Sr. No	Book Name	Author Name	Edition	Publication
1	Charak Samhita	Agnivesha	Reprint 1998.	Chaukhamba Bharati Academy. Varanasi.
2	Charak Samhita with Vidyotini commentary Vol. 1	Agnivesha	Edition Reprint 2011.	Chaukhamba Sanskrit Sansthan. Varanasi.
3	Sushrut Samhita	Maharshi Sushrut(Prof. K.R.Srikantha Muthy)	Vol. 1, Reprint edn. 2010.	Chaukhambha Orientalia. Varanasi.
4	Sushrut Samhita : Ayurved tatva Sandipika. Part. 1,	Maharshi Sushrut	Reprint edn. 2012.	Chaukhambha Sanskrit Sansthan. Varanasi.
5	Sushrut Sanhita : Sharir Sthan. Part I ,	Maharshi Sushrut, Dr. Ambikadatta Shastri	2002	Chaukhambha Sanskrit Sansthan. Varanasi,
6	Ashtanga Sangraha with Sashilekha commentary.	Vrudha Vagbhat	Ed. 1. 2006.	Chowkhamba Sanskrit Series Office. Varanasi.
7	Madhavnidan.	Shree Madhavkar	27th ed. 1997	Chaukhambha Sanskrit Bhawan. Varanasi.

8	Chikitsa Prabhakar	Prabhakar Ogala	Revised Edn. 1986.	Continental Book Service. Pune.
9	Sartha Vagbha	Dr. Ganesh Garde	Edn. 8th. 1996.	Raghuvanshi Prakashan. Pune.
10	Bhavprakash Samhita Vol. 2,	Bhavmishra	Edn. 1 2010.	Chaukhambha Orientalia. Varanasi.
11	Yogratnakar.	Bhishagratna Bhrahmashankar shastri	Edn.Reprint 2012	Chaukhamba Prakshan. Varanasi.
12	Bhavprakash Nighantu.	Prof. Krushnachanda Chunekar.	Edn: 2010.	Chaukhambha Bharati Academy. Varanasi.
13	Ayurvedic Pharmacology & Therapeutic uses of Medicinal Plants.	Vd. V.M.Gogte.	Edn.: Reprint 2009.	New Delhi, Chaukhambha Publications.
14	Dravyagunvidnyan.	Prof.Javalgekar.	Edn: 5th 1999.	Pune. Anmol Prakashan.
15	Bhaishajya Kalpana Vidnyan.	Dr. Manisha Joshi	Edn.1 2014	Ayurvedokta Prakashan, Solapur.
16	Rasatantrasarasidhayoga sangraha	Anonymous	1st edn. 2010	Rajasthan: Krishna Gopal Ayurveda Bhawan;
17	Rastarangini,	Pd.Kashinath Shastri	Edn.11th, 2014	Motilal Banarasidas. Bangalore.

18	Ayurvedic Pharmacopoeia of India Part 1 Volume I to IX.	Govt. of India Ministry of AYUSH	1st Edition.	Pharmacopoeia Commission for Indian Medicine and Homeopathy. Ghaziabad
19	Pharmacognosy	C.K. Kokate, A.P. Purohit, S.B. Gokhale	50th edition, 2014	Nirali Prakashan, Pune.
20	Protocol for testing Ayurvedic, Siddha and Unani drugs.	Govt. of India		Govt. of India Gaziabad.

Appendix I Quality of Life Score

1. How embarrassed or self conscious have you been because of your skin ?
   Very much __ A Lot__ A little__ Not at all __

2. How much your skin interfered with you going out shopping or looking after your home or garden?
   Very much __ A Lot__ A little__ Not at all __

3. How much your skin affected any social or leisure activities?
   Very much __ A Lot__ A little__ Not at all ___

4. How much your skin has been a problem at work or study place?
   Very much __ A Lot__ A little__ Not at all __

5. How much has your skin created problems with your partner?
   Very much __ A Lot__ A little__ Not at all __ Not relevant __

6. Has your skin affected your relation with your children?
   Very much __ A Lot__ A little__ Not at all __ Not relevant __

7. Has your skin caused any sexual difficulties ?
   Very much __ A Lot__ A little__ Not at all __ Not relevant __

8. How much of a problem has the treatment for your skin been for you by making your home messy or taking up time?
   Very much __ A Lot__ A little__ Not at all __ Not relevant __

9. Has your treatment for melasma ever been affected on financial grounds?
   Very much __ A Lot__ A little__ Not at all __

10. Has your skin affected your overall progress?
    Very much __ A Lot__ A little__ Not at all __ Not relevant __

Very much = 3, A Lot = 2, A little = 1, Not at all & Not relevant = 0

Score	**Interpretation**
0-1	No effect
2-5	Little/Minimal effect
6-10	Moderate effect
11-20	Very large effect
21-30	Extremely large effect

APPENDIX II. TNMC Prakriti 2004 Questionnaire

Date: *Prakriti*:

Name: Age: Sex:

Birth date: Actual birthplace: Place of intra-uterine life

Height: _____ cms. Weight: _____kg. Body Mass Index: _____

Occupation: _____

Address: _____

	Vata	*Pitta*	*Kapha*
Total points			

No.	**Character**	***Vata***	***Pitta***	***Kapha***
1.	Body frame	Lean long	Medium	Large, plump, fleshy, fatty
2.	Body Mass Index	< 19	19-25	> 25
	Speech			
3.	Speed	Fast	Fast	Slow
4.	Clarity	Diffuse words	Clear	Clear
5.	Character	Easily deviates from the topic, more talkative	Impressive speaker	Less talkative, likes to be reserved
	Eyes			
6.	Colour- Sclera	Blackish	Reddish, brown	Milky white Edges- reddish
	Lips			
7.	Character	Cracked, shapeless	Smooth, soft, thin	Smooth, glossy, Proportionate
8.	Colour	Blackish	Reddish	Pinkish
	Nails			
9.	Character	Small, Cracking, breaking, rough, easily break	Small, smooth &flat	Big, smooth, glossy
10.	Colour	Blackish	Reddish	Pinkish

	Hair			
11.	Texture	Rough & Dry	Soft & Delicate	Soft & Shiny
12.	Colour	Black	Gray/ Brown	Black
13.	Thickness	Less	Medium	More
	Skin			
14.	Character	Cracking, rough	Soft, oily, with moles, pimples,	Smooth, glossy
15.	Colour	Blackish tinge	freckles Yellowish tinge	Fair, pinkish
16.	Temperature	Cold	Warm	Cold
17.	**Body odor**	Absent	Present	Absent
	Appetite			
18.	Frequency of eating	More	More	Less
19.	Quantity at meal	Less	More	More
20.	Habit	Irregular	Profound	Not much
21.	If meal is skipped/ meal timings are changed/ style of food is changed	Constipation	Headache/vomiting	Nothing special
22.	**Thirst**	Irregular	More	Less
	Stool			
23.	Habit	Irregular	Regular	Regular
24.	Consistency	Hard	Semi-solid	Well-formed
25.	Colour	Blackish	Yellowish	Yellowish
	Sleep			
26.	Character	Interrupted, less	Uninterrupted, less	Sound, profound
27.	Duration	6 hours	6-8 hours	8 hours or more than 8 hours
28.	**Excitement**	Quickly, cools down quickly	Quickly, does not cool down quickly	Rarely
29.	**Working style**	Quickly	Medium	Slowly
30.	**Other movements**	Fast, unnecessary	Fast, precise	Slow steady

31.	**Strength**	Less, feel exhausted after doing some work	Medium, moderately gets tired	Good, do not feel tired
32.	**Style of tackling problem**	Worrying continuously without expressing	Losing self control, becoming angry/ irritated	With cool and stable mind
33.	**Control on desires**	Hardly, doesn't work hard for the same	Cannot, work hard, achieve it	Can control easily
34.	**Concentration on work**	Lack of concentration	Can concentrate on thing of interest	Can easily concentrate
	Cognition Process			
35.	Grasping	Quick, poor	Quick, good	Delayed
36.	Store	Poor	Average	Good
37.	Memory	Less	Average	Good

Melasma Area and Severity Index Score (MASI Score)

Melasma area severity index (MASI) is developed by Kimbrough-Green *et al* for the assessment of melasma. The severity of the melasma in each of the four regions (forehead30%, right malar region30%, left malar region30% and chin10%) is assessed based on three variables: percentage of the total area involved (A), darkness (D), and homogeneity(H).

A numerical value assigned for the corresponding percentage **area** (A) involved is as follows:

0 = No involvement;
1 = 10% involvement;
2 = 10-29% involvement;
3 = 30-49% involvement;
4 = 50-69% involvement;
5 = 70-89% involvement;
6 = 90-100% involvement

The **darkness** of the melasma (D) is compared to the normal skin and graded on a scale of 0 to 4 as follows:

0 = Normal skin color without evidence of hyperpigmentation;
1 = Barely visible hyperpigmentation;
2 = Mild hyperpigmentation;
3 = Moderate hyperpigmentation;
4 = Severe hyperpigmentation.

Homogeneity of the hyperpigmentation (H) is also graded on a scale of 0 to 4 as follows:

0 = Normal skin color without evidence of hyperpigmentation;
1 = Specks of involvement;
2 = Small patchy areas of involvement <1.5 cm diameter;
3 = Patches of involvement >2 cm diameter;
4 = uniform skin involvement without any clear areas

To calculate the MASI score, the sum of the severity grade for darkness (D) and homogeneity (H) is multiplied by the numerical value of the areas (A) involved and by the percentages of the four facial areas (10-30%).
Total MASI score =

Forehead 30% (D+H)A + right malar 30% (D+H)A + left malar 30% (D+H)A +chin10%(D+H)A

Fairnes Test

For Fairness test "Expert Fairness Meter" of 'Fair & Lovely advanced multivitamin' will be used.

It ranges from Scale 1-7, wherein 1 is lightest shade and 7 is darkest.

Melasma Severity Scale

Ranges from 0-3

0 = melasma lesions almost equivalent to surrounding normal skin or with minimal residual pigmentation;

1 = mild, slightly darker than surrounding normal skin;

2 = moderate, moderately darker than surrounding normal skin;

3 = severe, markedly darker than surrounding normal skin.

Melasma Status Scale

0 = Absence of melasma, colour is same as normal skin/minimum residual hyperpigmentation

1 = Mild melasma / colour slightly darker than normal skin

2 = Moderate melasma / Moderately darker than normal skin

3 = Severe melasma /Markedly darker than normal skin

Physicians Global assessment Scale (PGA)

0 = Clear, except for possible residual discoloration.

1 = Almost clear, very significant clearance (c. 90%); only minor evidence of hyperpigmentation remains.

2 = Marked improvement, significant improvement (c. 75%); some disease evidence of hyperpigmentation remains.

3 = Moderate improvement, intermediate between slight and marked improvement; (c. 50%) improvement in appearance of hyperpigmentation

4 = Slight improvement, some improvement (c. 25%); significant evidence of hyperpigmentation remains.

5 = No improvement; hyperpigmented condition unchanged.

6 = Worse; condition worse than at baseline.

Patient's Assessment Scale

1 = Marked/Very good improvement(> 75%)

2 = Moderate/Good improvement (>50-75%)

3 = Mild/Less improvement(>25 - 50%)

4 = No improvement (0-25%)

Clinical response to treatment Scale

-2 = Much worse

-1 = Worse

0 = No change

1 = Improved

2 = Much improved

APPENDIX IV. INFORMED CONSENT FORM

I, by my own will give my consent to participate in this research study. The doctor has explained to me in the language best understood by me about all the risks and benefits involved in this study**.** I am also ready for all the investigations to be carried on me during the study. At the same time I hold my right to withdraw from this study at any point of time.

_____	_____	_____
Name of Participant	Signature/ thumb impression	Date
_____	_____	_____
Name of the person administering consent	Signature of the person	Date

सम्मती पत्र

मी माझ्या स्वेच्छेने या शोध अभ्यासात सहभागी होण्याची सम्मती देत आहे. औषधोपचार करणाऱ्या वैद्ययाने मला समजेल अश्या भाषेत औषधामुळे होणारे संभावीत परिणाम व दुष्परिणाम या विषयी संपुर्ण माहिती दिली आहे. अभ्यासासाठी सर्व अवश्यक तपासण्या करून घेण्यास माझी तैयारी आहे. तसेच या अभ्यासातून कधीही मागार घेण्याचा अधिकार मी अबाधित ठेवत आहे.

रूग्ण नाव	स्वाक्षरी	दिनांक
वैद्य नाव	स्वाक्षरी	दिनांक

सम्मती पत्रक

मै स्वेच्छा से इस शोध अभ्यास मे सहभाग होने के लिए सम्मती देता / देती आहे . मेरे वैद्यने मुझे समझ आये इस भाषामे दवाई से होनेवाले सभी लाभ व नुकसान की जानकारी दी है. इस अभ्यास मे जरूरी सभी जांच के लिए मै तैयार हू . इस अभ्यास से जब चाहे बाहर निकलनेका मेरा अधिकार मै सुरक्षित रखता /रखती हू.

रूग्ण नाम	स्वाक्षरी	तारीख
वैद्य नाम	स्वाक्षरी	तारीख

APPENDIX V PATIENT'S INFORMATION SHEET

Project Title: A randomized controlled clinical study to evaluate the efficacy of *Lakshadi Malhar* in *Vyanga*.

Introduction

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a research participant.

Purpose of the study

For melasma or *vyanga*, as commonly known there are many herbs described in the classical Ayurvedic texts. As preferable mode is external application most of them are in lepa form. Few products are available in the market as well. Some combinations of drugs work some don't. The use of *lepa* is not feasible in today's times. Hence I have formulated a compound from the drugs given in various texts and prepared a cream of it. This will be easy for application to the patient and could also prove to be effective for *vyanga*.

Expected duration of the study and total number of participants

You will be one of the approximately 200 people (2 groups) who will participate in this study. You will the in the study for about 135 days. Medicine will be given for 105 days

Study procedures to be followed

If you agree to participate in this study you will

(a) Be randomly assigned to one of the 2 groups of the study. One is the drug group another is the control group by simple randomized technique (flipping of coin)

(b) be asked about previous medical problems, your current health and your medications;

(c) have a brief physical examination : pulse rate, blood pressure, respiration rate, temperature, height, weight.

(d) Need to undergo baseline investigation such as:

Skin examination will be done

Measuring the area of the patch.

Photograph taken of the patches (your identity will not be revealed)

You will have to answer the questionnaire meant to calculate the quality of life.

Once selected and allotted to a group, you have to come for follow up every 21 days for 5 visits and for 7^{th} visit after a month.

At each visit

(a) You will be asked about your health, side effects of medications,

(b) Your skin examination will be carried out,

(c) Photograph will be clicked

(d) Quality of life questionnaire will be filled on 1^{st} and 6^{th} visit.

(e) You will be given a new supply of study drug. At every visit you will get a fresh stock of medicine. You need to note down if you have missed out on any application in the last 15 days before visit.

On 6^{th} visit medication will be stopped and the last follow up is the 7^{th} visit

Total duration for drug application is 105 days.

Risks & Discomforts of participating

You will not be taking any additional treatment other than that required during your routine medical care.

There are no known risks and side effects associated with the drugs proposed for use here. Yet as each one's skin types are different, the drug might react differently to different skins. It is thus important that whenever you experience any side effects such as rash, redness, itching, oedema, burning sensation, stop the medication and contact your study physician immediately at the numbers given below,

Dr. Gayatri Gaonkar 9987544098 or 9820241058

The time spent by you can be a probable inconvenience. You will have to spare 15-20 minutes of your time at every visit.

Possible benefits of the study

The drugs selected for this trial are known drugs for melasma. By participating in this study, you may have a possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from being in this study. Your participation in this study may provide information that may in the future help other patients suffering from melasma.

What happens when the research trial stops?

Because this is a research trial, the test drug will not be available at the end of this trial (after 105 days) for treatment of melasma. Alternate therapy, if appropriate, will be provided once the trial is finished.

Treatment for study related injury

You will be provided medical care at this institute for any other illness that occurs during the trial. Also you will not give up any of your legal rights by signing this form.

Right to withdraw from the study

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute.

Confidentiality

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results of your treatment (details: contact, photographs, questionnaire.) may be published for scientific reasons. Your identity will not be revealed in these publications.

If in spite of reading the above documents you have any query you can contact Dr. Gayatri on the number given above.

रूग्ण माहिती पत्रक

शोध प्रबंध विषयः A randomized controlled clinical study to evaluate the efficacy of *Lakshadi Malhar* in *Vyanga*.

परिचय

आपण या शोध अभ्यासात भाग घेण्यासाठी निमंत्रीत आहात. या अभ्यासाबाबतची सर्व माहिती व तुमची भूमिका जाणून घेणे महत्तवाचे आहे. म्हणून तुमची या अभ्यासाबाबत सर्वता खात्री पटल्यावर तसेच तमचे सहभागी म्हणून असणारे अधिकार याची माहिती घेतल्यावरच या शोध अभ्यासात भाग घेण्याची सम्मती दयावी.

अभ्यासाचे प्रयोजन

व्यंग किंव्हा वांग़ या साठी आयुर्वेदात अनेक औषधी लेपांचा उल्लेख आहे. बाजारात देखील काही औषधी उपलब्ध आहेत परंतु काही औषधांचा उपयोग होतो तर काहींचा नाही. आधुनिक औषधांच्या प्रदीर्घ वापराचे अनेक दुष्परिणाम पहायला मिळतात. आयुर्वेदी सर्व औषधी लेप स्वरूपात वापरावयास सांगितले असून आजकालच्या धावपळीच्या जीवनात ते तितकेसे सोयीचे नाही. म्हणून मी व्यंगावरील काही औषधांची निवड करून त्यांचे किम तैयार केले आहे जेणेकरून रूग्णास ते वापरण्यास सोयीचे ठरेल व उपयुक्त ही.

अभ्यासाचे कालावधी व एकूण रूग्ण संखया ः

कालावधी ः १३५ दिवस. औषध वापरण्याचे कालावधी ः १०५ दिवस
एकूण रूग्ण संखया ः २०० (२ गट मिळून)

अभ्यासा दरम्यान तुमचे कर्तव्य ः

जर तुम्ही या अभ्यासात सहभागी होण्याची सम्मती दिली तर ...

- तुम्हाला कोणत्याही एका गटात (औषधी वा बिगर आषधी)समाविष्ट केले जाइल.
- तुमचे पुर्वीचे आजारपण सद्ययाचे स्वास्थ्य व घेत असलेले औषधी या विषयी माहीती विचारली जाइल.
- तुमची प्राथमीक तपासणी (नाडी रक्तदाब तापमान वजन उंची) केली जाइल.
- त्वचेची तपासणी केली जाइल. वांग वर्ण मप इ.

जर वरील सर्व चाचण्यातून निवड झाली तर एका गटात तुम्हाला समाविष्ट करून योग्य औषधी दिले जाइल. यानंतर तुम्हाला दर २१ दिवसाने रूग्णालयात यावे लागेल. असे ५ वेळा यावे लागेल.
प्रत्येक भेटीत.....

- तुम्हाला तुमचे स्वास्थ्य़ औषधाचे संभावीत दुष्परिणाम या बाबत विचारले जाइल.

- तुमचे त्वचेचे परिक्षण केले जाइल. औषध दिले जाइल.
- तुम्ही कधी औषध लावण्यास विसरलात तर याची नोंद ठेवणे अवश्यक आहे.
- वांगचे फोटो घेतले जातील.
- व जीवनावर होणरा परिणाम या विषयी प्रश्नमंजुषा पहिल्या व सहाव्या भेटीत भरून घतले जाइल.

सहभागी होण्याचे संभावीत दुष्परिणाम

या अभ्यासा दरम्यान तुम्हाला त्वचेसाठी इतर कुठलेही औषध वापरता येणार नाही. वरील औषधाचे अद्याप कुठलेच दुष्परिणाम आढळले नाही तरीही प्रत्येकाची त्वचा हि विशेष असल्याने ती औषधास कशी प्रतिसाद देइल हे सांगणे अवघड आहे.म्हणून तुम्हाला कधीही कुठल्याही प्रकारची प्रतिकिया जसे आरक्तता खाज सूज फोडी आढळल्यास त्वरीत औषध बंद करून आपल्या वैद्यास कळवावे.

वैद्य.गायत्री गांवकर ९९८७५४४०९८ □९८२०२४१०५८

तसेच औषधाचे होणाऱ्या मुलावर काय परिणाम होतील हे माहित नसल्याने तुम्ही महिला या अभ्यास दरम्यान गर्भवती होउ शकत नाही आणि जर तसे झालेच तर त्वरीता आपल्या वैद्यास कळवावे कारण मग तुम्हाला अभ्यासातून कमी करण्यात येइल.

दर भेटी दरम्यान १५□२० मी. डयावे लागेल.

सहभागी होण्याचे संभावीत फायदे

हया अभ्यासात निवडलेले औषधी हे व्यंगावरील उत्तम औषधी आहेत. या अभ्यासात सहभागी झाल्याने तुम्ही व्यंगापासून मुक्त होण्याची संभावना आहे परंतु याची पुर्णतः खात्री देता येणार नाही. तरीही या अभ्यासात तुमच्या सहभागाने भविष्यात अनेक रूग्णांना मदत होउ शकते.

अभ्यास थांबल्यावर..

अभ्यास थांबल्यावर जरी तुम्हाला अभ्यासातील औषधी बंद झाले तरी अवश्यकते नुसार नवीन औषध सुरू करण्यात येइल.

इतर आजारासाठी चिकित्सा

या अभ्यासा दरम्यान तुम्हाल होणाऱ्या कोणत्याही आजारपणासाठी योग्य ते उपचार दिले जाइल.

अभ्यासातून मागार घेण्याचा अधिकार

तुम्ही कधीही या अभ्यासातून मागार घेउ शकता. या करीता तुमच्यावर कोणताही दबाव होणार नाही तसेच भविश्यात या रूग्णालयाच्या सेवेत कमतरता येणार नाही.

गोपनीयता

या अभ्यासात तुमची मिळवलेली सर्व माहिती गोपनीय ठेवली जाइल.भविष्यात या अभ्यासाचे निष्कर्ष प्रकाशित झाले तरी तुमची माहिती कुठेही प्रकट होणार नाही.

वरील पत्रक वाचूनही जर तुमचे काही शंका असतील तर तुम्ही वैद्य.गायत्री यास वरील प्रमाणे संपर्क करा.

रूग्ण जानकारी पत्रक

शोध प्रबंध विषयः **A randomized controlled clinical study to evaluate the efficacy of *Lakshadi Malhar* in *Vyanga*.**

परिचय

आप इस शोध अभ्यास मे भाग लेने के लिए निमंत्रीत है. सबसे पहले इस अभ्यास और इसमे आपकी भूमिका के बारे मे जान लेना जरूरी है.ऐसा होंने के बाद और अपने अधिकार के बारे मे जानने के बादही आप सम्मती दे.

अभ्यास का उददेश्य

व्यंग या जीसे हम झाई कहते है इसकेलिए आयुर्वेद मे अनेक औषधी लेपो का उल्लेख आहे.बाजारामे भी कुछ औषधी उपलब्ध है परंतु कुछ औषधो का उपयोग होता है तो कुछ का नाही. आधुनिक औषधो का लंबे समय तक इस्तमाल से कही दुष्प्रभाव देखे जाते है. आयुर्वेद मे सब औषधी लेप स्वरूप मे बताये है जिसे आजकल की भागदौड भरी जिंदगी मे इस्तमाल करना मुश्किल हो जाता है. इसलिए मैने व्यंग पर उपयुक्त कुछ औषधी चूनकर उनकी क्रिम जिस्से वो लगाने मे आसान हो और उपयुक्त भी हो.

अभ्यास का अवधी व रूग्ण संख्या ः

अवधी ः १३५ दिन. दवाई लेने की अवधी ः १०५ दिवस
रूग्ण संख्या ः २०० (२ समुह मे)

अभ्यास के दौरान आपके कर्तव्य ः

अगर आप इस अभ्यास मे सहभागी होते है तो ...

- आपको किसी एक समूह मे (औषधी या बिगर आषधी)नियत किया जाएगा.
- आपको अतीत मे हुई बीमारी आपको स्वास्थ्य और ले रहे दवाईयो के बारे मे पुछा जाएगा.
- आपकी जांच (नाडी खुन का दाब तापमान वजन उंचाई) मापी जाएगी.
- त्वचा का परीक्षण जैसे व्यंग का वर्ण मप फोटो इ.

अगर सभी जांच मे आप खडे उतरते है तो आपको किसी एक समूहा मे नियत करके योग्य औषधी दि जाएगी. उसके बाद हर २१ दिन मे और ऐसे कुल ७ बार आपको आना पडेगा.
हर भेट के दौरान.....

- आपको आपके स्वास्थ्य और औषधी के बारे मे पुछा जाएगा.
- आपकी त्वचा का परिक्षण किया जाएगा. औषध दिया जाएगा.

- आप अगर कभी दवाइ लगाना भूल जाए तो इसका आपने उल्लेख करना जरूरी है.
- व्यंग को फोटो निकालागा जाएगा.
- और इसका जीवन पर होने वाला दुष्प्रभाव इसके लिए एक प्रश्नमंजुषा प्रथम व छटवी भेट मे पुछी जाएगी.

सहभागी होने के दुष्प्रभाव

इस अभ्यास के दौरान आप अपनी त्वचा के लिए कोई और दवाइ इस्तमाल नही कर सकते.इस दवाइ का अब तक कोई दुष्प्रभाव दिखाइ नही दिया है पर हर व्यक्ती की त्वचा अलग होने से वो किसी दवाइ के प्रति क्या असर दिखााए ये कहना मुश्किल है. इसी लिए आपको हर भेट मे होने वाले दुष्प्रभाव के बारे मे पुछा जाएगा.ऐसा होने पर तुरन्त दवाइ बंद कर अपने वैद्य से संपर्क करे.

वैद्य.गायत्री गांवकर ९९८७५४४०९८ ☐९८२०२४१०५८

इस दवाइ का होनेवाले बच्चे पर क्या असर होगा इसकी जानकारी न होने से आप इस अभ्यास के दौरान गभेवती नही हो सकते और अगर ऐसा हो तेा तुरन्त इसकी जानकारी अपने वैद्य को दे ताकी आपको इस अभ्यास से कम किया जाए.

हर भेट के दौरान १५☐२० मी.व्यतीत होंगे.

सहभागी होने के फायदे

इस अभ्यास मे प्रयुक्त दवाइ व्यंग की उत्तम औषधी है इसी लिए आप व्यंग मुक्त होने की संभावन है पर इसकी कोइ गारंटी नही. फीर भी आपके सहभाग से भविष्य मे अनेक रूग्णो को मदत मिलेगी.

अभ्यास रूकने के बाद..

अभ्यास रूकने के बाद भी आपकी जरूरत के मुताबीक आपको दुसरी दवाइ दी जाएगी.

दुसरी बीमारी की चिकित्सा

इस अभ्यास दौरान आपको होने वाली दुसरी बीमारीयो के लिए आपकौ योग्य उपचार दिया जाएगा.

अभ्यासा से पीछे हटने का अधिकार

आप कभीभी इस अभ्यास से पीछे हट सकते है. इसके लिए आपपर कोइ दबाव नही होगा औ इससे आपको इस रूग्णालय मे आगे उपचार लेने मे कोइ बाधा नही होगी.

गोपनीयता

इस अभ्यास मे लि गयी आपकी सभी जानकारी गुप्त रखी जाएगी . भविष्य मे इस अभ्यास के निकर्ष प्रकाशित भी हुए तबभी आपकी जानकारी कही प्रकट नही होगी.

ये पत्रक पठन करने के बावजूद अगर आपके मन मे कोइ संदेहा हो तो आप वैद्य.गायत्री से उपर दिए गये नंबर पे संपर्क करे.

APPENDIX VI. CASE RECORD FORM

TITLE: A randomized controlled clinical study to evaluate the efficacy of *Lakshadi Malhar* in *Vyanga* .

Name of Study Centre: R. A. Podar Medical College, Worli, Mumbai

Guide: Dr. Vilas A. Dole **Scholar: Dr. Gayatri Gaonkar**

Visit 1 /Day 0

Name of the Patient:_____

Sex : Male _____ Female _____ OPD No.:

Age : _____ yrs IPD No.:

Religion : Hindu _____ Muslim _____ Christian _____

Other _____

Education Status : _____

Occupation : _____

Economical Status : Poor ____Middle ____Higher Middle _____Higher ____

Address : _____

Pin Code : _____

Contact No : _____

Birth Date : _____ Birth Place :_____

Selection : Included _____ Excluded _____

A. Present Complaints

Colour of patches : Light Brown _____ Dark brown _____

Shape of Patches : Round _____ Irregular _____ Scatterred ____

Painful _____ Painless_____

Skin of patches : Thick _____ Thin_____

Number of Patches : Total _____

Distribution of patches:

				Area of patches (sq cms.)	
Sr. No	**Affected Part**	**No. of patches**	**Duration**	**Before treatment**	**After treatment**
1	**Forhead**				
2	**Nose**				
3	**Chin**				
4	**Rt Malar**				
5	**Lt. Malar**				

B. Other associated symptoms:

C. Special Examination of diseased skin

Touch : Warm _____ Cold _____ Normal _____
Surface : Moist _____ Dry _____ Oily _____
Colour of skin : Fair _____ Wheatish _____ Dark _____

D. Disease Description
- **a. Mode of onset : Sudden / Gradual**
- **b. History of causes**

Physical Injury				**Other Causes**	
Burns		**Trauma**		**Pregnancy**	
Sun Exposure		**Accident Abrasion**		**Parturition**	
Electrical		**Scratches of itch**		**Oral Contraceptives**	
Chemical		**Post surgery**		**By Birth**	
Direct Heat				**Psylogical**	

E. History of Medication for current disease

Ayurvedic	**Homeopathy**	**Allopathy**

F. Past History

Sr. No	**Past illness**	**Dated**	**Medication**
1			
2			

Are you suffering from any systemic diseases? Yes ____ No ____

If Yes, then which? _____ Duration _____

Are you suffering from any other skin problems? Yes _____ No ____

If Yes, then which? _____ Duration _____

Medication _____

G. Family History

Sr. No	Illness	Mother / Father	Remarks
1			
2			

H. General Examination :

Pulse : _____ Blood Pressure : _____ Height : _____

Weight : _____ Respiration Rate : _____ Temperature : _____

Tongue : Saam ____ Niraam _____

I. Prakruti : (Use TNMC questionnaire) _____

J. Other Details :

Stools : Normal _____ Loose _____ Constipated _____

Urine : Normal _____ Polyurea ____ Oligourea _____

Menses : Regular _____ Irregular _____ Menopause _____

Sleep : Sound _____ Disturbed _____

Addictions : Tea/Coffee ____ Tobacco _____ Smoking _____

Food : Veg _____ Mixed _____

Rasa in Food : Madhur ____ Amla ____ Lavana _____

Katu ____ Tikta ____Kashay ____

K. Evaluation of Ayurvedic Etiology/Nidan Panchak

1.Hetu

a. Aahar

Mityaaahar : Anashan ____ Adhyashan_____ Ajirna Adhyashan ____

Guna : Atidrava ____ Atiruksha _____ Atiushna _____

Rasa Pradhanta : Atilavana _____ Atiamla _____ Atikatu _____

b. Vihaara

Veg Dhaaran _____ Aatapsevan _____ Ativyavaay _____

c. Maanas

Krodha _____ Shoka _____

2.Poorvaroopa _____

3.Roopa

Twak varna :

Number of Mandals on Face :

Painful/Painless :

Margins or skin thin or thickened :

4.Samprapti

L. Assessment Criteria

Sr. No.	Assesment Criteria	Score
1	Fairness meter test no.*	
2	MASI Score	
3	Melasma Severity Scale	
4	Photographs	
5	Quality of Life Score	

M. Final Diagnosis : _____

Medication given: Yes _____ No ____

Next Scheduled Visit Date : _____

Visit 2 **Day 21**

Scheduled Date : **Actual Date of visit:**

Complaints if any :

Adverse events, if any :

Missed no. of applications, if any :

Assessment scores

Sr. No.	Criteria	Score
1	Fairness meter test no.	
2	MASI Score	
3	Patients assessment Scale	
4	Physicians global assessment Scale	
5	Clinical Response to treatment Scale	
6	Melasma Severity Scale	
7	Photograph	

Medication given :

Scheduled date for next visit :

Visit 3 **Day 42**

Scheduled Date : **Actual Date of visit:**

Complaints if any :

Adverse events, if any :

Missed no. of applications, if any :

Assessment scores

Sr. No.	Criteria	Score
1	Fairness meter test no.	
2	MASI Score	
3	Patients assessment Scale	
4	Physicians global assessment Scale	
5	Clinical Response to treatment Scale	
6	Melasma Severity Scale	
7	Photograph	

Medication given :

Scheduled date for next visit :

Visit 4 **Day 63**

Scheduled Date : **Actual Date of visit:**

Complaints if any :

Adverse events, if any :

Missed no. of applications, if any :

Assessment scores

Sr. No.	Criteria	Score
1	Fairness meter test no.	
2	MASI Score	
3	Patients assessment Scale	
4	Physicians global assessment Scale	
5	Clinical Response to treatment Scale	
6	Melasma Severity Scale	
7	Photograph	

Medication given :

Schedule date for next visit :

Visit 5 **Day 84**

Scheduled Date : **Actual Date of visit:**

Complaints if any :

Adverse events, if any :

Missed no. of applications, if any :

Assessment scores

Sr. No.	Criteria	Score
1	Fairness meter test no.	
2	MASI Score	
3	Patients assessment Scale	
4	Physicians global assessment Scale	
5	Clinical Response to treatment Scale	
6	Melasma Severity Scale	
7	Photograph	

Medication given :

Scheduled date for next visit :

Visit 6 **Day 105**

Scheduled Date : **Actual Date of visit:**

Complaints if any :

Adverse events, if any :

Missed no. of applications, if any :

Assessment scores

Sr. No.	Criteria	Score
1	Fairness meter test no.	
2	MASI Score	
3	Patients assessment Scale	
4	Physicians global assessment Scale	
5	Clinical Response to treatment Scale	
6	Melasma Severity Scale	
7	Photograph	
8	Quality of Life Score	

Medication stopped :

Scheduled date for next visit :

Visit 7

Day 135

Follow up visit after completion of treatment / Last Visit

Scheduled Date : **Actual Date of visit:**

Any Complaints :

Any Adverse events :

Is Relapse seen?

Assessment scores

Sr. No.	Criteria	Score
1	Fairness meter test no.	
2	MASI Score	
3	Patients assessment Scale	
4	Physicians global assessment Scale	
5	Clinical Response to treatment Scale	

Final note:

Schedule Dates : Initiation _____ Completion _____

Result : Cured _____ Moderate improvement _____

Mild improvement _____ Unchanged _____

APPENDIX VII.

PHYSICIAN'S ASSESSMENT SCALE

Trial Group								Control Group							
Sr.No.	**OPD No.**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**Sr. No.**	**OPD No.**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
1	11837	5	4	4	4	4	4	2	20829	4	4	4	4	3	3
3	16371	5	5	4	4	4	4	6	20836	5	4	4	4	4	4
4	20824	5	4	4	3	3	3	14	20895	5	5	5	4	4	4
7	20825	5	4	4	3	3	3	15	21095	5	5	5	4	4	4
9	20826	5	4	4	3	3	3	17	21096	5	5	4	4	5	5
10	20827	5	4	4	4	4	4	19	21097	5	5	4	4	4	4
11	20828	5	4	4	4	4	4	23	21098	5	5	4	4	4	4
13	20835	5	5	4	4	3	3	26	21099	5	4	4	4	4	4
21	20837	5	5	4	4	4	4	28	21100	5	5	4	4	4	4
25	20838	5	5	4	4	4	4	29	21101	5	5	5	4	4	4
27	20893	5	5	4	4	4	4	34	21102	5	5	5	4	4	4
30	20894	5	4	4	3	2	2	36	21103	5	5	4	4	4	4
32	20896	4	4	4	3	2	2	37	21104	5	5	4	4	4	4
33	20897	5	4	4	4	4	4	40	21105	5	5	4	4	4	4
39	20898	5	4	3	3	3	3	46	21106	5	4	4	4	4	4
42	20899	5	5	5	5	5	5	48	21106	5	4	4	3	3	3
44	20900	5	5	4	4	3	3	50	21107	5	5	4	5	5	5
45	20902	5	4	4	4	3	3	51	21108	5	4	4	4	4	4
49	20903	5	4	3	2	2	2	56	21109	5	4	4	4	4	4
53	20981	5	4	4	4	4	4	59	21110	5	5	4	4	4	4
55	20982	5	5	4	4	4	4	60	21111	5	5	5	4	4	4
57	20983	4	4	4	4	3	3	63	21112	5	4	4	3	3	3

61	20984	4	4	4	4	4	4	66	21113	5	4	4	3	3	3
64	20986	5	4	4	3	3	3	70	21114	5	5	5	5	4	4
67	20988	5	5	4	3	3	3	71	21250	5	5	5	5	5	5
69	20988	5	4	4	4	3	3	74	21264	5	5	4	4	4	4
72	20989	5	4	4	3	3	3	76	21266	5	5	4	4	4	4
73	20991	5	4	4	3	3	3	81	21272	5	5	4	4	4	4
79	20992	5	4	4	4	3	3	83	21276	5	5	4	4	4	4
80	20993	5	4	3	3	2	2	85	21279	5	5	4	4	4	4
84	20994	5	5	4	3	3	3	89	21312	5	5	4	4	4	4
87	20995	5	4	4	4	3	3	92	21313	5	5	4	4	4	4
91	20997	5	4	4	3	3	3	93	21314	5	4	4	4	4	4
94	20998	5	4	4	3	3	3	95	21316	5	4	4	4	4	4
97	20999	5	5	4	4	4	4	96	21317	5	5	5	4	4	4
99	21000	5	4	4	3	3	3	101	21318	5	5	4	4	4	4
100	21001	5	4	3	2	2	2	102	21319	5	5	4	4	4	4
105	21002	5	5	4	4	4	4	103	21320	5	4	4	4	4	4
107	21003	5	4	4	4	4	4	108	21321	4	4	3	4	3	3
109	21249	4	4	4	3	4	4	111	21322	5	4	4	4	4	4
115	21251	5	5	4	4	4	4	113	21323	5	4	4	4	4	4
116	21252	4	3	3	2	2	2	114	21324	5	4	4	4	4	4
119	21253	5	4	4	4	4	4	117	21325	5	5	4	4	4	4
120	21258	5	4	4	4	4	4	121	21326	5	5	4	4	4	4
122	21259	5	4	4	4	4	4	124	21327	5	4	4	4	4	4
123	21260	5	5	4	4	4	4	127	21328	5	4	4	4	4	4
125	21261	5	5	4	4	4	4	128	21329	5	5	4	4	4	4
131	21262	5	5	4	4	4	4	130	21330	5	5	5	5	5	5
134	21263	5	4	4	4	4	4	132	21334	5	4	4	4	4	4
136	21331	5	5	4	4	4	4	133	32790	5	4	4	4	4	4
137	32784	5	5	4	4	3	4	142	32791	5	5	5	5	4	4
140	32786	5	4	4	3	3	3	143	32792	5	4	4	4	4	4

141	32787	5	4	3	2	1	1	145	32793	5	5	4	4	4	4
147	32788	5	4	4	3	3	3	146	32794	5	4	4	3	3	3
149	32789	5	4	3	3	3	3	150	45783	5	5	5	5	5	5
151	32795	5	4	4	3	3	3	155	46114	5	4	4	4	4	4
152	47466	5	4	4	3	3	3	156	46115	5	4	4	4	4	4
153	47562	5	4	4	3	3	3	158	46117	5	5	4	4	4	4
159	53825	5	4	4	4	4	4	160	47563	5	4	4	4	4	4
163	67909	5	4	4	4	4	4	162	50383	5	5	4	4	4	4
166	68128	5	4	3	2	2	2	164	53779	5	5	5	5	5	5
167	68129	5	4	4	4	3	3	168	53821	5	5	4	4	4	4
169	68131	5	4	4	3	3	3	171	53822	5	4	4	4	4	4
170	68132	5	4	4	3	3	3	174	67885	5	4	4	4	4	4
173	68134	5	4	4	3	3	3	177	67886	5	4	4	4	4	4
175	68135	5	4	4	3	3	3	178	67902	5	4	4	4	4	4
176	68136	5	4	4	3	3	3	179	67905	5	5	4	4	4	4
182	68627	5	4	4	3	3	3	181	67906	5	5	5	4	4	4
187	68633	5	4	4	3	3	3	184	67907	5	4	4	3	3	3
188	68635	5	4	4	4	3	3	185	67908	5	5	4	4	4	4
190	68636	5	4	4	4	4	4	189	67910	5	4	4	4	4	4
194	68639	5	4	4	4	4	4	191	68130	5	4	4	4	4	4
197	68640	5	4	4	4	4	4	193	68138	5	5	5	5	5	5
199	68641	5	4	4	4	4	4	195	68140	5	4	4	4	4	4
201	68642	5	4	4	4	4	4	196	68632	5	5	3	0	0	0
206	68643	5	4	4	4	4	4	202	68634	5	4	4	4	4	4
208	68645	5	5	5	5	5	5	203	68637	5	5	4	4	4	4
210	68647	5	4	4	4	4	4	213	68638	5	4	4	4	4	4
212	68648	5	4	4	4	4	4	219	68644	5	4	4	4	4	4
214	68649	5	4	4	4	4	4	221	68646	5	4	4	4	4	4
216	68650	5	4	4	4	3	3	222	69442	5	4	4	3	3	3
220	69444	5	5	4	4	4	4	227	69443	5	4	4	3	3	3

223	69445	5	4	4	4	4	4	228	69446	5	4	4	4	4	4
225	69449	5	5	5	5	5	5	230	69447	5	5	4	4	4	4
229	69682	5	4	4	4	4	4	231	69448	5	4	3	3	3	3
233	69683	5	4	4	3	3	3	236	69450	5	4	4	4	4	4
234	69688	5	4	4	4	4	4	239	69451	5	4	4	4	4	4
237	69690	5	4	3	3	3	3	240	69684	5	4	4	4	4	4
241	69692	5	4	4	4	4	4	242	69685	5	4	4	4	4	4
243	70089	5	4	4	3	3	3	246	69686	5	4	4	4	4	4
247	70090	5	5	4	4	4	4	251	69687	5	4	4	4	4	4
249	70094	5	5	4	3	3	3	254	69689	5	4	4	4	4	4
250	70095	5	4	4	3	3	3	256	69691	5	4	4	4	4	4
253	70096	5	4	4	3	3	3	258	70092	5	4	4	4	4	4
257	70097	5	4	4	4	4	4	260	70093	5	4	4	4	4	4
259	70098	5	4	4	3	3	3	262	71308	5	4	4	4	4	4
261	70099	5	4	3	3	3	3	266	71310	5	4	4	4	4	4
263	71309	5	4	4	4	4	4	268	71312	5	4	4	4	4	4
265	71311	5	4	4	4	4	4	269	71316	5	4	4	4	4	4
267	70091	5	4	4	4	3	3	270	71318	5	4	4	4	4	4
	Total	**495**	**422**	**393**	**356**	**341**	**342**			**498**	**444**	**411**	**396**	**393**	**393**
	Median	**5**	**4**	**4**	**4**	**3**	**3**			**5**	**4**	**4**	**4**	**4**	**4**
	Max	**5**	**5**	**5**	**5**	**5**	**5**			**5**	**5**	**5**	**5**	**5**	**5**
	Min	**4**	**3**	**3**	**2**	**1**	**1**			**4**	**4**	**3**	**0**	**0**	**0**

CLINICAL RESPONSE TO TREATMENT SCALE

Trial Group								Control Group							
Sr.No.	OPD No.	V2	V3	V4	V5	V6	V7	Sr.No.	OPD No.	V2	V3	V4	V5	V6	V7
1	11837	0	0	1	1	1	1	2	20829	1	1	1	1	1	1
3	16371	0	0	1	1	1	1	6	20836	0	1	1	1	1	1
4	20824	0	1	1	1	1	1	14	20895	0	0	0	1	1	1
7	20825	0	1	1	1	2	2	15	21095	0	0	1	1	1	1
9	20826	0	1	1	1	1	1	17	21096	0	0	0	1	1	1
10	20827	0	1	1	1	1	1	19	21097	0	0	1	1	1	0
11	20828	0	0	0	1	1	1	23	21098	0	0	1	1	1	1
13	20835	0	0	1	1	1	1	26	21099	0	0	1	1	1	1
21	20837	0	0	1	1	1	1	28	21100	0	0	1	1	1	1
25	20838	0	0	0	1	1	1	29	21101	0	0	0	0	1	1
27	20893	0	0	1	1	1	1	34	21102	0	0	0	1	1	1
30	20894	0	1	1	1	2	2	36	21103	0	0	1	1	1	1
32	20896	1	1	1	1	2	2	37	21104	0	0	1	1	1	1
33	20897	0	1	1	1	1	1	40	21105	0	0	1	1	1	1
39	20898	0	1	1	1	2	2	46	21106	0	0	1	1	1	1
42	20899	0	0	0	0	0	0	48	21106	0	1	1	1	1	1
44	20900	0	0	1	1	1	1	50	21107	0	0	1	0	0	0
45	20902	0	0	1	1	1	1	51	21108	0	1	1	1	1	1
49	20903	1	1	1	1	1	1	56	21109	0	0	0	0	0	0
53	20981	0	0	1	1	1	1	59	21110	0	0	0	1	1	1
55	20982	0	0	1	1	1	1	60	21111	0	0	0	1	1	1
57	20983	0	1	1	1	1	1	63	21112	0	1	1	2	2	2
61	20984	0	1	1	1	1	1	66	21113	0	1	1	1	1	1
64	20986	0	1	1	1	1	1	70	21114	0	0	0	0	1	1
67	20988	0	0	1	1	1	1	71	21250	0	0	0	0	0	0

69	20988	0	1	1	1	1	1	74	21264	0	0	1	1	1	1
72	20989	0	1	1	1	1	1	76	21266	0	0	1	1	1	1
73	20991	0	1	1	1	1	1	81	21272	0	0	0	1	1	1
79	20992	0	1	1	1	1	1	83	21276	0	0	1	1	1	1
80	20993	0	1	1	1	2	2	85	21279	0	1	1	1	1	1
84	20994	0	0	1	1	1	1	89	21312	0	0	0	1	1	1
87	20995	0	1	1	1	2	2	92	21313	0	0	1	1	1	1
91	20997	0	1	1	1	1	1	93	21314	0	1	1	1	1	1
94	20998	0	1	1	1	1	1	95	21316	0	1	1	1	1	1
97	20999	0	0	1	1	1	1	96	21317	0	0	0	1	1	1
99	21000	0	1	1	1	1	1	101	21318	0	0	1	1	1	1
100	21001	0	1	1	1	2	2	102	21319	0	0	0	1	1	1
105	21002	0	1	1	1	1	1	103	21320	0	1	1	1	1	1
107	21003	0	1	1	1	1	1	108	21321	1	1	1	1	1	1
109	21249	1	1	1	1	1	1	111	21322	1	1	1	1	1	1
115	21251	0	0	1	1	1	1	113	21323	0	1	1	1	1	1
116	21252	1	1	1	2	2	2	114	21324	0	1	1	1	1	1
119	21253	0	0	0	1	1	1	117	21325	0	0	1	1	1	1
120	21258	0	1	1	1	1	1	121	21326	0	0	1	1	1	1
122	21259	0	0	1	1	1	1	124	21327	0	1	1	1	1	1
123	21260	0	0	1	1	1	1	127	21328	0	1	1	1	1	1
125	21261	0	0	1	1	1	1	128	21329	0	0	1	1	1	1
131	21262	0	0	1	1	1	1	130	21330	0	0	0	0	0	0
134	21263	0	1	1	1	1	1	132	21334	0	1	1	1	1	1
136	21331	0	0	1	1	1	1	133	32790	0	1	1	1	1	1
137	32784	0	0	1	1	1	1	142	32791	0	0	0	1	1	1
140	32786	0	1	1	2	2	2	143	32792	0	1	1	1	1	1
141	32787	0	1	1	2	2	2	145	32793	0	0	1	1	1	1
147	32788	0	1	1	2	2	2	146	32794	0	1	1	2	2	2
149	32789	0	1	1	1	1	1	150	45783	0	0	0	0	0	0

151	32795	0	1	1	2	2	2	155	46114	0	1	1	1	1	1
152	47466	0	1	1	2	2	2	156	46115	0	1	1	1	1	1
153	47562	0	1	1	2	2	2	158	46117	0	0	1	1	1	1
159	53825	0	1	1	1	1	1	160	47563	0	1	1	1	1	1
163	67909	0	1	1	1	1	1	162	50383	0	0	1	1	1	1
166	68128	0	1	1	1	2	2	164	53779	0	0	0	0	0	0
167	68129	0	1	1	2	2	2	168	53821	0	0	1	1	1	1
169	68131	0	1	1	1	2	2	171	53822	0	1	1	1	1	1
170	68132	0	1	1	1	2	2	174	67885	0	1	1	1	1	1
173	68134	0	1	1	1	1	1	177	67886	0	1	1	1	1	1
175	68135	0	1	1	2	2	2	178	67902	0	1	1	1	1	1
176	68136	0	1	1	2	2	2	179	67905	0	1	1	1	1	1
182	68627	0	1	1	2	2	2	181	67906	0	0	0	1	1	1
187	68633	0	1	1	2	2	2	184	67907	0	1	1	2	2	2
188	68635	0	1	1	1	2	2	185	67908	0	0	1	1	1	1
190	68636	0	1	1	1	1	1	189	67910	0	1	1	1	1	1
194	68639	0	1	1	1	2	2	191	68130	0	1	1	1	1	1
197	68640	0	1	1	1	1	1	193	68138	0	0	0	0	0	0
199	68641	0	1	1	1	1	1	195	68140	0	1	1	1	1	1
201	68642	0	1	1	1	1	1	196	68632	0	0	1	2	2	2
206	68643	0	1	1	1	2	2	202	68634	0	1	1	1	1	1
208	68645	0	0	0	0	0	0	203	68637	0	0	1	1	1	1
210	68647	0	1	1	1	1	1	213	68638	0	1	1	1	1	1
212	68648	0	1	1	1	1	1	219	68644	0	1	1	1	1	1
214	68649	0	1	1	1	1	1	221	68646	0	1	1	1	1	1
216	68650	0	1	1	1	1	1	222	69442	0	1	1	2	2	2
220	69444	0	0	1	1	1	1	227	69443	0	1	1	2	2	2
223	69445	0	1	1	1	1	1	228	69446	0	1	1	1	1	1
225	69449	0	0	0	0	0	0	230	69447	0	0	1	1	1	1
229	69682	0	1	1	1	1	1	231	69448	0	1	1	2	2	2

233	69683	0	1	1	2	2	2	236	69450	0	1	1	1	1	1
234	69688	0	1	1	1	1	1	239	69451	0	1	1	1	1	1
237	69690	0	1	2	2	2	2	240	69684	0	1	1	1	1	1
241	69692	0	1	1	1	1	1	242	69685	0	1	1	1	1	1
243	70089	0	1	1	1	1	1	246	69686	0	1	1	1	1	1
247	70090	0	0	1	1	1	1	251	69687	0	1	1	1	1	1
249	70094	0	0	1	1	2	2	254	69689	0	1	1	1	1	1
250	70095	0	0	1	1	2	2	256	69691	0	1	1	1	1	1
253	70096	0	1	1	1	1	1	258	70092	0	1	1	1	1	1
257	70097	0	1	1	1	1	1	260	70093	0	1	1	1	1	1
259	70098	0	1	1	2	2	2	262	71308	0	1	1	1	1	1
261	70099	0	1	2	2	2	2	266	71310	0	1	1	1	1	1
263	71309	0	1	1	1	1	1	268	71312	0	1	1	1	1	1
265	71311	0	1	1	1	1	1	269	71316	0	1	1	1	1	1
267	70091	0	1	1	1	2	2	270	71318	0	1	1	1	1	1
	Total	**4**	**71**	**96**	**113**	**129**	**129**			**3**	**55**	**81**	**98**	**100**	**99**
	Median	**0**	**1**	**1**	**1**	**1**	**1**			**0**	**1**	**1**	**1**	**1**	**1**
	Max	**1**	**1**	**2**	**2**	**2**	**2**			**1**	**1**	**1**	**2**	**2**	**2**
	Min	**0**	**0**	**0**	**0**	**0**	**0**			**0**	**0**	**0**	**0**	**0**	**0**

MASI SCORE

Trial Group									Control Group								
Sr.No.	OPD No.	V1	V2	V3	V4	V5	V6	V7	Sr.No.	OPD No.	V1	V2	V3	V4	V5	V6	V7
1	11837	1.5	1.5	0.8	0.8	0.8	0.8	0.8	2	20829	4.5	4.5	3.6	3.6	3.6	2.4	2.4
3	16371	13.8	13.8	10.8	9.9	9	8.1	8.1	6	20836	10.8	10.8	7.2	7.2	6	6	6
4	20824	6.3	6.3	5.4	5.4	4.5	3.6	3.6	14	20895	3.3	3.3	3.3	3.3	3	3	3
7	20825	12.6	12.6	10.8	9.9	7.8	7.8	7.8	15	21095	6.9	6.9	6.9	6.9	4.8	4.8	4.8
9	20826	9	9	7.5	7.5	7.5	7.5	7.5	17	21096	4.5	4.5	4.5	4.5	6	6	6
10	20827	4.8	4.8	4.2	4.2	3.6	3.6	3.6	19	21097	3.6	3.6	3.6	3	3	3	3
11	20828	6.3	6.3	5.4	5.4	4.5	3	3	23	21098	14.7	14.7	13.8	10.8	10.8	10.8	10.8
13	20835	4.2	4.2	3.9	3.3	2.1	2.1	2.1	26	21099	16.5	16.5	14.4	14.4	10.8	9	9
21	20837	2.7	2.7	2.7	1.8	1.8	1.2	1.2	28	21100	9	9	9	4.8	4.8	4.8	4.8
25	20838	9.9	9.9	9.9	9	9	7.5	7.5	29	21101	6	6	6	6	6	4.8	4.8
27	20893	10.8	10.8	10.8	9	9	7.2	7.2	34	21102	3.6	3.6	3.6	3.6	1.8	1.8	1.8
30	20894	4.8	4.8	2.4	2.4	1.2	1.2	1.2	36	21103	1.2	1.2	1.2	1.2	0.6	0.6	0.6
32	20896	12.6	10.8	10.8	9	5.4	5.4	5.4	37	21104	10.8	10.8	10.8	7.8	7.8	7.8	7.8
33	20897	7.5	7.5	6.3	6.3	6.3	4.8	4.8	40	21105	4.2	4.2	3.6	3.3	3.3	3.3	3.3
39	20898	16.8	16.8	13.5	12.6	9.9	9.9	9.9	46	21106	18	15	13.5	13.5	13.5	13.5	13.5
42	20899	3.6	3.6	3.6	3.6	3.6	3.6	3.6	48	21106	4.8	4.8	4.8	4.8	2.7	2.7	2.7
44	20900	14.4	14.4	12	12	9.3	7.2	7.2	50	21107	14.4	14.4	14.4	9.9	9.9	9.9	9.9
45	20902	12.6	12.6	9.9	7.8	7.8	6.9	6.9	51	21108	14.4	14.4	14.4	14.4	10.8	10.8	10.8
49	20903	14.4	14.4	10.8	6	4.8	4.8	4.8	56	21109	5.4	10.5	9	9	9	9	9
53	20981	4.8	4.8	3.6	3.6	2.4	2.4	2.4	59	21110	1.8	1.8	1.2	1.2	1.2	1.2	1.2
55	20982	9.9	9.9	7.5	6	6	4.8	4.8	60	21111	6.3	6.3	8.1	8.1	7.2	6.3	6.3
57	20983	10.5	10.5	9	9	6.9	4.2	4.2	63	21112	13.8	13.8	10.8	10.8	7.8	7.8	7.8
61	20984	3.6	3.6	3.6	3	1.5	0.9	0.9	66	21113	9.9	9.9	9	6	6	4.8	4.8
64	20986	2.7	2.7	7.8	7.8	4.8	2.4	2.4	70	21114	8.4	6	6	9	6	4.8	4.8

67	20988	2.4	2.4	2.4	1.5	1.2	1.2	1.2	71	21250	19.2	19.2	14.4	14.4	14.4	14.4	14.4
69	20988	10.9	10.9	9	9	4.8	4.8	4.8	74	21264	6	6	6	4.8	4.8	3.6	3.6
72	20989	9.9	9.9	12	10.2	6	4.5	4.5	76	21266	3	3	3	2.4	2.4	2.4	2.4
73	20991	3	3	2.4	2.4	1.8	1.8	1.8	81	21272	11.7	11.7	11.7	9	9	8.1	8.1
79	20992	25.2	25.2	21.6	15	9.3	9.3	9.3	83	21276	8.4	8.4	8.4	6	6	6	6
80	20993	9	9	4.8	4.8	4.5	4.5	4.5	85	21279	9.9	9.9	9	5.4	5.4	5.4	5.4
84	20994	5.1	7.2	7.2	4.8	4.8	2.1	2.1	89	21312	1.8	1.8	1.8	1.2	1.2	1.2	1.2
87	20995	10.8	10.8	9	9	4.8	4.8	4.8	92	21313	9	9	8.1	8.1	7.2	7.2	7.2
91	20997	9	9	7.5	6	5.4	4.8	4.8	93	21314	9.9	9.9	9	9	6	6	6
94	20998	4.8	4.8	3.6	1.8	1.8	1.8	1.8	95	21316	6	6	4.8	4.8	4.8	4.8	4.8
97	20999	2.7	2.7	2.7	2.7	2.7	2.7	2.7	96	21317	3.6	3.6	3.6	3	3	3	3
99	21000	2.1	2.1	1.5	1.5	1.8	1.2	1.2	101	21318	NA	NA	NA	NA	NA	NA	NA
100	21001	10.8	10.8	10.8	7.5	7.5	4.8	4.8	102	21319	7.2	7.2	7.2	4.8	4.8	4.2	4.2
105	21002	9	9	9	7.2	7.2	7.2	7.2	103	21320	7.2	7.2	6	6	6	6	6
107	21003	16.8	14.4	14.4	12	9	9	9	108	21321	14.7	12.6	12.6	12	12	11.4	11.4
109	21249	3.9	3	6.6	6.6	2.7	2.7	2.7	111	21322	3.6	4.8	4.8	3.6	3.6	2.4	2.4
115	21251	5.1	7.8	11.7	6.9	5.1	5.1	5.1	113	21323	4.8	4.8	3.6	3.6	3.6	3.6	3.6
116	21252	2.1	2.1	1.8	1.8	1.8	0.6	0.6	114	21324	3.6	3.6	3.3	3	3	3	3
119	21253	1.8	2.4	1.8	1.8	1.8	1.2	1.2	117	21325	9	9	9	6.6	6.6	6.6	6.6
120	21258	12.6	12.6	6.6	6	6	4.8	4.8	121	21326	4.8	4.8	4.8	3.6	3.6	3.6	3.6
122	21259	3	3	2.4	2.4	2.4	1.8	1.8	124	21327	6	6	4.8	4.8	4.8	4.8	4.8
123	21260	15	15	9	9	9	9	9	127	21328	12.6	12.6	12.3	11.4	10.8	10.8	10.8
125	21261	13.8	13.8	12.6	8.4	8.4	6.6	6.6	128	21329	6	6	6	5.4	5.4	4.8	4.8
131	21262	3	3	3	2.4	2.4	2.4	2.4	130	21330	4.8	4.8	4.8	4.8	4.8	4.8	4.8
134	21263	11.7	11.7	9.9	9.9	9.9	9.9	9.9	132	21334	14.4	14.4	10.5	10.5	10.5	10.5	10.5
136	21331	14.4.	14.4	9	9	9	9	9	133	32790	7.2	7.2	7.2	6	6	6	6
137	32784	6	6	4.2	4.2	4.2	1.8	1.8	142	32791	NA	NA	NA	NA	NA	NA	NA
140	32786	11.4	10.5	9.6	6	5.1	5.1	5.1	143	32792	10.8	10.8	9	9	7.5	7.5	7.5
141	32787	1.2	1.2	0.6	0.6	0	0	0	145	32793	7.2	7.2	7.2	6	6	6	6
147	32788	6	6	5.4	5.4	4.8	3.6	3.6	146	32794	1.2	1.2	1.2	0.6	0.6	0.6	0.6

149	32789	6	6	4.8	4.2	3.6	3.6	3.6	150	45783	4.8	4.8	4.8	4.8	4.8	4.8	4.8
151	32795	2.4	2.4	1.8	1.8	1.2	1.2	1.2	155	46114	8.4	8.4	7.2	7.2	7.2	7.2	7.2
152	47466	9	9	6	6	4.8	3.6	3.6	156	46115	2.4	2.4	1.8	1.8	1.8	1.8	1.8
153	47562	4.8	4.8	2.4	2.4	1.8	1.8	1.8	158	46117	1.8	1.8	1.5	1.5	1.2	1.2	1.2
159	53825	6	6	4.8	4.8	4.8	4.8	4.8	160	47563	7.2	7.2	6	6	6	6	6
163	67909	7.2	7.2	6	4.8	4.8	4.8	4.8	162	50383	1.2	1.2	1.2	0.6	0.6	0.6	0.6
166	68128	1.2	1.2	1.2	1.2	0	0	0	164	53779	2.4	2.4	2.4	2.4	2.4	2.4	2.4
167	68129	4.2	4.2	3.6	3.6	3	3	3	168	53821	3.6	3.6	3.6	2.4	2.4	2.4	2.4
169	68131	10.8	10.8	9	9	6.6	4.8	4.8	171	53822	6.9	6.9	6.9	6	6	6	6
170	68132	3	3	2.4	2.1	1.8	1.8	1.8	174	67885	4.8	4.8	4.8	4.8	4.8	4.8	4.8
173	68134	7.2	7.2	5.4	3.6	3.6	3.6	3.6	177	67886	2.1	2.1	1.8	1.8	1.8	1.8	1.8
175	68135	12.6	10.8	9	6	4.8	4.8	4.8	178	67902	4.5	4.5	3	2.7	2.7	2.7	2.7
176	68136	4.8	4.8	3.6	3	2.1	2.1	2.1	179	67905	2.4	2.4	2.4	2.1	2.1	2.1	2.1
182	68627	4.8	4.8	2.7	1.5	1.5	1.5	1.5	181	67906	4.8	4.8	4.8	4.8	4.8	4.8	4.8
187	68633	3	3	2.7	2.4	2.1	1.8	1.8	184	67907	9.9	9.9	8.4	7.5	5.7	5.7	5.7
188	68635	9	9	8.1	7.2	6	4.8	4.8	185	67908	2.4	2.4	2.4	2.1	2.1	2.1	2.1
190	68636	4.8	4.8	4.2	4.2	3.6	3.6	3.6	189	67910	7.2	7.2	6.3	5.4	5.4	5.4	5.4
194	68639	9	9	8.1	7.2	7.2	6	6	191	68130	9	9	7.5	7.5	6	6	6
197	68640	5.4	5.4	4.5	4.5	3.6	3.6	3.6	193	68138	4.8	4.8	4.8	4.8	4.8	4.8	4.8
199	68641	6	6	5.4	5.4	5.4	5.4	5.4	195	68140	4.8	4.8	4.2	3.6	3.6	3.6	3.6
201	68642	6	6	5.4	5.4	5.4	5.4	5.4	196	68632	1.2	1.2	1.2	0.6	0	0	0
206	68643	7.2	7.2	6	6	6	4.8	4.8	202	68634	9	9	8.1	7.2	7.2	7.2	7.2
208	68645	4.8	4.8	4.8	4.8	4.8	4.8	4.8	203	68637	4.8	4.8	4.8	3.3	3.3	3.3	3.3
210	68647	6	6	5.4	4.8	4.8	4.8	4.8	213	68638	5.4	5.4	4.8	4.8	4.8	4.8	4.8
212	68648	1.8	1.8	1.8	1.8	1.8	1.8	1.8	219	68644	9.6	9.6	7.2	7.2	7.2	7.2	7.2
214	68649	4.8	4.8	3.6	3.6	3.6	3.6	3.6	221	68646	7.2	7.2	6.3	6.3	6.3	6.3	6.3
216	68650	4.5	4.5	4.2	3.6	3.6	3.6	3.6	222	69442	7.2	7.2	6.3	5.4	5.4	5.4	5.4
220	69444	4.8	4.8	4.8	4.2	3.6	3.6	3.6	227	69443	7.5	7.5	6	6	4.8	4.8	4.8
223	69445	10.8	10.8	9.9	9	9	9	9	228	69446	4.8	4.8	4.2	3.6	3.6	3.6	3.6
225	69449	2.4	2.4	2.4	2.4	2.4	2.4	2.4	230	69447	NA	NA	NA	NA	NA	NA	NA

229	69682	6.9	6.9	6	6	4.8	4.8	4.8	231	69448	4.8	4.8	4.2	2.7	2.7	2.7	2.7
233	69683	6	6	4.8	4.8	3.6	3.6	3.6	236	69450	6	6	4.8	4.8	4.8	4.8	4.8
234	69688	4.8	4.8	3.6	3.6	3.6	3.6	3.6	239	69451	9	9	7.2	7.2	6	6	6
237	69690	7.8	7.8	5.4	4.8	4.8	4.8	4.8	240	69684	6.6	6.6	4.2	4.2	4.2	4.2	4.2
241	69692	6.6	6.6	4.8	4.8	4.8	4.8	4.8	242	69685	7.5	7.5	6.9	6.9	4.8	4.8	4.8
243	70089	12.6	12.6	10.8	10.8	9	9	9	246	69686	6.9	6.9	4.8	4.8	4.8	4.8	4.8
247	70090	7.5	7.5	7.5	6	6	6	6	251	69687	3.6	3.6	2.4	2.4	2.4	2.4	2.4
249	70094	1.2	1.2	1.2	1.2	0.6	0.6	0.6	254	69689	2.4	2.4	1.8	1.8	1.8	1.8	1.8
250	70095	6	6	4.8	4.8	3.6	3.6	3.6	256	69691	6	6	5.1	5.1	4.2	4.2	4.2
253	70096	10.5	10.5	9	7.2	7.2	6	6	258	70092	4.2	4.2	3.6	3.6	3.6	3.6	3.6
257	70097	6.9	6.9	5.7	5.7	5.1	5.1	5.1	260	70093	7.5	7.5	6.6	6.6	6	6	6
259	70098	5.4	5.4	4.5	3.6	2.4	2.4	2.4	262	71308	7.2	7.2	6.6	6	6	5.4	5.4
261	70099	4.8	4.8	4.2	2.4	2.4	2.4	2.4	266	71310	5.1	5.1	4.2	4.2	4.2	4.2	4.2
263	71309	6	6	4.8	4.8	4.2	4.2	4.2	268	71312	9	9	7.2	7.2	7.2	7.2	7.2
265	71311	3	3	2.7	2.4	2.4	2.4	2.4	269	71316	6	6	4.8	4.8	4.8	4.8	4.8
267	70091	9	9	7.5	6	6	4.8	4.8	270	71318	4.5	4.5	3.6	3.6	3.6	3.6	3.6
	Total	303.9	301.2	251.1	226	202	189	189			267.6	267.6	230.1	215.7	204	203.4	203.4
	Mean	**7.15**	**7.19**	**6.16**	**5.41**	**4.63**	**4.18**	**4.18**			**6.79**	**6.78**	**6.08**	**5.54**	**5.16**	**5.02**	**5.02**
	Sd	**4.26**	**4.19**	**3.61**	**2.98**	**2.52**	**2.38**	**2.38**			**3.86**	**3.74**	**3.34**	**3.12**	**2.83**	**2.78**	**2.78**
	Median	**6**	**6**	**5.4**	**4.8**	**4.8**	**3.9**	**3.9**			**6**	**6**	**5.1**	**4.8**	**4.8**	**4.8**	**4.8**
	Min	**1.2**	**1.2**	**0.6**	**0.6**	**0**	**0**	**0**			**1.2**	**1.2**	**1.2**	**0.6**	**0**	**0**	**0**
	Max	**25.2**	**25.2**	**21.6**	**15**	**9.9**	**9.9**	**9.9**			**19.2**	**19.2**	**14.4**	**14.4**	**14.4**	**14.4**	**14.4**

MELASMA SEVERITY SCALE

Trial Group								Control Group							
Sr.No.	OPD No.	V1	V2	V3	V4	V5	V6	Sr. No.	OPD No.	V1	V2	V3	V4	V5	V6
1	11837	2	2	2	2	1	1	2	20829	2	2	2	1	1	1
3	16371	3	3	3	2	2	2	6	20836	2	2	2	2	2	2
4	20824	1	1	1	1	1	1	14	20895	2	2	2	2	2	2
7	20825	3	3	2	2	2	2	15	21095	3	3	3	3	2	2
9	20826	2	2	2	2	2	2	17	21096	1	1	1	1	2	2
10	20827	1	1	1	1	1	1	19	21097	2	2	2	2	2	2
11	20828	2	2	2	2	1	1	23	21098	3	3	3	2	2	2
13	20835	2	2	2	1	1	1	26	21099	2	2	2	1	1	1
21	20837	1	1	1	1	1	1	28	21100	1	1	1	1	1	1
25	20838	2	2	2	2	2	2	29	21101	1	1	1	1	1	1
27	20893	3	3	2	2	2	2	34	21102	1	1	1	1	1	1
30	20894	2	2	2	2	1	1	36	21103	2	2	2	2	1	1
32	20896	2	2	1	1	1	1	37	21104	3	3	3	2	2	2
33	20897	3	3	2	2	2	2	40	21105	3	3	3	3	2	2
39	20898	3	3	3	2	2	2	46	21106	2	2	2	2	2	2
42	20899	3	3	3	3	3	3	48	21106	2	2	1	1	1	1
44	20900	2	2	2	2	2	1	50	21107	2	2	2	2	2	2
45	20902	2	2	2	2	1	1	51	21108	2	2	2	2	2	2
49	20903	3	3	3	2	2	2	56	21109	2	2	2	2	2	2
53	20981	2	2	2	2	2	2	59	21110	1	1	1	1	1	1
55	20982	3	3	3	2	2	2	60	21111	2	2	2	2	2	2
57	20983	2	2	2	2	1	1	63	21112	1	1	1	1	1	1
61	20984	2	2	2	1	1	1	66	21113	2	2	2	2	1	1
64	20986	2	2	2	2	2	1	70	21114	3	3	2	2	2	2
67	20988	2	2	2	1	1	1	71	21250	3	3	3	3	3	3

69	20988	2	2	2	2	2	2	74	21264	3	3	3	2	2	2
72	20989	3	3	2	2	2	2	76	21266	2	2	2	2	2	2
73	20991	3	3	3	3	2	2	81	21272	3	3	3	3	3	3
79	20992	3	3	3	3	2	2	83	21276	2	2	2	2	2	2
80	20993	2	2	2	2	1	1	85	21279	2	2	2	2	2	2
84	20994	2	2	2	2	1	1	89	21312	1	1	1	1	1	1
87	20995	2	2	2	2	2	1	92	21313	2	2	2	2	2	2
91	20997	2	2	2	2	1	1	93	21314	3	3	3	2	2	2
94	20998	2	2	2	1	1	1	95	21316	2	2	2	2	2	2
97	20999	2	2	2	1	1	1	96	21317	2	2	2	2	2	2
99	21000	1	1	1	1	1	1	101	21318	3	3	3	2	2	2
100	21001	2	2	2	2	2	2	102	21319	2	2	2	2	2	2
105	21002	1	1	1	1	1	1	103	21320	2	2	2	2	2	2
107	21003	3	3	3	3	3	2	108	21321	3	3	3	2	2	2
109	21249	1	1	1	1	1	1	111	21322	1	1	1	1	1	1
115	21251	2	2	2	2	2	2	113	21323	2	2	2	2	2	2
116	21252	1	1	1	1	1	0	114	21324	2	2	2	2	2	2
119	21253	1	1	1	1	1	1	117	21325	3	3	3	2	2	2
120	21258	2	2	2	2	2	2	121	21326	2	2	2	2	2	2
122	21259	2	2	2	2	1	1	124	21327	2	2	2	2	2	2
123	21260	3	3	3	3	2	2	127	21328	3	3	3	2	2	2
125	21261	3	3	3	2	2	2	128	21329	2	2	2	2	2	2
131	21262	2	2	2	2	2	2	130	21330	2	2	2	2	2	2
134	21263	3	3	3	3	2	2	132	21334	3	3	3	2	2	2
136	21331	3	3	3	3	2	2	133	32790	2	2	2	2	2	2
137	32784	2	2	2	1	1	1	142	32791	2	2	2	2	2	2
140	32786	3	3	3	2	1	1	143	32792	3	3	3	2	2	2
141	32787	1	1	1	1	0	0	145	32793	2	2	2	2	1	1
147	32788	2	2	2	2	1	1	146	32794	1	1	1	1	1	1
149	32789	2	2	2	2	1	1	150	45783	2	2	2	2	2	2

151	32795	1	1	1	1	1	1	155	46114	2	2	2	2	2	2
152	47466	3	3	2	2	1	1	156	46115	2	2	1	1	1	1
153	47562	2	2	1	1	1	1	158	46117	1	1	1	1	1	1
159	53825	3	3	2	2	2	1	160	47563	3	3	2	2	2	2
163	67909	2	2	2	2	1	1	162	50383	1	1	1	1	1	1
166	68128	1	1	1	1	0	0	164	53779	2	2	2	2	2	2
167	68129	2	2	2	2	1	1	168	53821	2	2	2	2	2	2
169	68131	3	3	3	2	2	2	171	53822	2	2	2	2	2	2
170	68132	2	2	2	2	1	1	174	67885	2	2	2	2	2	2
173	68134	2	2	2	2	1	1	177	67886	2	2	2	2	2	2
175	68135	3	3	3	2	2	2	178	67902	3	3	3	3	2	2
176	68136	2	2	2	1	1	1	179	67905	2	2	2	2	2	2
182	68627	2	2	2	1	1	1	181	67906	2	2	2	2	2	2
187	68633	3	3	3	2	2	2	184	67907	3	3	3	2	2	2
188	68635	3	3	3	2	2	2	185	67908	2	2	2	2	2	2
190	68636	2	2	2	2	2	2	189	67910	2	2	2	2	2	2
194	68639	3	3	3	2	2	2	191	68130	2	2	2	2	2	2
197	68640	2	2	2	2	2	2	193	68138	2	2	2	2	2	2
199	68641	2	2	2	2	2	2	195	68140	3	3	3	2	2	2
201	68642	3	3	2	2	2	2	196	68632	1	1	1	1	0	0
206	68643	2	2	2	2	2	1	202	68634	2	2	2	2	2	2
208	68645	2	2	2	2	2	2	203	68637	2	2	2	2	2	2
210	68647	2	2	2	1	1	1	213	68638	3	3	2	2	2	2
212	68648	2	2	2	2	2	2	219	68644	2	2	1	1	1	1
214	68649	2	2	1	1	1	1	221	68646	2	2	2	2	2	2
216	68650	3	3	2	2	2	2	222	69442	2	2	2	1	1	1
220	69444	2	2	2	1	1	1	227	69443	2	2	2	2	1	1
223	69445	3	3	3	3	3	3	228	69446	2	2	2	1	1	1
225	69449	2	2	2	2	2	2	230	69447	2	2	2	2	2	1
229	69682	2	2	2	2	1	1	231	69448	2	2	2	1	1	1

233	69683	2	2	2	2	1	1	236	69450	2	2	2	2	2	2
234	69688	2	2	1	1	1	1	239	69451	3	3	3	2	2	2
237	69690	2	2	2	1	1	1	240	69684	2	2	2	2	2	2
241	69692	2	2	1	1	1	1	242	69685	2	2	2	2	1	1
243	70089	3	3	3	3	2	2	246	69686	2	2	2	2	2	2
247	70090	3	3	3	3	2	2	251	69687	2	2	1	1	1	1
249	70094	1	1	1	1	1	1	254	69689	2	2	1	1	1	1
250	70095	2	2	2	2	1	1	256	69691	2	2	1	1	1	1
253	70096	2	2	2	1	1	1	258	70092	2	2	2	2	2	2
257	70097	3	3	2	2	2	2	260	70093	2	2	2	2	2	2
259	70098	2	2	2	1	1	1	262	71308	3	3	3	2	2	2
261	70099	2	2	2	1	1	1	266	71310	2	2	2	2	2	2
263	71309	2	2	2	2	1	1	268	71312	3	3	3	3	3	3
265	71311	3	3	2	2	2	2	269	71316	3	3	2	2	2	2
267	70091	3	3	3	2	2	2	270	71318	2	2	2	2	2	2
	Total	**220**	**220**	**205**	**179**	**149**	**142**			**212**	**212**	**202**	**183**	**175**	**174**
	Median	**2**	**2**	**2**	**2**	**1**	**1**			**2**	**2**	**2**	**2**	**2**	**2**
	Max	**3**	**3**	**3**	**3**	**3**	**3**			**3**	**3**	**3**	**3**	**3**	**3**
	Min	**1**	**1**	**1**	**1**	**0**	**0**			**1**	**1**	**1**	**1**	**0**	**0**

FAIRNESS METER TEST

Trial Group									Control Group								
Sr.No.	OPD No.	V1	V2	V3	V4	V5	V6	V7	Sr.No.	OPD No.	V1	V2	V3	V4	V5	V6	V7
1	11837	4	4	4	3	3	3	3	2	20829	5	5	4	4	4	3	3
3	16371	7	7	7	6	6	5	5	6	20836	7	7	6	6	5	5	5
4	20824	5	5	4	4	3	3	3	14	20895	5	5	5	5	4	4	4
7	20825	7	7	6	6	5	5	5	15	21095	5	5	5	5	4	4	4
9	20826	5	5	4	4	4	4	4	17	21096	4	4	4	4	5	5	5
10	20827	5	5	4	4	4	4	4	19	21097	7	7	6	6	6	5	5
11	20828	6	6	5	5	5	4	4	23	21098	6	6	6	5	5	5	5
13	20835	5	5	5	4	4	4	4	26	21099	4	4	4	4	4	3	3
21	20837	5	5	5	4	4	4	4	28	21100	6	6	6	5	5	5	5
25	20838	5	5	5	4	4	4	4	29	21101	4	4	4	4	4	4	4
27	20893	6	6	5	5	5	5	5	34	21102	4	4	4	4	3	3	3
30	20894	6	6	5	5	4	4	4	36	21103	4	4	4	3	3	3	3
32	20896	7	7	6	6	5	5	5	37	21104	6	6	6	5	5	5	5
33	20897	6	6	6	6	5	5	5	40	21105	6	6	5	5	5	5	5
39	20898	7	7	6	6	5	5	5	46	21106	5	5	4	4	4	4	4
42	20899	7	7	7	7	7	7	7	48	21106	4	4	4	4	4	4	4
44	20900	6	6	6	5	5	5	5	50	21107	5	5	5	4	5	6	6
45	20902	6	6	5	5	5	4	4	51	21108	5	5	5	5	5	5	5
49	20903	7	7	6	5	5	5	5	56	21109	5	5	5	5	5	5	5
53	20981	5	5	5	4	4	4	4	59	21110	4	4	4	4	4	4	4
55	20982	5	5	5	4	4	4	4	60	21111	6	6	5	5	5	5	5
57	20983	6	6	5	5	5	4	4	63	21112	6	5	4	4	4	4	4
61	20984	7	7	6	6	5	5	5	66	21113	5	5	4	4	4	4	4
64	20986	5	5	5	5	5	4	4	70	21114	6	6	6	6	6	5	5
67	20988	6	6	5	4	4	4	4	71	21250	6	6	6	6	6	6	6

69	20988	7	6	5	5	5	4	4	74	21264	5	5	5	5	4	4	4
72	20989	7	7	6	5	5	5	5	76	21266	7	7	6	6	5	6	6
73	20991	7	7	7	6	6	6	6	81	21272	6	6	6	5	5	5	5
79	20992	7	7	6	5	5	5	5	83	21276	7	7	6	6	5	5	5
80	20993	6	6	5	5	4	4	4	85	21279	5	5	5	4	4	4	4
84	20994	7	7	6	6	5	4	4	89	21312	6	6	6	5	5	5	5
87	20995	5	5	5	4	4	3	3	92	21313	5	5	5	4	4	4	4
91	20997	6	6	5	5	4	4	5	93	21314	7	7	6	6	6	6	6
94	20998	6	6	5	4	5	5	4	95	21316	6	6	6	5	6	5	5
97	20999	6	6	6	5	5	5	5	96	21317	6	6	6	5	5	5	5
99	21000	4	4	4	4	4	4	3	101	21318	7	7	7	6	6	6	6
100	21001	5	5	5	4	4	4	4	102	21319	5	5	5	4	4	4	4
105	21002	4	4	6	5	5	5	5	103	21320	6	6	6	6	5	5	5
107	21003	5	5	5	5	5	5	5	108	21321	7	7	7	6	6	6	6
109	21249	6	6	5	5	5	5	5	111	21322	5	5	5	4	4	4	4
115	21251	7	7	7	6	6	6	6	113	21323	6	6	5	5	5	5	5
116	21252	4	4	3	3	2	2	2	114	21324	6	6	5	5	5	5	5
119	21253	7	7	6	6	5	5	5	117	21325	6	6	6	5	5	5	5
120	21258	4	4	3	3	3	3	3	121	21326	5	5	5	5	4	4	4
122	21259	6	6	5	5	5	4	4	124	21327	6	6	5	5	5	5	5
123	21260	7	7	6	6	5	4	4	127	21328	6	6	5	5	5	5	5
125	21261	6	6	6	5	5	4	4	128	21329	6	6	6	5	5	5	5
131	21262	6	6	6	5	5	5	5	130	21330	5	5	5	5	5	5	5
134	21263	7	7	6	6	6	5	5	132	21334	6	6	5	5	5	5	5
136	21331	6	6	5	5	5	5	5	133	32790	6	6	6	5	5	5	5
137	32784	5	5	4	4	4	4	4	142	32791	5	5	5	4	4	4	4
140	32786	6	6	5	4	4	4	4	143	32792	6	6	5	5	5	5	5
141	32787	4	4	4	3	3	3	3	145	32793	5	5	5	5	4	4	4
147	32788	7	7	6	6	5	5	5	146	32794	5	5	5	4	4	4	4
149	32789	6	6	5	5	4	4	4	150	45783	6	6	6	6	6	6	6

151	32795	5	5	4	5	4	4	4	155	46114	6	6	5	5	5	5	5
152	47466	5	5	4	4	4	4	4	156	46115	6	6	5	5	5	5	5
153	47562	5	5	4	4	4	4	4	158	46117	7	7	6	6	6	6	6
159	53825	6	6	5	5	5	5	5	160	47563	6	6	5	5	5	5	5
163	67909	6	6	6	5	5	5	5	162	50383	5	5	5	4	4	4	4
166	68128	5	5	4	4	3	3	3	164	53779	6	6	6	6	6	6	6
167	68129	5	5	4	4	4	4	4	168	53821	6	6	6	5	5	5	5
169	68131	7	7	6	6	5	5	5	171	53822	6	6	5	5	5	5	5
170	68132	7	7	6	6	5	5	5	174	67885	6	6	6	5	5	5	5
173	68134	6	6	5	5	4	4	4	177	67886	6	6	5	5	5	5	5
175	68135	6	6	5	5	4	4	4	178	67902	7	7	6	6	6	6	6
176	68136	6	6	5	5	4	4	4	179	67905	6	6	5	5	5	5	5
182	68627	5	5	4	4	4	4	4	181	67906	6	6	6	5	5	5	5
187	68633	6	6	5	5	4	4	4	184	67907	6	6	5	5	5	5	5
188	68635	6	6	5	5	5	4	4	185	67908	6	6	6	5	5	5	5
190	68636	6	6	5	5	5	5	5	189	67910	5	5	5	5	5	5	5
194	68639	7	7	6	6	5	5	5	191	68130	5	5	5	5	5	5	5
197	68640	6	6	5	5	5	5	5	193	68138	6	6	6	5	5	5	5
199	68641	6	6	5	5	5	5	5	195	68140	6	6	5	5	5	5	5
201	68642	6	6	6	5	5	5	5	196	68632	5	5	5	4	4	4	4
206	68643	7	7	6	6	6	5	5	202	68634	6	6	5	5	5	5	5
208	68645	6	6	6	6	6	6	6	203	68637	6	6	6	5	5	5	5
210	68647	7	7	6	6	6	6	6	213	68638	7	7	6	6	6	6	6
212	68648	6	6	6	5	5	5	5	219	68644	6	6	5	5	5	5	5
214	68649	6	6	5	5	5	5	5	221	68646	6	6	5	5	5	5	5
216	68650	7	7	6	6	6	5	5	222	69442	6	6	5	5	4	4	4
220	69444	6	6	6	5	5	5	5	227	69443	6	6	5	5	5	5	5
223	69445	7	7	6	6	6	6	6	228	69446	6	6	5	5	5	5	5
225	69449	6	6	5	5	5	5	5	230	69447	6	6	6	5	5	5	5
229	69682	6	6	5	5	5	5	5	231	69448	6	6	5	4	4	4	4

233	69683	6	6	6	5	5	4	4	236	69450	6	6	5	5	5	5	5
234	69688	5	5	5	4	4	4	4	239	69451	6	6	5	5	5	5	5
237	69690	6	6	5	4	4	4	4	240	69684	6	6	5	5	5	5	5
241	69692	6	6	5	5	5	5	5	242	69685	6	6	5	5	5	5	5
243	70089	6	6	6	6	5	5	5	246	69686	6	6	5	5	5	5	5
247	70090	6	6	6	6	5	5	5	251	69687	6	6	5	5	5	5	5
249	70094	5	5	5	4	4	4	4	254	69689	7	7	6	6	6	5	5
250	70095	6	6	5	5	5	5	5	256	69691	5	5	5	5	4	4	4
253	70096	6	6	5	5	5	4	4	258	70092	6	6	5	5	5	5	5
257	70097	6	6	5	5	5	5	5	260	70093	6	6	5	5	5	5	5
259	70098	6	6	5	4	4	4	4	262	71308	7	7	6	6	6	5	5
261	70099	6	6	5	4	4	4	4	266	71310	7	7	6	6	5	5	5
263	71309	6	6	5	5	5	4	4	268	71312	7	7	6	6	6	6	6
265	71311	6	6	5	4	4	4	4	269	71316	7	7	6	6	5	5	5
267	70091	6	6	5	5	5	4	4	270	71318	6	6	5	5	5	5	5
	Total	**591**	**590**	**524**	**491**	**466**	**447**	**446**			**578**	**577**	**528**	**498**	**487**	**482**	**482**
	Median	**6**	**6**	**5**	**5**	**5**	**4**	**4**			**6**	**6**	**5**	**5**	**5**	**5**	**5**
	Max	**7**	**7**	**7**	**7**	**7**	**7**	**7**			**7**	**7**	**7**	**6**	**6**	**6**	**6**
	Min	**4**	**4**	**3**	**3**	**2**	**2**	**2**			**4**	**4**	**4**	**3**	**3**	**3**	**3**

PATIENT'S ASSESSMENT SCALE

Trial Group								Control Group							
Sr.No.	OPD No.	V2	V3	V4	V5	V6	V7	Sr.No.	OPD No.	V2	V3	V4	V5	V6	V7
1	11837	4	3	3	3	3	3	2	20829	3	3	3	3	2	2
3	16371	3	3	3	3	3	3	6	20836	4	3	3	3	3	3
4	20824	4	3	3	3	3	3	14	20895	4	4	3	3	3	3
7	20825	4	4	4	3	3	3	15	21095	4	3	3	3	3	3
9	20826	4	3	3	3	3	3	17	21096	4	4	4	4	4	4
10	20827	4	3	3	3	3	3	19	21097	4	4	3	3	3	3
11	20828	4	3	3	3	3	3	23	21098	4	4	4	3	3	3
13	20835	4	4	3	3	3	3	26	21099	4	4	4	3	3	3
21	20837	4	4	3	3	3	3	28	21100	4	4	3	3	3	3
25	20838	4	4	3	3	3	3	29	21101	4	4	3	3	3	3
27	20893	4	3	3	3	3	3	34	21102	4	4	4	3	3	3
30	20894	4	3	2	2	2	2	36	21103	4	4	3	3	3	3
32	20896	4	3	3	3	3	2	37	21104	4	4	3	3	3	3
33	20897	4	3	3	3	3	3	40	21105	4	4	3	3	3	3
39	20898	4	3	3	3	3	3	46	21106	4	3	3	3	3	3
42	20899	4	3	3	4	4	4	48	21106	4	3	3	3	3	3
44	20900	4	4	3	3	2	2	50	21107	4	4	3	4	4	4
45	20902	4	3	3	3	2	2	51	21108	4	4	3	3	3	3
49	20903	4	4	3	2	2	2	56	21109	4	3	3	3	3	3
53	20981	4	3	3	3	3	3	59	21110	4	4	4	3	3	3
55	20982	4	3	3	3	3	3	60	21111	4	4	4	3	3	3
57	20983	4	3	3	3	2	2	63	21112	4	4	3	3	2	2
61	20984	4	4	3	3	3	3	66	21113	4	4	3	3	3	3
64	20986	4	4	3	2	2	2	70	21114	4	4	4	4	3	3
67	20988	4	4	3	3	3	3	71	21250	4	4	4	4	4	4

69	20988	4	3	3	3	3	3	74	21264	4	4	4	3	3	3
72	20989	4	3	3	2	2	2	76	21266	4	4	3	3	3	3
73	20991	4	3	3	3	3	3	81	21272	4	3	3	3	3	3
79	20992	4	3	3	3	3	3	83	21276	4	4	3	3	3	3
80	20993	4	3	3	2	1	1	85	21279	4	4	3	3	3	3
84	20994	4	4	3	3	2	2	89	21312	4	4	3	3	3	3
87	20995	4	4	3	3	2	2	92	21313	4	3	3	3	3	3
91	20997	4	3	3	3	3	3	93	21314	4	3	3	3	3	3
94	20998	4	3	3	2	2	2	95	21316	4	3	3	3	3	3
97	20999	4	4	3	3	3	3	96	21317	4	4	3	3	3	3
99	21000	4	4	3	3	2	2	101	21318	4	4	3	3	3	3
100	21001	4	3	2	2	1	1	102	21319	4	4	4	3	3	3
105	21002	4	4	3	3	3	3	103	21320	4	3	3	3	3	3
107	21003	4	3	3	3	3	3	108	21321	4	3	3	2	2	2
109	21249	4	3	3	3	3	3	111	21322	4	4	3	3	3	3
115	21251	4	4	3	3	3	3	113	21323	4	3	3	3	3	3
116	21252	4	3	3	2	2	2	114	21324	4	4	3	3	3	3
119	21253	4	4	4	3	3	3	117	21325	4	3	3	3	3	3
120	21258	4	3	3	3	3	3	121	21326	4	4	3	3	3	3
122	21259	4	3	3	3	3	3	124	21327	4	3	3	3	3	3
123	21260	4	3	3	3	3	3	127	21328	4	3	3	3	3	3
125	21261	4	4	3	3	3	3	128	21329	4	4	3	3	3	3
131	21262	4	4	3	3	3	3	130	21330	4	4	4	4	4	4
134	21263	4	3	3	3	3	3	132	21334	4	3	3	3	3	3
136	21331	4	4	3	3	3	3	133	32790	4	4	3	3	3	3
137	32784	4	4	3	3	2	2	142	32791	4	4	3	3	3	3
140	32786	4	3	2	2	2	2	143	32792	4	3	3	3	3	3
141	32787	4	3	2	2	2	2	145	32793	4	4	3	3	3	3
147	32788	4	3	3	2	2	2	146	32794	4	3	3	2	2	2
149	32789	4	3	3	3	3	3	150	45783	4	4	4	4	4	4

151	32795	4	3	3	2	2	2	155	46114	4	3	3	3	3	3
152	47466	4	3	3	2	2	2	156	46115	4	3	3	3	3	3
153	47562	4	3	3	2	2	2	158	46117	4	4	3	3	3	3
159	53825	4	3	3	3	3	3	160	47563	4	4	3	3	3	3
163	67909	4	3	3	3	3	3	162	50383	4	4	3	3	3	3
166	68128	4	3	3	2	2	2	164	53779	4	4	4	4	4	4
167	68129	4	3	3	3	3	3	168	53821	4	4	4	3	3	3
169	68131	4	3	3	3	2	2	171	53822	4	3	3	3	3	3
170	68132	4	4	3	3	3	3	174	67885	4	3	3	3	3	3
173	68134	4	4	3	3	3	3	177	67886	4	3	3	3	3	3
175	68135	4	3	3	3	3	3	178	67902	4	3	3	3	3	3
176	68136	4	3	3	2	2	2	179	67905	4	4	3	3	3	3
182	68627	4	3	3	2	2	2	181	67906	4	4	4	3	3	3
187	68633	4	3	3	2	2	2	184	67907	4	3	3	2	2	2
188	68635	4	3	3	3	2	2	185	67908	4	4	3	3	3	3
190	68636	4	3	3	3	3	3	189	67910	4	3	3	3	3	3
194	68639	4	3	3	3	3	3	191	68130	4	3	3	3	3	3
197	68640	4	3	3	3	3	3	193	68138	4	4	4	4	4	4
199	68641	4	3	3	3	3	3	195	68140	4	3	3	3	3	3
201	68642	4	3	3	3	3	3	196	68632	4	4	2	1	1	1
206	68643	4	3	3	3	3	3	202	68634	4	3	3	3	3	3
208	68645	4	4	4	4	4	4	203	68637	4	4	3	3	3	3
210	68647	4	4	3	3	2	2	213	68638	4	3	3	3	3	3
212	68648	4	3	3	3	3	3	219	68644	4	3	3	3	3	3
214	68649	4	3	3	3	3	3	221	68646	4	3	3	3	3	3
216	68650	4	3	3	3	3	3	222	69442	4	3	3	3	3	3
220	69444	4	4	3	3	3	3	227	69443	4	3	3	2	2	2
223	69445	4	3	3	3	3	3	228	69446	4	3	3	3	3	3
225	69449	4	4	4	4	4	4	230	69447	4	4	3	3	3	3
229	69682	4	3	3	3	3	3	231	69448	4	3	2	2	2	2

233	69683	4	3	3	3	3	3	236	69450	4	3	3	3	3	3
234	69688	4	3	3	3	3	3	239	69451	4	3	3	3	3	3
237	69690	4	3	2	2	2	2	240	69684	4	3	3	3	3	3
241	69692	4	3	3	3	3	3	242	69685	4	3	3	3	3	3
243	70089	4	3	3	3	3	3	246	69686	4	3	3	3	3	3
247	70090	4	4	3	3	3	3	251	69687	4	3	3	3	3	3
249	70094	4	4	3	2	2	2	254	69689	4	3	3	3	3	3
250	70095	4	3	3	2	2	2	256	69691	4	3	3	3	3	3
253	70096	4	4	3	3	3	3	258	70092	4	3	3	3	3	3
257	70097	4	3	3	3	3	3	260	70093	4	3	3	3	3	3
259	70098	4	3	3	2	2	2	262	71308	4	3	3	3	3	3
261	70099	4	3	2	2	2	2	266	71310	4	3	3	3	3	3
263	71309	4	3	3	3	3	3	268	71312	4	3	3	3	3	3
265	71311	4	3	3	3	3	3	269	71316	4	3	3	3	3	3
267	70091	4	3	3	3	2	2	270	71318	4	3	3	3	3	3
	Total	**399**	**329**	**298**	**280**	**267**	**266**		**Total**	**399**	**348**	**314**	**301**	**298**	**298**
	Median	**4**	**3**	**3**	**3**	**3**	**3**		**Median**	**4**	**3**	**3**	**3**	**3**	**3**
	Max	**4**	**4**	**4**	**4**	**4**	**4**		**Max**	**4**	**4**	**4**	**4**	**4**	**4**
	Min	**3**	**3**	**2**	**2**	**1**	**1**		**Min**	**3**	**3**	**2**	**1**	**1**	**1**

APPENDIX VIII

QUALITY OF LIFE SCORE IN PATIENTS OF DRUG GROUP

Sr.No.	OPD No.	V1 Score	V6 Score
1	11837	9: Moderate effect	3: Little/Minimal effect
3	16371	8: Moderate effect	8: Moderate effect
4	20824	0: No effect	0: No effect
7	20825	4: Little/Minimal effect	2: Little/Minimal effect
9	20826	0: No effect	0: No effect
10	20827	1: No effect	1: No effect
11	20828	0: No effect	0: No effect
13	20835	1: No effect	1: No effect
21	20837	0: No effect	0: No effect
25	20838	0: No effect	0: No effect
27	20893	0: No effect	0: No effect
30	20894	0: No effect	0: No effect
32	20896	0: No effect	0: No effect
33	20897	2: Little/Minimal effect	2: Little/Minimal effect
39	20898	4: Little/Minimal effect	4: Little/Minimal effect
42	20899	2: Little/Minimal effect	2: Little/Minimal effect
44	20900	15: Very large effect	4: Little/Minimal effect
45	20902	0: No effect	0: No effect
49	20903	0: No effect	0: No effect
53	20981	0: No effect	0: No effect
55	20982	2: Little/Minimal effect	2: Little/Minimal effect
57	20983	0: No effect	0: No effect
61	20984	0: No effect	0: No effect
64	20986	0: No effect	0: No effect
67	20988	5: Little/Minimal effect	2: Little/Minimal effect
69	20988	1: No effect	1: No effect
72	20989	5: Little/Minimal effect	2: Little/Minimal effect
73	20991	0: No effect	0: No effect
79	20992	1: No effect	1: No effect
80	20993	0: No effect	0: No effect
84	20994	0: No effect	0: No effect
87	20995	0: No effect	0: No effect
91	20997	8: Moderate effect	4: Little/Minimal effect
94	20998	2: Little/Minimal effect	2: Little/Minimal effect
97	20999	3: Little/Minimal effect	3: Little/Minimal effect
99	21000	2: Little/Minimal effect	2: Little/Minimal effect
100	21001	0: No effect	0: No effect
105	21002	3 : Little/Minimal effect	2: Little/Minimal effect

107	21003	1: No effect	1: No effect
109	21249	5 : Little/Minimal effect	2: Little/Minimal effect
115	21251	6: Moderate effect	4: Little/Minimal effect
116	21252	0: No effect	0: No effect
119	21253	3: Little/Minimal effect	3: Little/Minimal effect
120	21258	3: Little/Minimal effect	3: Little/Minimal effect
122	21259	0: No effect	0: No effect
123	21260	0: No effect	0: No effect
125	21261	5: Little/Minimal effect	2: Little/Minimal effect
131	21262	0: No effect	0: No effect
134	21263	0: No effect	0: No effect
136	21331	0: No effect	0: No effect
137	32784	6: moderate effect	3: Little/Minimal effect
140	32786	3: Little/Minimal effect	0: No effect
141	32787	3: Little/Minimal effect	0: No effect
147	32788	0: No effect	0: No effect
149	32789	3: Little/Minimal effect	3: Little/Minimal effect
151	32795	0: No effect	0: No effect
152	47466	0: No effect	0: No effect
153	47562	4: Little/Minimal effect	0: No effect
159	53825	0: No effect	0: No effect
163	67909	0: No effect	0: No effect
166	68128	6: moderate effect	0: No effect
167	68129	5: Little/Minimal effect	2: Little/Minimal effect
169	68131	5: Little/Minimal effect	5: Little/Minimal effect
170	68132	0: No effect	0: No effect
173	68134	2: Little/Minimal effect	0: No effect
175	68135	2: Little/Minimal effect	0: No effect
176	68136	0: No effect	0: No effect
182	68627	1: No effect	1: No effect
187	68633	0: No effect	0: No effect
188	68635	0: No effect	0: No effect
190	68636	4: Little/Minimal effect	4: Little/Minimal effect
194	68639	0: No effect	0: No effect
197	68640	0: No effect	0: No effect
199	68641	3 : Little/Minimal effect	3 : Little/Minimal effect
201	68642	0: No effect	0: No effect
206	68643	0: No effect	0: No effect
208	68645	3 : Little/Minimal effect	3 : Little/Minimal effect
210	68647	6: moderate effect	3 : Little/Minimal effect
212	68648	9: Moderate effect	5: Little/Minimal effect
214	68649	9: Moderate effect	6: moderate effect
216	68650	5: Little/Minimal effect	3 : Little/Minimal effect
220	69444	3 : Little/Minimal effect	3 : Little/Minimal effect
223	69445	8: Moderate effect	5: Little/Minimal effect
225	69449	3 : Little/Minimal effect	3 : Little/Minimal effect

229	69682	9: Moderate effect	6: moderate effect
233	69683	3 : Little/Minimal effect	3 : Little/Minimal effect
234	69688	0: No effect	0: No effect
237	69690	0: No effect	0: No effect
241	69692	3 : Little/Minimal effect	3 : Little/Minimal effect
243	70089	0: No effect	0: No effect
247	70090	4: Little/Minimal effect	0: No effect
249	70094	6: moderate effect	3 : Little/Minimal effect
250	70095	3 : Little/Minimal effect	0: No effect
253	70096	8: Moderate effect	5: Little/Minimal effect
257	70097	9: Moderate effect	4: Little/Minimal effect
259	70098	5: Little/Minimal effect	0: No effect
261	70099	2: Little/Minimal effect	0: No effect
263	71309	0: No effect	0: No effect
265	71311	0: No effect	0: No effect
267	70091	9: Moderate effect	6: moderate effect

QUALITY OF LIFE SCORE IN PATIENTS OF CONTROL GROUP

Sr. No.	OPD No.	V1 Score	V6 Score
2	20829	0: No effect	0: No effect
6	20836	1: No effect	1: No effect
14	20895	3: Little/Minimal effect	3: Little/Minimal effect
15	21095	1: No effect	1: No effect
17	21096	8: Moderate effect	8: Moderate effect
19	21097	3: Little/Minimal effect	3: Little/Minimal effect
23	21098	5: Little/Minimal effect	5: Little/Minimal effect
26	21099	4: Little/Minimal effect	4: Little/Minimal effect
28	21100	5: Little/Minimal effect	5: Little/Minimal effect
29	21101	0: No effect	0: No effect
34	21102	2: Little/Minimal effect	2: Little/Minimal effect
36	21103	1: No effect	1: No effect
37	21104	2: Little/Minimal effect	2: Little/Minimal effect
40	21105	2: Little/Minimal effect	2: Little/Minimal effect
46	21106	4: Little/Minimal effect	4: Little/Minimal effect
48	21106	1: No effect	1: No effect
50	21107	0: No effect	0: No effect
51	21108	5: Little/Minimal effect	4: Little/Minimal effect
56	21109	3: Little/Minimal effect	3: Little/Minimal effect
59	21110	4: Little/Minimal effect	4: Little/Minimal effect
60	21111	0: No effect	0: No effect
63	21112	1: No effect	1: No effect
66	21113	0: No effect	0: No effect
70	21114	4: Little/Minimal effect	4: Little/Minimal effect
71	21250	12 :Very large effect	8: Moderate effect
74	21264	1: No effect	1: No effect
76	21266	0: No effect	0: No effect
81	21272	0: No effect	0: No effect
83	21276	2: Little/Minimal effect	2: Little/Minimal effect
85	21279	0: No effect	0: No effect
89	21312	6: Moderate effect	4: Little/Minimal effect
92	21313	6: Moderate effect	4: Little/Minimal effect
93	21314	1: No effect	1: No effect
95	21316	0: No effect	0: No effect
96	21317	2: Little/Minimal effect	2: Little/Minimal effect
101	21318	0: No effect	0: No effect
102	21319	7 : Moderate effect	5 : Little/Minimal effect
103	21320	3: Little/Minimal effect	3: Little/Minimal effect
108	21321	3: Little/Minimal effect	1: No effect
111	21322	2: Little/Minimal effect	2: Little/Minimal effect
113	21323	2: Little/Minimal effect	2: Little/Minimal effect

114	21324	2: Little/Minimal effect	2: Little/Minimal effect
117	21325	0: No effect	0: No effect
121	21326	0: No effect	0: No effect
124	21327	0: No effect	0: No effect
127	21328	0: No effect	0: No effect
128	21329	5: Little/Minimal effect	4: Little/Minimal effect
130	21330	0: No effect	0: No effect
132	21334	3: Little/Minimal effect	3: Little/Minimal effect
133	32790	2: Little/Minimal effect	2: Little/Minimal effect
142	32791	1: No effect	1: No effect
143	32792	0: No effect	0: No effect
145	32793	5: Little/Minimal effect	4: Little/Minimal effect
146	32794	0: No effect	0: No effect
150	45783	0: No effect	0: No effect
155	46114	0: No effect	0: No effect
156	46115	8: Moderate effect	5: Little/Minimal effect
158	46117	0: No effect	0: No effect
160	47563	0: No effect	0: No effect
162	50383	5: Little/Minimal effect	3: Little/Minimal effect
164	53779	5: Little/Minimal effect	5: Little/Minimal effect
168	53821	8: Moderate effect	5: Little/Minimal effect
171	53822	3: Little/Minimal effect	3: Little/Minimal effect
174	67885	0: No effect	0: No effect
177	67886	0: No effect	0: No effect
178	67902	5: Little/Minimal effect	5: Little/Minimal effect
179	67905	6: Moderate effect	6: Moderate effect
181	67906	3: Little/Minimal effect	3: Little/Minimal effect
184	67907	5: Little/Minimal effect	3: Little/Minimal effect
185	67908	1: No effect	1: No effect
189	67910	4: Little/Minimal effect	4: Little/Minimal effect
191	68130	3: Little/Minimal effect	3: Little/Minimal effect
193	68138	5: Little/Minimal effect	5: Little/Minimal effect
195	68140	4: Little/Minimal effect	4: Little/Minimal effect
196	68632	3: Little/Minimal effect	0: No effect
202	68634	0: No effect	0: No effect
203	68637	6: Moderate effect	3: Little/Minimal effect
213	68638	0: No effect	0: No effect
219	68644	4: Little/Minimal effect	1: No effect
221	68646	6: Moderate effect	6: Moderate effect
222	69442	1: No effect	1: No effect
227	69443	0: No effect	0: No effect
228	69446	2: Little/Minimal effect	2: Little/Minimal effect
230	69447	7 : Moderate effect	3: Little/Minimal effect
231	69448	5: Little/Minimal effect	5: Little/Minimal effect
236	69450	3: Little/Minimal effect	3: Little/Minimal effect
239	69451	0: No effect	0: No effect

240	69684	4: Little/Minimal effect	2: Little/Minimal effect
242	69685	0: No effect	0: No effect
246	69686	6: Moderate effect	3: Little/Minimal effect
251	69687	3 : Little/Minimal effect	3 : Little/Minimal effect
254	69689	1: No effect	1: No effect
256	69691	0: No effect	0: No effect
258	70092	1: No effect	1: No effect
260	70093	1: No effect	1: No effect
262	71308	0: No effect	0: No effect
266	71310	1: No effect	1: No effect
268	71312	0: No effect	0: No effect
269	71316	0: No effect	0: No effect
270	71318	7 : Moderate effect	7 : Moderate effect

0-1 : No effect

2-5 : Little/Minimal effect

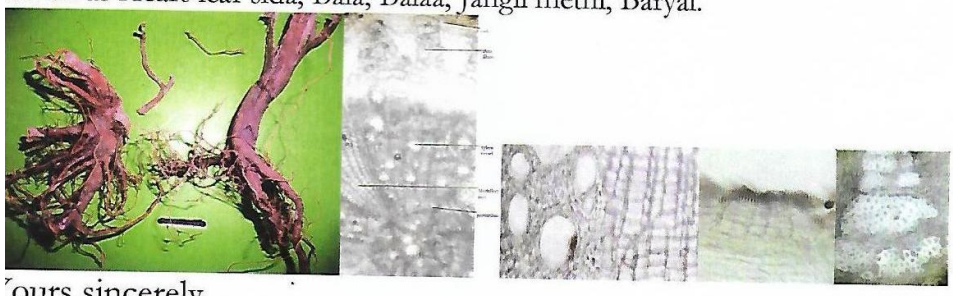
6 -10 : Moderate effect

11 -20 : Very large effect

21 -30 : Extremely large effect

Sida cordifolia Linn.

This is with reference to material in the form of roots provided by you for dentification.The material has tap root as the main root with lateral root and rootlets is well root hairs. In transverse section root is circular, bark thin, cork tangentially elongated cells, phellogen of rectangular cells. With parenchymatous cortex containing calcium oxalate crystals, minute starch grains. Secondary phloem with bast fibres. Secondary xylem with vessels, parenchyma,fibres and prominent medullary rays uniseriate or biseriate. The material (**specimen #: gg p 1050214**) is the root system of ***Sida cordifolia*** Linn. synonym ***Sida herbacea*** Cav., ***Sida hongkingense*** Gand., ***Sida rotundifolia*** Lam ex. Cav. belonging to family Malvaceae. It is commonly known as Heart-leaf sida, Bala, Balaa, Jangli methi, Baryal.

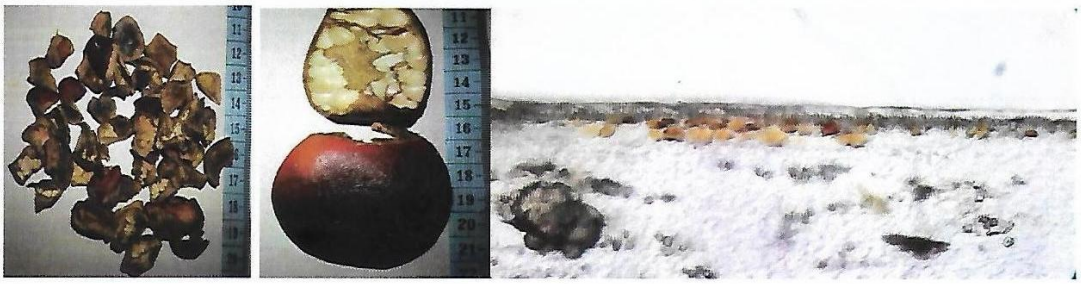


Yours sincerely

Harshad M. Pandit

Punica granatum Linn.

This is with reference to material provided by you for identification. The material was in the form of dried pieces of exocarp of fruit as well as fresh pieces of exocarp. The material is concave dark red in colour with inner surface pale yellow. The transverse section of the peel shows thin cuticle, single layered epidermis, followed by a layer of cells with pigments, rest of the peel has parenchymatous cells, some cells are sclerenchymatous constituting the stone cells, few cells contain rosettes of calcium oxalate crystals. The material (**specimen #:gg p 1040992**) is identified as the peel of the fruit of ***Punica granatum*** Linn. belonging to family Punicaceae. It is commonly known as Pome granate rind(fruit peel), Dadam, Anaar, Dalim, Dadima, Dalimba-sal.

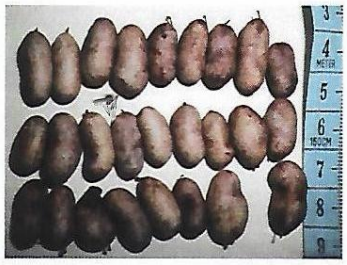


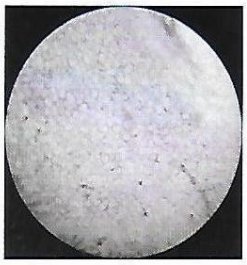
Yours sincerely,

Harshad M. Pandit

Syzygium cuminii (Linn.) Skeels

This is with reference to material in the form of seeds provided by you for identification. The entire seed is enclosed in pinkish cream coloured coriaceous covering. The seed is approximately 1to 1.2 cm long and 0.6 cm wide, smooth, kidney shaped, black. Internally it has single epidermis with isodiametric thin-walled parenchymatous cells containing starch grains with few schizogenous cavities. The seeds(**specimen #: gg p 1050100**)belong to ***Syzygium cuminii*** (Linn.) Skeels synonym ***Eugenia cumini*** (L.) Druce, ***Eugenia jambolana*** Lam. of family Myrtaceae. It is commonly known as Black plum, Malabar plum, Jamun, Jamun beej.





Your sincerely,

Harshad M. Pandit

Kerria lacca Kerr

This is with reference to material provided for identification. The material is in the form of scarlet resinous material of various size. The material (**specimen #: gg p 1050129**)is resinous secretions of ***Kerria lacca*** Kerr synonym ***Laccifer lacca*** Cockerell belonging to family Laccaferinae. It is commonly known as Lac, sticklac, Laaksha.

Figure 1 **Figure 2**

(Fig.1 Sample, Fig. 2 Published work)

Yours sincerely

Harshad M. Pandit

z

Mangifera indica Linn.

This is with reference to material in the form of dried shell or pit v inside it. The shell is fibrous hard approximately 8.3 cm and splits when cc dry. The seed is approximately 5 cm long with thin brown papery cover material (**specimen #: gg p 1040985**)is the pit and seed of ***Mangifera indic*** belonging to family Anacardiaceae. It is commonly known as Indian mango, Amba.

Yours sincerely

Harshad M. Pandit

Glycyrrhiza glabra Linn.

This is with reference to material provided by you for identification. The material consists of stolon which are cylindrical 4 to 5.2 cm in length to 1.3 cm in diameter longitudinally wrinkled, dark gresyish in colour. In transverse section the section is circular in outline, tubular cork cells, followed by parenchymatous secondary cortex with calcium oxalate crystals, secondary phloem, fibrous tissue, inner to the cambium, secondary xylem with large prominent vessels with parenchymatous pith. The material(**specimen #: gg p 1040996**) represent the stolons of ***Glycyrrhiza glabra*** Linn. synonym ***Glycyrrhiza glabra*** Linn. family Fabaceae. It is commonly known as Common liquorice, True licorice, Jethimadh, Yastimadhuka, Jestamadh, Multhei.

Your sincerely,

Harshad M. Pandit

Sub: - Report of analysis of the Mango seed Sample provided by you.

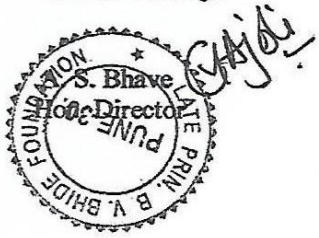
The samples provided by you were analyzed as per your requirements and the results of the samples were as follows,

Sr. No.	Name of the Test	Result obtained (%)
1.	Description	Reddish brown colour : tasteless: odour faint
2.	pH	5.58
	Moisture content @ 110^0C	6.08%
3.	Ash Value	1.42%
4.	Water Soluble Extract	11.49%
5.	Heavy metal	Done
	Arsenic	1.2 ppm
	Cadmium	0.227 ppm
	Lead	3.16 ppm
	Mercury	1.46 ppm
6.	Phytochemical Test	Done
	Tannin	Present

All the tests were performed according to standard methods. In case of any queries regarding, the results, please feel free to contact us back.

Thanking You

Yours Sincerely,



A. S. Bhave
Hon. Director

(Note:-This report reflects our findings at the time and place of testing. This report is for technical support and Late.Prin. B.V. Bhide Foundation lab will not involve in any legal matter arising from this report)

Sub: - Report of analysis of the Jamun seed Sample provided by you.

The samples provided by you were analyzed as per your requirements and the results of the samples were as follows,

Sr. No.	Name of the Test	Result obtained (%)
1.	Description	Brownish colour : odour characteristic:taste astringent
2.	pH	5.40
	Moisture content @ 110^0C	6.30%
3.	Ash Value	3.12%
4.	Water Soluble Extract	15.21%
5.	Heavy metal	Done
	Arsenic	1.4 ppm
	Cadmium	0.477 ppm
	Lead	3.07 ppm
	Mercury	1.36 ppm
6.	Phytochemical Test	Done
	Saponins, Tannin	Present

All the tests were performed according to standard methods. In case of any queries regarding, the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

S. Bhave
Hon. Director

LATE PRIN. B. V. BHIDE FOUNDATION PUNE

(Note:-This report reflects our findings at the time and place of testing. This report is for technical support and Late.Prin. B.V. Bhide Foundation lab will not involve in any legal matter arising from this report)

Sub: - Report of analysis of the Dadim peel Sample provided by you.

The samples provided by you were analyzed as per your requirements and the results of the samples were as follows,

Sr. No.	Name of the Test	Result obtained (%)
1.	Description	Reddish brown colour : odour faint :taste sweet
2.	pH	4.60
	Moisture content @ 110^{0}C	5.01%
3.	Ash Value	3.10%
4.	Water Soluble Extract	24.56%
5.	Heavy metal	Done
	Arsenic	1.6 ppm
	Cadmium	0.667 ppm
	Lead	2.17 ppm
	Mercury	0.68 ppm
6.	Phytochemical Test	Done
	Proteins, Carbohydrates	Present

All the tests were performed according to standard methods. In case of any queries regarding, the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

LATE PRIN. B. V. BHIDE FOUNDATION PUNE 30

S. Bhave
Hon. Director

(Note:-This report reflects our findings at the time and place of testing. This report is for technical support and Late.Prin. B.V. Bhide Foundation lab will not involve in any legal matter arising from this report)

Sub: - Report of analysis of the Yashtimadhu root Sample provided by you.

The samples provided by you were analyzed as per your requirements and the results of the samples were as follows,

Sr. No.	Name of the Test	Result obtained (%)
1.	Description	Yellowish colour : odour characteristic :taste sweet
2.	pH	5.40
	Moisture content @ 110^{0}C	4.59%
3.	Ash Value	5.30%
4.	Water Soluble Extract	24.44%
5.	Heavy metal	Done
	Arsenic	2.1 ppm
	Cadmium	0.594 ppm
	Lead	7.02 ppm
	Mercury	1.04 ppm
6.	Phytochemical Test	Done
	Starch, Carbohydrates	Present

All the tests were performed according to standard methods. In case of any queries regarding, the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

S. Bhave
Hon. Director

LATE PRIN. B. V. BHIDE FOUNDATION * PUNE 30

Note:-This report reflects our findings at the time and place of testing. This report is for technical support and Late.Prin. B.V. Bhide Foundation lab will not involve in any legal matter arising from this report)

Sub: - Report of analysis of the Bala root Sample provided by you.

The samples provided by you were analyzed as per your requirements and the results of the samples were as follows,

Sr. No.	Name of the Test	Result obtained (%)
1.	Description	Faint brownish yellow colour : odour characteristic :tasteless
2.	pH	6.38
	Moisture content @ 110^0C	4.26%
3.	Ash Value	5.08%
4.	Water Soluble Extract	5.33%
5.	Heavy metal	Done
	Arsenic	2.4 ppm
	Cadmium	0.415 ppm
	Lead	4054 ppm
	Mercury	1.72 ppm
6.	Phytochemical Test	Done
	Alkaloid	Present

All the tests were performed according to standard methods. In case of any queries regarding, the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

S. Bhave
Hon. Director

(Note:-This report reflects our findings at the time and place of testing. This report is for technical support and Late.Prin. B.V. Bhide Foundation lab will not involve in any legal matter arising from this report)

Sub: - Report of analysis of the Laksha Sample provided by you.

The samples provided by you were analyzed as per your requirements and the results of the samples were as follows,

Sr. No.	Name of the Test	Result obtained (%)
1.	Description	Reddish brown colour : tasteless: odour faint
2.	pH	4.21
	Moisture content @ 110^0C	7.50%
3.	Ash Value	8.695%
4.	Water Soluble Extract	25.11%
5.	Heavy metal	Done
	Arsenic	3.9 ppm
	Cadmium	0.569 ppm
	Lead	6.52 ppm
	Mercury	1.65 ppm
6.	Phytochemical Test	Done
	Resin	Present

All the tests were performed according to standard methods. In case of any queries regarding, the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

LATE PRIN. B. V. BHIDE FOUNDATION PUNE

S. Bhave
Hon. Director

(Note:-This report reflects our findings at the time and place of testing. This report is for technical support and Late.Prin. B.V. Bhide Foundation lab will not involve in any legal matter arising from this report)

Sub: Report of analysis of the Mango Seed sample provided by you

The samples provided by you were analyzed as per your requirements and the details of the samples were as follows.

Sr.No.	Test Name	Result obtained
1	Total Viable count (CFU/ml)	73×10^2
2	Total Fungal count (CFU/ml)	8×10^2

All the tests were performed according to standard methods. In case of any queries regarding. the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

A.S. Bhave
Hon. Director

LATE PRIN. B. V. BHOIR EDUCATION SOCIETY'S JUNE-30.

Sub: Report of analysis of the Jamdu Seed sample provided by you

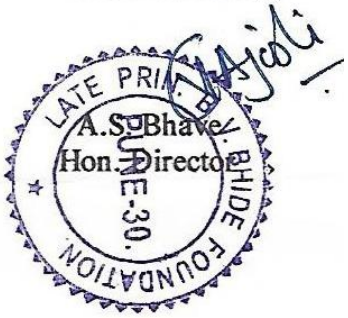
The samples provided by you were analyzed as per your requirements and the details of the samples were as follows.

Sr.No.	Test Name	Result obtained
1	Total Viable count (CFU/ml)	10×10^3
2	Total Fungal count (CFU/ml)	50×10^2

All the tests were performed according to standard methods. In case of any queries regarding. the results, please feel free to contact us back.

Thanking You

Yours Sincerely,



Sub: Report of analysis of the Pomegranate Peel sample provided by you

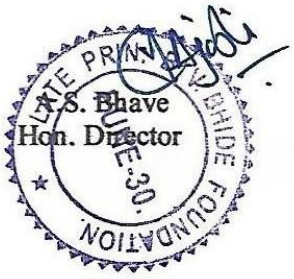
The samples provided by you were analyzed as per your requirements and the details of the samples were as follows.

Sr.No.	Test Name	Result obtained
1	Total Viable count (CFU/ml)	40×10^2
2	Total Fungal count (CFU/ml)	40×10^2

All the tests were performed according to standard methods. In case of any queries regarding. the results, please feel free to contact us back.

Thanking You

Yours Sincerely,



A.S. Bhave
Hon. Director

Sub: Report of analysis of the Yashtimadhu sample provided by you

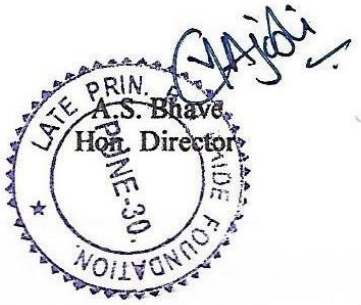
The samples provided by you were analyzed as per your requirements and the details of the samples were as follows.

Sr.No.	Test Name	Result obtained
1	Total Viable count (CFU/ml)	16×10^2
2	Total Fungal count (CFU/ml)	65×10^2

All the tests were performed according to standard methods. In case of any queries regarding. the results, please feel free to contact us back.

Thanking You

Yours Sincerely,



A.S. Bhave
Hon. Director

Sub: Report of analysis of the Bala Root sample provided by you

The samples provided by you were analyzed as per your requirements and the details of the samples were as follows.

Sr.No.	Test Name	Result obtained
1	Total Viable count (CFU/ml)	12×10^3
2	Total Fungal count (CFU/ml)	45×10^2

All the tests were performed according to standard methods. In case of any queries regarding. the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

LATE PRIN. A.S. BHAVE FOUNDATION
A.S. Bhave
Hon. Director
JUNE-30.

Sub: Report of analysis of the Laksha sample provided by you

The samples provided by you were analyzed as per your requirements and the details of the samples were as follows.

Sr.No.	Test Name	Result obtained
1	Total Viable count (CFU/ml)	10×10^2
2	Total Fungal count (CFU/ml)	Nil

All the tests were performed according to standard methods. In case of any queries regarding the results, please feel free to contact us back.

Thanking You

Yours Sincerely,

M.S. Bhave
Hon. Director

Sample(s) Drawn by The Laboratory	No
Date of Sample Received	31/01/2017
Date of Starting Analysis	11/02/2017
Date of Completion	16/02/2017
Sample Description	**Mango Seeds (Mangifera Indica)**
Sample Details	Nature: Solid, Qty: 99gms, Stamped/Sealed: No, Packing: Zip lock bag

PARAMETER NAME	RESULT	UOM	METHOD
Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expresed as dieldrin)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlordane (residue to be measured as cis plus trans chlordane)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Diazinon	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dichlorvos (content of di-chloroacetaldehyde (D.C.A.) be reported where possible)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dicofol	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan A	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan B	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770478 REPORT DATE: 16/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Endosulfan-Sulphate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenitrothion	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Alpha Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Beta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Gamma Isomer (Known as Lindane) - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Delta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion methyl (combined residues of parathion methyl and its oxygen analogue to be determined and expressed as parathion methyl)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethion (Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Monocrotophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosalone	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Thiometon (Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Acephate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Methamidophos (A metabolite of acephate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cypermethrin (sum of isomers) (fat soluble residue)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Decamethrin / Deltamethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthion (sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthoate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770478 REPORT DATE: 16/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Phorate (sum of Phorate, its oxygen analogue and their sulphoxides and sulphones, expressed as phorate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Pirimiphos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorothalonil	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Allethrin and Bioallethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Oxydemeton- methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Permethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Quinalphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Triazophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenpropathrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cyfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glyphosate	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
Transfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Lambda-cyhalothrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenvalerate and Esefenvalerate (Sum of RS & SR isomers)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glufosinate-ammonium	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
tau-Fluvalinate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion Ethyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethofenprox	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Bifenthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
4-bromo-2-chlorophenol (metabolite of Profenophos)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

REPORT NO.: 161770478 REPORT DATE: 16/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Chlorfenvinphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Etrimfos*	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Omethoate (refer to Dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Iprobenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Propetamphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Temephos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

Remark : BLQ : Below Limit of Quantification, Quantification Limit : 0.01 mg/kg

..... END .....

Authorized Signatory 17/02/17

Note: 1. Test results relate to the submitted sample(s) only.
2. Test report shall not be reproduced except in full, without written approval of the laboratory.
3. Laboratory is not responsible for the authenticity of photocopied test report.
4. The test items will not be retained for perishable products and 1 months in the case of non-perishable samples unless otherwise agreed with the customer or as required by the applicable regulation.
5. The tests marked with (*) are not accredited by NABL.
6. The Report no. with suffix R - Revised Report.

Sample(s) Drawn by The Laboratory	No
Date of Sample Received	31/01/2017
Date of Starting Analysis	11/02/2017
Date of Completion	16/02/2017
Sample Description	**Jamun Seeds (Syzygium Cumini)**
Sample Details	Nature: Solid, Qty: 86gms, Stamped/Sealed: No, Packing: Zip lock bag

PARAMETER NAME	RESULT	UOM	METHOD
Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expresed as dieldrin)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlordane (residue to be measured as cis plus trans chlordane)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Diazinon	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dichlorvos (content of di-chloroacetaldehyde (D.C.A.) be reported where possible)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dicofol	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan A	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan B	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770477 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Endosulfan-Sulphate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenitrothion	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Alpha Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Beta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Gamma Isomer (Known as Lindane) - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Delta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion methyl (combined residues of parathion methyl and its oxygen analogue to be determined and expressed as parathion methyl)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethion (Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Monocrotophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosalone	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Thiometon (Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Acephate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Methamidophos (A metabolite of Acephate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cypermethrin (sum of isomers) (fat soluble residue)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Decamethrin / Deltamethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Edifenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthion (sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phenthoate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770477 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Phorate (sum of Phorate, its oxygen analogue and their sulphoxides and sulphones, expressed as phorate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Pirimiphos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorothalonil	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Allethrin and Bioallethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Oxydemeton- methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Permethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Quinalphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Triazophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenpropathrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cyfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glyphosate	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
Transfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Lambda-cyhalothrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenvalerate and Esefenvalerate (Sum of RS & SR isomers)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glufosinate-ammonium	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
tau-Fluvalinate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion Ethyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethofenprox	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Bifenthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
4-bromo-2-chlorophenol (metabolite of Profenophos)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770477 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Chlorfenvinphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Etrimfos*	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Omethoate (refer to Dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Iprobenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Propetamphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Temephos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

Remark : BLQ : Below Limit of Quantification, Quantification Limit : 0.01 mg/kg

..... END .....

Authorized Signatory 17/02/17

Note: 1. Test results relate to the submitted sample(s) only.
2. Test report shall not be reproduced except in full, without written approval of the laboratory.
3. Laboratory is not responsible for the authenticity of photocopied test report.
4. The test items will not be retained for perishable products and 1 months in the case of non-perishable samples unless otherwise agreed with the customer or as required by the applicable regulation.
5. The tests marked with (*) are not accredited by NABL.
6. The Report no. with suffix R - Revised Report.

Sample(s) Drawn by The Laboratory	No
Date of Sample Received	31/01/2017
Date of Starting Analysis	11/02/2017
Date of Completion	16/02/2017
Sample Description	**Pomogranate Peel (Punica Granatum)**
Sample Details	Nature: Solid, Qty: 97gms, Stamped/Sealed: No, Packing: Zip lock bag

PARAMETER NAME	RESULT	UOM	METHOD
Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expresed as dieldrin)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlordane (residue to be measured as cis plus trans chlordane)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Diazinon	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dichlorvos (content of di-chloroacetaldehyde (D.C.A.) be reported where possible)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dicofol	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan A	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan B	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770476 REPORT DATE: 16/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Endosulfan-Sulphate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenitrothion	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Alpha Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Beta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Gamma Isomer (Known as Lindane) - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Delta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion methyl (combined residues of parathion methyl and its oxygen analogue to be determined and expressed as parathion methyl)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethion (Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Monocrotophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosalone	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Thiometon (Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Acephate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Methamidophos (A metabolite of Acephate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cypermethrin (sum of isomers) (fat soluble residue)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Decamethrin / Deltamethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Edifenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthion (sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phenthoate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770476 REPORT DATE: 16/02/2017

ARAMETER NAME	RESULT	UOM	METHOD
horate (sum of Phorate, its oxygen nalogue and their sulphoxides and ulphones, expressed as phorate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
irimiphos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
hlorothalonil	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
llethrin and Bioallethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Oxydemeton- methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Permethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Quinalphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Triazophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenpropathrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cyfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glyphosate	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
Transfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Lambda-cyhalothrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenvalerate and Esefenvalerate (Sum of RS & SR isomers)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glufosinate-ammonium	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
tau-Fluvalinate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion Ethyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethofenprox	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Bifenthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
4-bromo-2-chlorophenol (metabolite of Profenophos)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770476 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Chlorfenvinphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Etrimfos*	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Omethoate (refer to Dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Iprobenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Propetamphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Temephos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

Remark : BLQ : Below Limit of Quantification, Quantification Limit : 0.01 mg/kg

..... END .....

Authorized Signatory 17/02/17

Note: 1. Test results relate to the submitted sample(s) only.
2. Test report shall not be reproduced except in full, without written approval of the laboratory.
3. Laboratory is not responsible for the authenticity of photocopied test report.
4. The test items will not be retained for perishable products and 1 months in the case of non-perishable samples unless otherwise agreed with the customer or as required by the applicable regulation.
5. The tests marked with (*) are not accredited by NABL.
6. The Report no. with suffix R - Revised Report.

Sample(s) Drawn by The Laboratory	No
Date of Sample Received	31/01/2017
Date of Starting Analysis	14/02/2017
Date of Completion	16/02/2017
Sample Description	**Yashtimadhu Root (Glycyrrhiza Glabra)**
Sample Details	Nature: Solid, Qty: 99gms, Stamped/Sealed: No, Packing: Plastic Pack

PARAMETER NAME	RESULT	UOM	METHOD
Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expresed as dieldrin)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlordane (residue to be measured as cis plus trans chlordane)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Diazinon	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dichlorvos (content of di-chloroacetaldehyde (D.C.A.) be reported where possible)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dicofol	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan A	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan B	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770475 REPORT DATE: 16/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Endosulfan-Sulphate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenitrothion	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Alpha Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Beta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Gamma Isomer (Known as Lindane) - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Delta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion methyl (combined residues of parathion methyl and its oxygen analogue to be determined and expressed as parathion methyl)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethion (Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Monocrotophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosalone	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Thiometon (Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Acephate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Methamidophos (A metabolite of Acephate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cypermethrin (sum of isomers) (fat soluble residue)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Decamethrin / Deltamethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Edifenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthion (sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phenthoate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770475 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Phorate (sum of Phorate, its oxygen analogue and their sulphoxides and sulphones, expressed as phorate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Pirimiphos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorothalonil	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Allethrin and Bioallethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Oxydemeton- methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Permethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Quinalphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Triazophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenpropathrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cyfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glyphosate	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
Transfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Lambda-cyhalothrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenvalerate and Esefenvalerate (Sum of RS & SR isomers)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glufosinate-ammonium	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
tau-Fluvalinate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion Ethyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethofenprox	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Bifenthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
4-bromo-2-chlorophenol (metabolite of Profenophos)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770475 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Chlorfenvinphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Etrimfos*	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Omethoate (refer to Dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Iprobenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Propetamphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Temephos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

Remark : BLQ : Below Limit of Quantification, Quantification Limit : 0.01 mg/kg

..... END .....

Authorized Signatory 17/02

Note: 1. Test results relate to the submitted sample(s) only.
2. Test report shall not be reproduced except in full, without written approval of the laboratory.
3. Laboratory is not responsible for the authenticity of photocopied test report.
4. The test items will not be retained for perishable products and 1 months in the case of non-perishable samples unless otherwise agreed with the customer or as required by the applicable regulation.
5. The tests marked with (*) are not accredited by NABL.
6. The Report no. with suffix R - Revised Report.

Sample(s) Drawn by The Laboratory	No
Date of Sample Received	31/01/2017
Date of Starting Analysis	11/02/2017
Date of Completion	16/02/2017
Sample Description	**Bala Root (Sida Cordifolia)**
Sample Details	Nature: Solid, Qty: 100gms, Stamped/Sealed: No, Packing: Zip lock bag

PARAMETER NAME	RESULT	UOM	METHOD
Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expresed as dieldrin)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlordane (residue to be measured as cis plus trans chlordane)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Diazinon	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dichlorvos (content of di-chloroacetaldehyde (D.C.A.) be reported where possible)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dicofol	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan A	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan B	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770474 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Endosulfan-Sulphate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenitrothion	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Alpha Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Beta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Gamma Isomer (Known as Lindane) - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Delta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion methyl (combined residues of parathion methyl and its oxygen analogue to be determined and expressed as parathion methyl)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethion (Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Monocrotophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosalone	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Thiometon (Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Acephate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Methamidophos (A metabolite of Acephate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cypermethrin (sum of isomers) (fat soluble residue)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Decamethrin / Deltamethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Edifenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthion (sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phenthoate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770474 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Phorate (sum of Phorate, its oxygen analogue and their sulphoxides and sulphones, expressed as phorate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Pirimiphos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorothalonil	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Allethrin and Bioallethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Oxydemeton- methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Permethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Quinalphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Triazophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenpropathrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cyfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glyphosate	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
Transfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Lambda-cyhalothrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenvalerate and Esefenvalerate (Sum of RS & SR isomers)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glufosinate-ammonium	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
tau-Fluvalinate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion Ethyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethofenprox	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Bifenthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
4-bromo-2-chlorophenol (metabolite of Profenophos)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770474 **REPORT DATE: 16/02/2017**

PARAMETER NAME	RESULT	UOM	METHOD
Chlorfenvinphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Etrimfos*	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Omethoate (refer to Dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Iprobenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Propetamphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Temephos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

Remark : BLQ : Below Limit of Quantification, Quantification Limit : 0.01 mg/kg

..... END .....

Authorized Signatory 17/02/17

Note: 1. Test results relate to the submitted sample(s) only.
2. Test report shall not be reproduced except in full, without written approval of the laboratory.
3. Laboratory is not responsible for the authenticity of photocopied test report.
4. The test items will not be retained for perishable products and 1 months in the case of non-perishable samples unless otherwise agreed with the customer or as required by the applicable regulation.
5. The tests marked with (*) are not accredited by NABL.
6. The Report no. with suffix R - Revised Report.

Sample(s) Drawn by The Laboratory	No
Date of Sample Received	31/01/2017
Date of Starting Analysis	15/02/2017
Date of Completion	17/02/2017
Sample Description	**Laksha (Laccifer Lacca)**
Sample Details	Nature: Solid, Qty: 92gms, Stamped/Sealed: No, Packing: Zip lock bag

PARAMETER NAME	RESULT	UOM	METHOD
Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expresed as dieldrin)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlordane (residue to be measured as cis plus trans chlordane)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
o p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDD	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDE	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Diazinon	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dichlorvos (content of di-chloroacetaldehyde (D.C.A.) be reported where possible)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
p p - DDT	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dicofol	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan A	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endosulfan B	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770479 REPORT DATE: 17/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Endosulfan-Sulphate	BLQ	mg/kg	MC/SOP/INS/34 based or AOAC 2007.01
Fenitrothion	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Alpha Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Beta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Gamma Isomer (Known as Lindane) - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Delta Isomer - HCH	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion methyl (combined residues of parathion methyl and its oxygen analogue to be determined and expressed as parathion methyl)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethion (Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Monocrotophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phosalone	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Thiometon (Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Acephate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Methamidophos (A metabolite of Acephate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cypermethrin (sum of isomers) (fat soluble residue)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Decamethrin / Deltamethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Edifenphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenthion (sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as fenthion)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Phenthoate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

TEST REPORT

REPORT NO.: 161770479 REPORT DATE: 17/02/2017

PARAMETER NAME	RESULT	UOM	METHOD
Phorate (sum of Phorate, its oxygen analogue and their sulphoxides and sulphones, expressed as phorate)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Pirimiphos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorothalonil	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Allethrin and Bioallethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Oxydemeton- methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Permethrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Quinalphos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Triazophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Profenophos	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenpropathrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Chlorpyrifos Methyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Cyfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Endrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glyphosate	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
Transfluthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Lambda-cyhalothrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Fenvalerate and Esefenvalerate (Sum of RS & SR isomers)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Glufosinate-ammonium	BLQ	mg/kg	MC/SOP/INS/41 based on NRCG-EURL -SRM-VERSION 7.1 Nov 2013
tau-Fluvalinate	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Parathion Ethyl	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Ethofenprox	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
Bifenthrin	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01
4-bromo-2-chlorophenol (metabolite of Profenophos)	BLQ	mg/kg	MC/SOP/INS/34 based on AOAC 2007.01

ANALYTICAL REPORT: KWATH 1

TEST	RESULT
APPEARANCE	**Syrupy liquid with suspended particle**
COLOUR	**Light Brown Colour**
ODOUR	**Aromatic**
TASTE	**Sweet & Sour**
pH	**4.6**
DENSITY	**1.01 gm/ml**
TOTAL SOLID CONTENT	**1.25 %**

ANALYTICAL REPORT : KWATH 2

TEST	RESULT
APPEARANCE	**Syrupy liquid with suspended particle**
COLOUR	**Light Brown Colour**
ODOUR	**Aromatic**
TASTE	**Sweet & Sour**
pH	**4.6**
DENSITY	**1.02 gm/ml**
TOTAL SOLID CONTENT	**1.22 %**

ANALYTICAL REPORT : KWATH 3

TEST	RESULT
APPEARANCE	**Syrupy liquid with suspended particle**
COLOUR	**Light Brown Colour**
ODOUR	**Aromatic**
TASTE	**Sweet & Sour**
pH	**4.6**
DENSITY	**1.04 gm/ml**
TOTAL SOLID CONTENT	**1.18%**

ANALYTICAL REPORT

BATCH: 1 CREAM (CM)

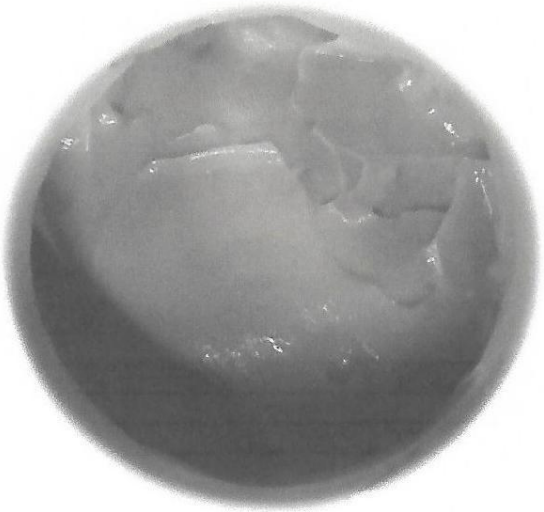
TEST	RESULT
APPEARANCE	Semi Solid Soft Cream
COLOUR	Light Brown
ODOUR	Characteristic
TASTE	Slightly Bitter
LOSS ON DRYING	6 %
pH	4.06
ACID VALUE	9.45
PEROXIDE VALUE	1.1 meq/kg.
TEST FOR AFLATOXINS	Negative
DENSITY	0.8825 gm/ml

ALARSIN

ANALYTICAL REPORT

BATCH: 2 CREAM (CM)

TEST	RESULT
APPEARANCE	Semi Solid Soft Cream
COLOUR	Light Brown
ODOUR	Characteristic
TASTE	Slightly Bitter
LOSS ON DRYING	5.8 %
pH	4.1
ACID VALUE	9.28
PEROXIDE VALUE	1.3 meq/kg.
TEST FOR AFLATOXINS	Negative
DENSITY	0.8973 gm/ml



ALARSIN

ANALYTICAL REPORT

BATCH: 3 CREAM (CM)

TEST	RESULT
APPEARANCE	Semi Solid Soft Cream
COLOUR	Light Brown
ODOUR	Characteristic
TASTE	Slightly Bitter
LOSS ON DRYING	6.2 %
pH	4.3
ACID VALUE	9.45
PEROXIDE VALUE	1.1 meq/kg.
TEST FOR AFLATOXINS	Negative
DENSITY	0.8973 gm/ml

ALARSIN

ANALYTICAL REPORT

BATCH: 1 CREAM (LM)

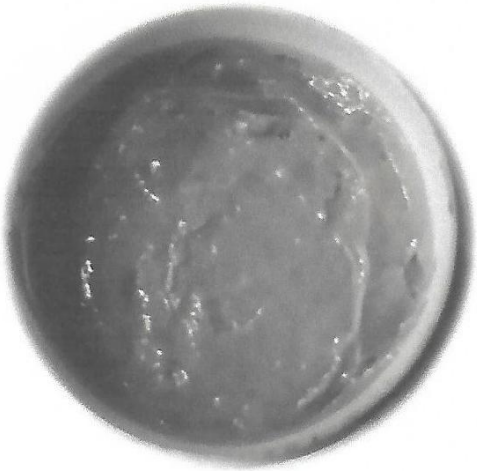
TEST	RESULT
APPEARANCE	Semi Solid Soft Cream
COLOUR	Light Brown
ODOUR	Characteristic
TASTE	Slightly Bitter
LOSS ON DRYING	5.7 %
pH	5.6
ACID VALUE	11.2
PEROXIDE VALUE	1.5 meq / Kg
TEST FOR AFLATOXINS	Negative
DENSITY	0.8427 gm/ml

ALARSIN

ANALYTICAL REPORT

BATCH: 2 CREAM (LM)

TEST	RESULT
APPEARANCE	Semi Solid Soft Cream
COLOUR	Light Brown
ODOUR	Characteristic
TASTE	Slightly Bitter
LOSS ON DRYING	5.1 %
pH	5.5
ACID VALUE	10.36
PEROXIDE VALUE	1.6 meq / kg.
TEST FOR AFLATOXINS	Negative
DENSITY	0.8404 gm/ml

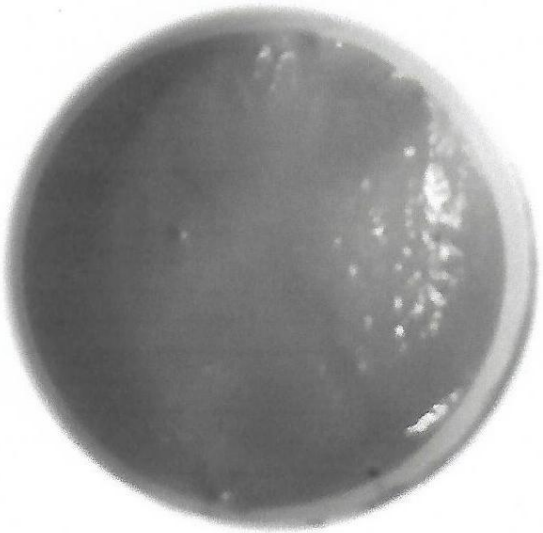


ALARSIN

ANALYTICAL REPORT

BATCH: 3 CREAM (LM)

TEST	RESULT
APPEARANCE	Semi Solid Soft Cream
COLOUR	Dark Brown
ODOUR	Characteristic
TASTE	Slightly Bitter
LOSS ON DRYING	5.75 %
pH	5.8
ACID VALUE	9.9
PEROXIDE VALUE	1.2 meq / kg
TEST FOR AFLATOXINS	Negative
DENSITY	0.8423 gm/ml



ALARSIN