## AN OPEN LABELED, RANDOMIZED, TWO ARM STUDY OF EFFECT OF YASHTIMADHU CHOORNA WITH MILK ON HEALTH AND COGNITIVE PARAMETERS IN HEALTHY VOLUNTEERS – A SCHOOL BASED STUDY

#### A Thesis

# SUBMITTED TO THE TILAK MAHARASHTRA VIDYAPEETH PUNE

# FOR THE DEGRE OF DOCTOR OF PHILOSOPHY

In Ayurveda (Kayachikitsa) Under the Board of Ayurveda Studies



By

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UNDER THE GUIDANCE OF

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Year 2021

### CERTIFICATE OF THE SUPERVISOR

It is certified that work "An Open Labeled, Randomized, Two Arm Study of Effect of Yashtimadhu Choorna with Milk on Health and Cognitive Parameters in Healthy Volunteers – A School Based Study" is an original research work done by Dr. Vaishali Shailesh Deshpande under my supervision for the degree of Doctor of Philosophy in Ayurveda (Kayachikitsa) to be awarded by Tilak Maharashtra Vidyapeeth, Pune.

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#### INTRODUCTION

Longevity of life in perfect healthy state of mind and body is the dream seen by our sages for every individual since centuries and eras. Thousands of years ago when man had his first interaction with disease, they found for him a perfect tool called 'Ayurveda'. After Herculean efforts they brought it on the earth. It helped them in understanding the disease as well as health and empowered them with weapons of herbs, minerals, metals and various animal products to combat with diseases and regain health. It also helped them to maintain health. It taught them about types of life happy, unhappy, healthy, unhealthy and various means to live happy and healthy life. It also taught them various fundamentals of science like Pancha Mahabhoota Siddhanta, Samanya Vishesh Siddhanta, and Tridosha Siddhanta etc. All in all it gave a clear understanding of what a life is. Such a science that gives full knowledge and understanding of a **Tatva** is called as **Darshan Shastra**. So we can say that Ayurveda is not merely a science of life, it is **Darshan Shastra of Life**. It has served humankind for thousands of years and is still serving them in their struggle for health.

Assurance given by Ayurveda to human race is 'healthy and long life'. This is achieved by two fold aim of Ayurveda i.e. maintenance of health in healthy individual and treating the diseased individual. Rasayana is distinct branch in Ayurved. It aims to delay degenerative process by maintaining strength of Deha, Mana and Indriyas even in older age as well as maintains health. So an old person can have same vigor and vitality as a young. Rasayana is mentioned in great details in almost all the classical treatises. Separate Adhyayas are dedicated to Rasayana explaining its classification in different ways, indications, contraindications, methods etc. One of its types is Medhya Rasayana. Anything that improves intellect, memory and other functions related to Indriya, Mana and Buddhi is Medhya. Medhya Rasayanas are the herbs/ formulations which improve the intellect. Four Medhya Rasayana are mentioned in Charak Samhita; administration of Yashtimadhu Choorna along with milk is amongst them.

Aacharya Sushruta has defined health as, "The state of equilibrium of all the Doshas, Agni, Dhatus and Malas accompanied by normal functions of Dhatu and Malas as well as tranquility of Atma, Indriya & Mana is said to be health", 6 which is also appreciated by World Health

Organization. For healthy status harmony of all the body constituents is required. Human being is the intelligent living organism in the universe. Brain and its complex working process separate it from other living creatures. Major functions of brain include obtaining information, storage and recollection of information when needed, application of information etc. To live meaningful life, healthy status along with sound mind and intellectual abilities are required. In today's competitive scenario everyone has to take great efforts to achieve their goals. For this achievement sound body, mind, spiritual state is required. The goals can be achieved if both physical fitness as well as intelligence is present. Mere presence of intelligence is not sufficient. Children are backbone of the country. They are more prone to illness, infections etc and also have to tackle academic burden. If Medhya Rasayana like Yashtimadhu, is administered in the developing age, better physical as well as intellectual functions can be attained. According to modern medical science Rasayana is, "A product having properties of antioxidant, immunomodulatory, anti-stress, anti ageing, nootropic, and provides promotion of health."

The knowledge of various medicinal herbs, herbal and herbomineral formulations are nothing but the weapons given by Ayurveda to mankind. In Sharangdhar Samhita Poorvakhanda Adhyaya 1 it is nicely quoted that diversity of flora and fauna has no bounds. Hundreds of thousands of members of Plant Kingdom are spread all through the lands and oceans varying from small, unicelluar, micoscopic algae to gigantic ones penetrating hundreds of meters in the sky. With the boon to relieve from diseases, they appear to man as thirty three million Gods told in oriental literature offering their blessings to him. And in the shape of wise administrator of this plethora of medicines, according to their properties and actions comes the Bhishak. Doubtless knowledge of various properties and actions of the plant, their combinations and permutations, various formulations enables him to show to the world surprising works a medicine can do. That's why it is wisely said that a single drug with correct knowledge and correct usage in terms of indications, dose, suitable form, suitable vehicle, suitable time of administration etc can show miraculous effects and can help to achieve the things in Ehalok as well as Paralok.

Yashtimadhu (Glycerrhiza glabra) is a common herb which is used abundantly in the treatment of various diseases. It is greatly useful as Chakshushya (drug of choice in

ophthalmic diseases), Vrishya (aphrodisiac), Keshya (useful in problems related to hair like graying of hair, hair loss etc), Kanthya (beneficial for disease of throat), Varnya (improves colour/complexion of skin), Virajaniya (brings normal colour), Ropaniya (improve wear and tear). Yashtimadhu is sweet, bitter in taste (Madhur, Tikta Rasa), has cold potency (Sheet Veerya) and sweet post digestive effect (Madhur Vipaka). It is widely used in various diseases of gastrointestinal, musculoskeletal, respiratory, nervous system. Ksheera (milk) is sweet in taste, has cold potency and sweet post digestive effect (Madhur Vipaka).

Ayurveda has remained unexplored as far as remedies for improving and maintaining better quality of life is concerned. The Shastra is enriched with number of herbal, hrebo-mineral preparations for the treatment of different types of diseases. Rasayana Chikitsa is one of the constructive tools of Ayurveda which is most important for delayed ageing process as well as prevention of occurrence of diseases.

The present research topic entitled, "An Open Labeled, Randomized, Two Arm Study of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study" was planned with aim to undertake a clinical evaluation of the effect of consumption of Yashtimadhu Choorna with milk on health and cognitive parameters in healthy volunteers. To evaluate the effect various assessment parameters like Digit Letter Substitution Test (DLST), Six Letter Cancellation Test (SLCT) were used. The health status of children were also paid attention with respect to episodes, severity and duration of illnesses, energy levels, growth parameters like height and weight, number of absent days from school due to illness etc.

It is a humble effort under the expert guidance of esteemed Guide to explore the treatise of Ayurveda to find an effective and cheaper solution for physical as well as cognitive development of children.

An Open Labeled, Randomized, Two Arm Study of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study Page 3

<sup>&</sup>lt;sup>1</sup>Paradkar H.S.(2009).Sutrasthana Aayushkamiya Adhyaya. In A.M. Kunte & K.R. Navare (EDs), Ashtanga Hridaya (5).Varanasi:Chaukhamba Publications.

<sup>&</sup>lt;sup>2</sup>Acharya Y.T. (2009). Chikitsasthana Rasayanadhyaya. In Y.T. Acharya (Eds), Charaksamhita (376-390). Varanasi: Chaukhamba Publications.

<sup>3</sup>Acharya Y.T. & Acharya N.R. (2010). Chikitsasthana Sarvopghata Shamaniya-Nivrutsantapiya Rasayan Adhyaya. In Y.T. Acharya & N.R. Acharya (Eds), Sushruta Samhita (498-507). Varanasi: Chaukhamba Publications.

<sup>4</sup>Paradkar H.S. (2009). Uttar Tantra Rasayan Vidhi Adhyaya. In A.M. Kunte & K.R. Navare (EDs), Ashtanga Hridaya (923-939). Varanasi: Chaukhamba Publications.

<sup>5</sup>Acharya Y.T. (2009). Chikitsasthana Rasayanadhyaya – Karprachitiya Pada In Y.T. Acharya (Eds), Charaksamhita (385). Varanasi: Chaukhamba Publications.

<sup>6</sup>Acharya Y.T. & Acharya N.R. (2010). Sutrasasthana Doshadhatumalakshayavriddhi Vidnyaniyadhyaya. In Y.T. Acharya & N.R. Acharya (Eds), Sushruta Samhita (124). Varanasi: Chaukhamba Publications.

<sup>7</sup>Acharya Y.T. (2009). Sutrasthana Yajjapurushiya Adhyaya. In Y.T. Acharya (Eds), Charaksamhita (132). Varanasi: Chaukhamba Publications.

#### REVIEW OF AYURVEDIC LITERATURE

A long and healthy life has been cherished by Man since antiquinity. Ayurveda is the science of life through which a prolonged happy and healthy life can be attained.[Sh.Su.1/15, Ch.Su.30/23]. This ancient holistic science has a dwell motto of maintaining the health of a healthy person and to alleviate disorders of diseased. [Sh.Su.1/15, Ch.Su.30] Ayurveda still remains a vital health care system even in today's urbanized advanced world, shows its vitality and inherent strength. Even in the primeval classical period Ayurveda was already a well developed science of medicine and was practiced in the form of Astang Ayurveda i.e. Medicine with eight specialties viz, Kayachikitsa, Shalakya, Shalya, Visha, Bhoot, Kaumar, Rasayan and Vajikaran Tantras. The two fold aim of ayurveda can be very well furnished through the special branch Rasayan. All individuals want to look forever young and increase our life-span by staying healthy. Rasayanas or vitalizers, as they are called, do exactly the same. They replenish the vital fluids of our body, thus keeping us away from diseases

Rasayana appears to have been practiced as an important specialty aiming at rejuvenation, geriatric care, mental competence, increased immunity, etc to possess a long and healthy disease free life. Thus it was the key for maintaining positive health and longevity. Rasayana stood testimony for keeping up human hay and healthy and thus fulfilling the commitment made by ayurveda. It deals with preservation and promotion of health and vigor and thereby is more for promotional health i.e. even the normal individuals can make use of this branch to increase body strength, health, and body resistance to protect them from any ailment. As Rasayanas are indicated for Jaranashana, they can be utilized in Swastha individuals to maintain the Swasthya and to delay the ageing process. Aachrya Sharangdhara has mentioned the best suitable Rasayana herb for each decade of life starting from 1<sup>st</sup> yr to 100<sup>th</sup> yr.

Rasayana not only shows effects the body (physical status) but effects equally on the mind (mental status) as well. Accordingly Rasayana have been classified as

## 1) Sharir Rasayana:-

Sharir Rasayana primarily aims at equilibrium of Sharir Doshas and Dhatus, improving Agni, reviewing the abnormality in the Srotas and imparting strength to the body. For e.g. Triphala, Ghee, Milk, Shatavari, Amalaki, Haritaki, etc.

### 2) Manas Rasayana:-

Manas Rasayana are meant for enhancing the total mental level of a person by pacifying the manas doshas. It helps in achieving the Sattvik Avastha of Manas leading to Salvation. Ojas Agni, immunity, strength and above all even the normalcy of the body depends on the mental state and its happiness (Manas swasthaya). Vishada or instability of the mind is considered as foremost in causing and increasing disease. To keep the mental state in balance and to assure happiness of the mind these Rasayanas are advocated .They are called as 'Medhya Rasayana'. Also these Rasayanas improve the Dhi, Dhruti, Smruthi, (i.e. improves intellect and memory). Medhya Rasayanas have been described at various places in all the classical texts. Brahmi, Shankhpushpi, Mandukparni, Yastimadhu, Ghee, and Aachar Rasayana are some of the examples of Medhya Rasayana.

In ayurvedic literature various terms have been used to describe the intellect, cognition process and perception of knowledge. These terms include Buddhi, Dhi, Dhruti, Smruti, Medha, Pradnya, Prama etc. to understand the Medhya Rasayana concept in depth knowledge regarding these terminologies is essential.

#### 1. Buddhi

## Shabdakalpadruma

बुद्धिः, स्त्री, (बुध्यतेऽनयेति । बुध् + क्तिन् ।) निश्चयात्मिकान्तःकरणवृत्तिः । इति वेदान्त- सारः ॥सविकल्पकज्ञानम् । इति चण्डी- टीकायां नागभट्टः ॥ तत्पर्य्यायः । मनीषा २ धिषणा ३ धीः ४ प्रज्ञा ५ शेमुषी ६ मतिः ७ प्रेक्षा ८ उपलब्धिः ९ चित् १० सम्बित् ११ प्रतिपत् १२ ज्ञिप्तिः १३ चेतना १४ । इत्यमरः । १ । ५ । १ ॥ धारणा १५ प्रतिपत्तिः १६ मेधा १७ मननम् १८ मनः १९ ज्ञानम् २० बोधः २१ हृल्लेखः २२ संख्या २३ प्रतिभा २४ । इति राजनिर्घण्टः ॥ आत्मजा २५ पण्डा २६ विज्ञा- नम् २७ । इति शब्दरत्नावली ॥ \* ॥ अस्याः स्वरूपं यथा, -- "बुद्धिर्विवेचनारूपा सा ज्ञानजननी श्रुतौ ॥" इति ब्रह्मवैवर्ते प्रकृतिखण्डे २३ अध्यायः ॥ अस्या अध्यात्माधिभूताधिदैवतानि यथा, -- "अध्यात्मं बुद्धिरित्याहुः षडिन्द्रियविचारिणी । अधिभूतञ्च मन्तव्यं ब्रह्मा तत्राधिदैवतम् ॥" इति महाभारते आश्वमेधिकपर्व्य ॥ \* ॥ सा च सात्त्विकराजसतामसभेदेन त्रिविधा । सात्त्विकी यथा, -- "प्रवृत्तिञ्च निवृत्तिञ्च कार्य्याकार्य्ये भयाभये । बन्धं मोक्षञ्च या वेत्ति बुद्धिः सा पार्थ ! सात्त्विकी ॥" राजसी यथा, -- "यथा धर्म्मधर्म्भञ्च कार्य्यञ्चाकार्यमेव च । अयथावत्

प्रजानाति बुद्धिः सा पार्थ ! राजसी ॥" तामसी यथा, -- "अधम्मै धर्म्ममिति या मन्यते तमसावृता । सर्व्वार्थान् विपरीतांश्च बुद्धिः सा पार्थ ! तामसी ॥" इति श्रीभगवद्गीता ॥ तस्याः पञ्च गुणा यथा, -- "इष्टानिष्टविपत्तिश्च व्यवसायः समाधिता । संशयः प्रतिपत्तिश्च बुद्धेः पञ्च गुणान् विदुः ॥" इति महाभारते मोक्षधर्मः । इष्टानिष्टविपत्तिः इष्टानिष्टानां वृत्तिविशेषाणां विपत्तिर्नाशः निद्रारूपा वृत्तिरित्यर्थः । व्यव- सायः उत्साहः । समाधिता चित्तस्थैर्यं चित्तवृत्तिनिरोध इत्यर्थः । संशयः कोटिद्वयस्पृक् ज्ञानम् । प्रतिपत्तिः प्रत्यक्षादिप्रमाणवृत्तिः । इति तट्टीका ॥ \* ॥ तस्याः सप्त गुणा यथा -- "शुश्रूषा श्रवणञ्चैव ग्रहणं धारणन्तथा । ऊहोपोहोऽर्थविज्ञानं तत्त्वज्ञानञ्च धीगुणाः ॥" इति हेमचन्द्रः ॥ \* ॥ तस्या वृत्तिः पञ्चधा यथा । प्रमाणम् १ विप- र्य्ययः २ विकल्पः ३ निद्रा ४ स्मृतिः ५ । इति पातञ्जलम् ॥ \* ॥ बुद्धिक्षयकरा यथा, -- "शोकः कोधश्च लोभश्च कामो मोहः परासुता । ईर्ष्या मानो विचिकित्सा कृपासूया जुगुप्सता ॥ द्वादशैते बुद्धिनाशहेतवो मानसा मलाः ।" इति कालिकापुराणे १८ अध्यायः ॥ \* ॥ अपि च । "बुद्धिक्षयकरा एते माषकासवमृत्तिकाः ॥" बुद्धिवृद्धिकरा यथा, -- "निम्वाटरूषवृन्ताश्च बुद्धिवृद्धिकरा मताः ॥ बुद्धिश्वयकरान्नित्यं त्यजेद्राजा च भोजने । भोजयेदन्वहं बुद्धिवृद्धिहेतुं नृपोत्तम ! ॥" इति कालिकापुराणे ८९ अध्यायः ॥ \* ॥ न्यायमते सा विभुगुणः पुनिर्द्वविधा अनुभूतिः स्मृतिश्च । यथा, -- "विभुर्बुद्ध्यादिगुणवान् बुद्धिस्तु द्विविधा मता । अनुभूतिः स्मृतिश्च स्यादनुभूतिश्चतुर्विधा ॥ प्रत्यक्षमप्यतिस्त्वशेपमितिशव्दजे।" इति भाषापरिच्छेदः ॥

#### Amarkosha

बुद्धि स्त्री।

बुद्धिःसमानार्थकःबुद्धि,मनीषा,धिषणा,धी,प्रज्ञा,शेमुषी,मति,प्रेक्षा,उपलब्धि,चित्,संविद्,प्रतिपत्,ज्ञप्ति,चेतना,संज्ञा,आ त्मन्,प्रधान,प्रज्ञान 1।5।1।1।1

बुद्धिर्मनीषा धिषणा धीः प्रज्ञा शेमुषी मतिः। प्रेक्षोपलब्धिश्चित्संवित्प्रतिपत्ज्ञप्तिचेतना॥

अवयव : वासना

वैशिष्ट्यवत् : निश्चयः धारणावत्बुद्धिः, तर्कः, निश्चयः, मोक्षोपयोगिबुद्धिः, शिल्पादिविषयकबुद्धिः, मोक्षः, शङ्का, अन्यशुभद्रेषबुद्धिः, वितर्कः

पदार्थ-विभागः : , गुणः, बुद्धिः

## Vachaspatyam

'''बुद्धि'''¦ स्त्री॰ बुध--क्तिन्।

१ ज्ञाने.

२ सुखदुःखाद्यष्टबिध-धर्मयुते प्रकृतिपरिणामभेदे

"महत्तत्त्वमिति प्रोक्तं बुद्धि-तत्त्वं तदुच्यते" सां॰ प्र॰ भा॰ धृतवाक्यम्। वेदान्तोक्तेनिश्चयात्मकवृत्तियुते

३ अन्तःकरणे च।

"मनोबुद्धिरह-ङ्कारश्चित्तं करणयान्तरम्। संशयो निश्चयो गर्बः स्मरणंविषया अमी" वेदान्तप॰।

४ धर्मपत्नीभेदे भा॰ आ॰

६६ अ॰। कणा॰ सूत्रोपस्करवृत्तौ सांख्यमतसिद्धमहत्तत्वरूपबुद्धितत्व-निराकरणेन बुद्धेर्ज्ञानपर्य्यायता तद्भोदाश्चोका यथा "द्र-व्येषु ज्ञानं व्याख्यातम्" सू॰ "विषयेण तिषयिणं तृतीया-ध्यायस्थमुपलक्षयति।

"इन्द्रियार्यप्रसिद्धिरिन्द्रियार्थेभ्योऽर्थान्तरस्य हेतुः"

"आत्मेन्द्रियार्थसन्निकर्षाद् यन्निष्पद्यते तद-न्यत्र" इत्येताभ्यां स्ताभ्यां ज्ञानं व्याख्यातिमत्यर्था"। तत्रबुद्धिरुपलिध्यर्जानं प्रत्यय इति पर्य्यायाः" गौ॰ सू॰ समान-तन्त्रे बुद्धिलक्षणे साङ्ख्यमतिनरासार्थं पर्थ्यायाभिधानम्। साङ्ख्या हि बुद्ध्यादिशब्दानामर्थभेदमाचक्षते तथा हि सत्त्व-रजस्तमसां साम्यावस्था प्रकृतिः, सा चैकैव पुरुषास्तु परंभिद्यन्ते ते च कूटस्था नित्या अपरिणाभिनो नित्यचैतन्य-स्वभावाः ते च पङ्गवोऽपरिणामित्वात् पकृतिस्त्वन्धा जड-वात यदा विषयभोनेच्छा प्रकृतिपुरुषभेददिदृक्षा च प्रकृते-र्भवित तदा सा पुरुषोपरागवशात् परिणमेत् तस्याश्चाद्यःगरिणामो द्धिरन्तःकरणविशेषः बुद्धिरेव महत्तत्र तदु-[Page4584-b+ 38] क्तम् "प्रकृतेर्सहान्" इति सां॰ सू॰। सा च बुद्धिर्दर्पणवान्नर्मला तस्याश्च बहिरिन्द्रियप्रणाडिकया विषयाकारो यःपरिणितिभेदो घट इति पट इत्याद्याकारस्तज्ज्ञानं वृत्ति-रिति चाख्यायते खच्छार्या बुद्धौ वर्त्तमानेन ज्ञानेन चैत-ज्यस्य पुरुषस्य भेदाग्रहादहं जानामीति यौऽभिमानविशेषःसैवोपलिधः। स्रक्चन्दनादिविषयसित्र कर्षादिन्द्रियप्रणा-डिकयैव सुखदुःखाद्याकारो बुद्धरेव यः परिणामविशेषःस प्रत्ययः। अतएव ज्ञानसुखदुःखेच्छाद्वेषप्रयत्नसंस्कारध-र्माऽधर्माः सर्वएव बुद्धेः परिणामविशेषाः सूक्ष्ममात्रयाप्रकृतावे वर्त्तमाना अवस्थाभेदादाविर्भवन्ति तिरोभवन्तिच। पुरुषस्तु पृष्करपलाशवित्रर्लेपः प्रतिविम्बते परं

बुद्धा-वितिं यन्मन्यन्ते। तदनेन पर्य्यायाभिधानस्चितप्रमाणेनिनराक्रियते तथा हि बुद्धिशब्दो यदि बुध्यतेऽनयेति कर-णव्युत्पन्नस्तदा मन एव तत्पर्य्वस्यित नच मनः प्रत्यक्षम्बुद्धिस्त्वहं बुध्ये इति प्रत्यक्षवेद्यैव। नचान्तःकरणस्य ज्ञाना-द्याधर्मा कर्तृधर्मत्वेनैव तेषां सिद्धेः भवित हि अहं जानेअहं प्रत्येमि अहमुपलभे इत्यहन्त्वसामानाधिकरण्येनप्रतिभासः। अभिमानोऽसाविति चेत् तात्त्विकत्वे वाधका-भावात्। पुरुषस्यागन्तुकधरानाधारत्वं कूटस्थत्वं तदेवबाधकिमिति चेन्नामन्तुकधर्माधारत्वेऽि नित्यत्वसम्भवात्व हि धर्मी धर्मश्चेत्येकं तत्त्वं येन धर्मोत्पादिवनाशावेवधर्म्युत्पादिवनाशौ स्यातां तथा च यएव चेतायते स एवबुध्यते जानात्युपलभ्यते पत्येति चेति नार्थान्तरकल्पनायुक्तेति दिक्। तच्च ज्ञानं द्विविधं विद्या चाविद्या चतिद्या चतुर्व्विधा प्रत्यक्षलैङ्गिकस्मृत्यार्षलक्षणा। अवि॰द्याऽिप चतुर्व्विधा संशयविपर्य्ययस्वप्रानध्यावसायलक्षणा। तत्र यल्लैङ्गिकं तदिनिन्द्रियजम् कृतएतदित्याहं उप॰ वृ॰। "तत्रात्मा मनश्चाप्रत्यक्षे" कणा॰ सू॰।

"आत्माऽत्र परात्मा स्वात्मा वा खात्मिनि मानसस्य क्वा॰चित्काहम्प्रत्ययस्याहं गौरः कृशो

महाबाहुरिव्यादिप्रत्ययतिरस्कृतत्वात् स्वात्मनोऽप्यप्रत्यक्षतोक्ता। चकारादा-काशकालदिशां षायोः परमाण्नाञ्च द्रव्याणामुपग्रहः। इन्द्रियजमपि द्विविधं सर्वज्ञीयमसर्वज्ञीयञ्च सर्वज्ञीयं योग-जधर्मलक्षणया प्रत्यासत्त्या तत्तत्पदार्थसार्थज्ञानं तथा हिपरमाणवः प्रत्यक्षप्रसक्ताः प्रमेयत्वादिभिधेयत्वात्सत्त्वात्। सामग्रीविरहात् कथमेवं महत्त्वस्यापि प्रत्यक्षंप्रति कारणत्वात् न च परमाणवो महन्तः रूपवत्त्व-स्यापि चाक्षुषप्रत्यक्षकारणत्वात् न च दिगादयो रूपवन्त्व[Page4585-a+ 38] इति चेन्न योगजधर्मसहकारिणा मनसैव तत्सम्भवात्तदुपग्रहाञ्चक्षुरादिना वा। अचिन्त्त्यप्रभावोहि योगजोधर्मो न सहकार्यन्तरमपेक्षते। विवादाध्यासितः पुरुषोन सर्वज्ञः पुरुषत्वादहमिवेत्यादि तु प्रमामकरो न मीमां-साभिज्ञः पुरुषत्वादहमिवेत्यादिवद्विपक्षवाधकतर्कशून्य-त्वादप्रयोजकम्। असर्वज्ञीयञ्च प्रत्यक्षं द्विविधं सिविकल्पकंञ्च सविकल्पकं ज्ञानं न प्रमाणमिति कीर्त्ति-दिङ्नागादयः तथा हि अभिलापर्ससगेयोग्यप्रतिभासंहि तत् नह्यभिलापेन नाम्ना सम्भवत्यर्थस्य सम्बन्धो येनघट इति पट इति वा नामानुरञ्जितः प्रत्ययः स्यात्वच जात्यादि परमार्थसत् येन तद्वैशिष्ट्यं विषयेषु इन्द्रियगोचरः तस्मादिन्द्रियेणालोचनं जन्यते आलोचनमहिम्नाच सिवेकल्पकमृत्पद्यमानं तत्रार्थे प्रवर्त्तयत् प्रत्यक्षमितिचोच्यते इति। तञ्चैतदन्पपन्नमभिलापसंसर्गयोग्यप्रति-भासञ्च भवेत् प्रमाणञ्चेन्द्रियार्थसित्वर्णवन्न स्यादितिसन्दिग्धव्यतिरेकित्वं

नामवैशिष्ठ्यञ्च चाक्षुषज्ञाने सम्भव-त्येव सुरभि चन्दनमितिवदुवनीतभानसम्भवात्। यद्वासंज्ञावैशिष्ठ्यं प्रत्यक्षज्ञाने न भासते संज्ञायाः स्मरणमात्रम्स्मृतैव साऽर्थव्यावर्त्तिका अभावज्ञाने प्रतियोगिस्मरणवत्जात्यादिकञ्च वस्तुभृतं साधितमेबातः सविकल्पकमपीन्द्रि-यार्थसन्निकर्षजत्वात् प्रत्यक्षम् प्रमाणम्। नन् निर्विकल्पकंन व्यवहारप्रवर्त्तकं न वा व्यवहारविषय इति किन्तत्रप्रमाणमिति चेत् सविकल्पकमेव तद्धि विशिष्टज्ञानम् न चिवशेषणज्ञानमन्तरेण तदुत्पद्यते विशिष्टज्ञाने हि विशेषणज्ञानविशेष्येन्द्रियसन्निकर्षतट्भयासंसर्गाग्रहस्य कार-णत्वावधारणात्" उपस्करवृत्तिः। "सा च सात्त्विकराजसतामसभेदेन त्रिविधा। तत्र सा-त्त्विकी यथा "प्रवृत्तिञ्च निवृत्तिञ्च कार्य्याकार्य्ये भयाभये। बन्धं मोक्षञ्च या वेत्ति बुद्धिः सा पार्थ! सात्त्विकी"। राजसी यथा "यया धर्ममधर्मञ्च कार्य्यञ्चाकार्य्यमेव च। अयथावत् प्रजानाति बुद्धिः सा पार्थ! राजसी"। तामसी यथा "अधर्मं धर्ममिति या मन्यते तमसावृता। मर्वा-र्थान् विपरीतांश्च बुद्धिः सा पार्थ! तामसी" गीता॰तस्याः पञ्चगुणा यथा।"इष्टाऽनिष्टविपत्तिश्च व्यव-सायः समाधिता। संशयप्रतिपत्तिश्च बुद्धेः पञ्च गु-णान् विदुः" महाभारते मोक्षधर्मः"इष्टानि-ष्टविपत्तिः इष्टानिष्टार्ना वृत्तिविशेषाणां विपत्तिर्नाशःनिद्रास्वपा वृत्तिरित्यर्थः। व्यवसायः उत्साहः। समा-[Page4585-b+ 38] धिता चित्तस्थैर्य्यं चित्तवृत्तिनिरोध इत्यर्थः संशयःद्वयस्पृक् ज्ञानम्। प्रतिपत्तिः प्रत्यक्षादिप्रमाणवृत्तिः" तट्टीका। तस्याः सप्त गुणा यथा "शुश्रूषा श्रवण-ञ्चैव ग्रहणं धारणन्तथा। ऊहापोहोऽर्थविज्ञानं तत्त्व-ज्ञानञ्च धीगुणाः" हेमच॰। तस्या वृत्तिः पञ्चधा यथा। "प्रमाणविपर्य्ययविकल्पनिद्रास्मृतयः" पात॰ सु॰ तल्लक्षणंच तत्तच्छब्दे दृश्यम्। बुद्धिक्षयकरा यथा "शोकः क्रोधश्च लोभश्च कामो मोहःपरासुता। ईर्ष्या मानो विचिकित्सा हिंसाऽसूयाज्गृप्सता। द्वादशैते बृद्धिनाशहेतवो मानसा मलाः"। कालिकापु॰१८ अ॰। बृद्धिक्षयकरा एते माषकासार-मृत्तिकाः"। बुद्धिवृद्धिकरा यथा "निम्बाटरूषवृन्ताश्चबुद्धिवृद्धिकरा मताः। बुद्धिक्षयकरान्नित्यं त्यजेद्राजाच भोजने। भोजयेदन्वहं बुद्धिवृद्धिहेतुं नृपोत्तमः। काकिकापु॰८९ अ॰।

Very detailed information about the term 'Buddhi' is available in Sanskrit - Sankrit dictionaries/encyclopedias like Amarkosha, Shabdakalpadruma, Vachaspatyam etc. these cover information regarding the definition, synonyms, nature, types, Gunas(qualities) and Vritti. In Brahmavaivarta Purana in Prakrutikhanda Adhyaya its nature is described as Vivechanarupa. Buddhi is a Sanskrit word which means the intellectual capacity. The word is

derived for the root *Budh* (ৰুধ্), which literally means "to wake, be awake, observe, heed, attend, learn, become aware of, to know, be conscious again.

## Synonyms of Buddhi –

**Amarkosha** – Manisha, Dhishana, Dhi, Pradnya, Shemushi, Mati, Preksha, Upalabdhi, Chit, Sambit, Pratipat, Dnyapti, Chetana.

**Rajnighantu** – Dharana, Pratipatti, Medha, Mananam, Manah, Dnyanam, Bodha, Hrullekha, Sankhya, Pratibha

Shabda Ratnavali – Aatmaja, Panda, Vidnyanam

Accoding to Monier – Wiliams Buddhi is the power of forming and retaining conceptions and general notions, intelligence, reason, intellect, mind, discernment, judgement, perception, comprehension, apprehension, understanding, knowledge of one's self psychology, In Sankhya the intellectual faculty or faculty of mental perception, the second of the 25 tatwas, presence of mind, an opinion, view, notion, idea, conjecture thought about or meditation on(loc. or comp), intention, purpose, right opinion, correct or reasonable view.

In Ayurvedic treaties like Brihattrayi the word Buddhi is used at multiple places eg. in Charaksamhita Moola Grantha it is used 129 times whereas in Chakrapani Tika it is used 100 times. In Sushruta Samhita Moola Grantha it is used at 61 different places whereas in Dalhana Tika it is found at 55 different places. The details are quoted in references

#### 2. **Dhi**

#### Shabdakalpadruma

धी, ओ ङ य आराधे । नादरे । इति कविकल्प- द्रुमः ॥ (दिवां-आत्मं-सकं-अनिट् ।) अनादर इति कातन्त्रादौ । ओ, धीनः । ङ य, धीयते खलं लोकः । इति दुर्गादासः ॥धीः, स्त्री, (ध्यै चिन्तने + भावे क्विप् । सम्प्रसार- णञ्च ।) बुद्धिः । इत्यमरः । १ । ५ । १ ॥ (यथा, मनौ । ६ । ९२ । "धृतिः क्षमा दमोऽस्तेयं शौचिमिन्द्रियनिग्रहः । धीर्विद्या सत्यमक्रोधो दशकं धर्म्मलक्षणम् ॥")

#### Amarkosha

धी स्त्री। बुद्धिः समानार्थक :बुद्धि, मनीषा, धिषणा, धी, प्रज्ञा, शेमुषी, मित, प्रेक्षा, उपलब्धि, चित्, संविद्, प्रतिपत्, ज्ञप्ति, संज्ञा, चेतना,आत्मन्,प्रधान,प्रज्ञान 1।5।1।1।4

बुद्धिर्मनीषा धिषणा धीः प्रज्ञा शेमुषी मितः। प्रेक्षोपलिब्धिश्चित्संवित्प्रतिपत्ज्ञप्तिचेतना॥ अवयव : वासना वैशिष्ट्यवत् : निश्चयः धारणावत्बुद्धिः, तर्कः, निश्चयः, मोक्षोपयोगिबुद्धिः, शिल्पादिविषयकबुद्धिः, मोक्षः, शङ्का, अन्यशुभद्वेषबुद्धिः, वितर्कः पदार्थ-विभागः : , गुणः, बुद्धिः

## Vachaspatyam

"'धी'"¦ अनादरे आराधने च दिवा॰ आत्म॰ सक॰ अनिट्। धीयते अधेष्ट। दिध्ये ओदित् धीनः।
"सत्यं परंधीमिह" भाग. १ कातन्त्रमतेऽस्य ओदित्त्वं नास्तिधीत इति। वेदे तु न ओदित् "धीतः विश्वान्यश्विना-युधं
प्रधीतान्यगच्छम्" ऋ॰ १०"सखीयते संधीत-मश्रुतम्"

३ । आधारे अक॰ इत्यन्ये। "'धी"'¦ स्त्री ध्यै सम्प॰ भावे--क्विप् संप्रसारणञ्च।

१ बुद्धौ ज्ञानेअमरः।

"प्रसीद कथयात्मानं न धियां पथि। वर्त्तसे" कुमा॰।

## २ मानसवृत्तिभेदे

"तत्राज्ञानं धिया नश्ये-दाभासात्तु घटः स्फुरेत्" वेदान्त॰ "धियो योनःप्रचोदयात्" गायत्री सा च न्यायनये आत्मवृत्तिः। "बुद्ध्यादि षट्कं संख्यादिपञ्चकं भावना तथा। धर्मा-धर्मौ गुणा एते आत्मनः स्युश्चतुर्दश" भाषा॰। वेदान्तमते[Page3892-a+ 38] मनोवृत्तिः। "कामः संकल्पो विचिकित्सा श्रद्धाऽश्रद्धाधृतिरधृतिर्हीधीभीरित्येतत्सर्वं मन एव" श्रुतिः।

४ क-र्मणि च

"उधः स धियामुदञ्चनः" ऋ॰

"धियां कर्मणाम्" भा॰ "धीभिश्चन मनसा स्वेभिर-क्षभिः" ऋ॰२५ मनसि च "धीजवनोऽसिसोम!" ऋ॰ ३"धीजवनः मनोवेगः" भा॰धीगुणशब्दे दृश्यम्।

'<u>Dhī,'</u> 'thought,' is used several times in the Rigveda i. 3, 5; 135, 5; 151, 6; 185, 8; ii. 3, 8 (where it is connected with Sarasvatī);40, 5, etc. to denote the 'prayer' or 'hymn of praise' of the singer. One poet speaks of himself as 'weaving' such a prayer, Rv. ii. 28,5. while another refers to his ancient ancestral hymn,' which he refurbishes presumably for use. Rv. iii. 39, 2.

#### Monier - Wiliams

Various meanings of the word 'Dhi' as given in Monier Wiliams are - perceive, think, reflect; wish, desire, thought, (esp.) religious thought, reflection, meditation, devotion, prayer(pl. Holy Thoughts personified), understanding, intelligence, wisdom (personified as the wife of रुद्र-मन्यु), knowledge, science, art, mind, disposition, intention, design, notion, opinion, the taking for, according to thy wisdom or will, to contain, bold, to slight, disregard; to propitiate.

The literal meaning of 'Dhi' is thought. It corresponds to Buddhi. Hence its meaning can be taken as activity of mind, understanding, intelligence etc. It is one of the ten essentials rules for observance of Dharma; as mentioned in Manusmruti. The ten listed rules in Manusmruti are

Dhruti(patience), Kshama (forgiveness), Dama (selfcontrol), Asteya (honesty), Shauch (purity ), Indriya-nigrah (control of senses), Dhi (reasoning), Satya (truthfulness), Akrodha (control of anger) and Vidya (knowledge and learning).

In Ayurveda literature like Charak Samhita in Moola Grantha and Chakrapani Tika it is found abundantly. The prominent reference is observed in the context of description of causative factors of disease where 'Pradnyaparadha' is mentioned as one of the three major causes. The definition is Pradnyaparadha is given as the harmful actions performed by the body due to malfunctioning of Dhi, Dhruti and Smruti. Dhi can be considered as real perception of knowledge.

#### 3. Dhruti

#### Shabdakalpadruma

धृतिः, पुं, (ध्रियते इति । धृ + क्तिन् । अभिधा- नात् पुंस्त्वम् ।) इष्टिः । इति मेदिनी । ते, २९ ॥ (विश्वेदेवविशेषः । यथा, महाभारते । १३ । ९१ । ३० । "वलं धृतिर्व्विपाप्मा च पुण्यकृत् पावनस्तथा ॥" चन्द्रवंशीयनृपविशेषस्य विजयस्य पुत्त्रः । यथा, हरिवंशे । ३१ । ५५ । "विजयस्य धृतिः पुत्त्रस्तस्य पुत्त्रो धृतव्रतः ॥" निमिवंशीयानामेकतमः । यथा, भागवते । ९ । १३ । २६ । "शुनकस्तत्सुतो जज्ञे वीतहत्र्यो धृतिस्ततः ॥" यदुवंशीयवभ्रोः पुत्त्रः । इति विष्णुपुराणे । ४ । १२ । १५ । "रोमपादाद्वभ्रः वभ्रोः पुत्त्रो धृतिः ॥")

धृतिः, स्त्री, (धृ + क्तिन् ।) तुष्टिः । (यथा, मनुः । ६ । ९२ । "धृतिः क्षमा दमोऽस्तेयं शौचिमिन्द्रियनिग्रहः । धीर्विवद्या सत्यमक्रोधो दशकं धर्म्मलक्षणम् ॥") योगभेदः । धैर्य्यम् । (यथा, वाजसनेयसंहिता- याम् । ३४ । ३ । "यत्प्रज्ञानमृत चेतो धृतिश्च यज्ज्योतिरन्तरमृतं प्रजासु ॥") धारणम् । इति मेदिनी । ते, २९ ॥ सुखम् । इति हेमचन्द्रः । २ । २२२ ॥ (क्रतुः । यथा, कात्यायनश्रौतसूत्रे । २० । २ । ८ । "राजन्यो धृतिषु युद्धजपयुक्ताः ॥") षोडशमातृकान्तर्गतत्रयोदशमातृका । इति भवदेवः ॥ अष्टादशाक्षरावृत्तिच्छन्दोमात्रम् । इति छन्दीमञ्जरी ॥ \* ॥ धृतियोगजातफलं यथा, -- "धृतियोगसमृत्पन्नः प्राज्ञः संहृष्टमानसः । वावदूकः सभायाञ्च सुशीलो विनयान्वितः ॥" इति कोष्ठीप्रदीपः ॥ धारणा । सा त्रिधा । यथा, -- "धृत्या यया धारयते मनःप्राणेन्द्रियक्रियाः । योगेनाव्यभिचारिण्या धृतिः सा पार्थ सात्त्विकी ॥ यया तु धर्म्मकामार्थान् धृत्या धारयतेऽर्ज्जुन ! । प्रसङ्गेन फलाकाङ्क्षी धृतिः सा पार्थ ! राजसी ॥ यया स्वप्नं भयं शोकं विषादं मदमेव च । न विमुञ्जति दुर्म्मेधा धृतिः सा तामसी मता ॥" इति श्रीभगवद्गीतायाम् । १८ । ३३-३५ ॥

#### Amarkosha

धृति स्त्री। धारणम् समानार्थक:धृति 3।3।74।2।2

वनिता जनितात्यर्थानुरागायां च योषिति। गुप्तिः क्षितिव्युदासेऽपि धृतिर्धारणधैर्ययोः॥

पदार्थ-विभागः : , क्रिया

धृति स्त्री। धैर्यम् समानार्थक:धृति 3।3।74।2।2

वनिता जनितात्यर्थानुरागायां च योषिति। गुप्तिः क्षितिव्युदासेऽपि धृतिर्धारणधैर्ययोः॥

पदार्थ-विभागः : , गुणः, मानसिकभावः

## Vachaspatyam

"'धृति"'¦ स्त्री धृ--क्तिन्। १ धारणे २ तुष्टौ

३ धैर्य्ये

- "धृतिर-स्तमिता रतिश्च्युता" रघुः "धृतिर्धैर्यं प्रीतिर्वा" मल्लि∘। विष्कम्भादिमध्ये
- ४ अष्टमे योगभेदेमेदि॰।
- "अतिगण्डः सुकर्मा च धृतिः शूलं तथैव" ज्यो॰।
- ५ सुखे हेमच॰। गौर्य्यादिषोडशमातृमध्ये
- ६ मातृकाभेदे। मातृकाशब्दे दृश्यम्। अष्टाद-शाक्षरपादकछन्दोमात्रे उक्तात्युक्तेत्युपक्रमे धृति-श्चातिधृतिश्चैव कृतिः प्रकृतिराकृतिः" वृ॰ र॰।
- ७ मानसधारणाभेदे
- "धृतिरधृतिर्ह्णीर्वीर्भीरित्येतत् सर्वंमनएव" श्रुतिः। सा च सात्विकादिभेदेन त्रिधायथाह गीतायाम् "धृत्या यया धारयते मनःप्राणे-िन्द्रियक्रियाः। योगेनाव्यभिचारिण्या धृतिः सा पार्थ। सात्विकी। यया तु धर्मकामार्थान् धृत्या धारय-तेऽर्जुन!। प्रसङ्गेन फलाकाङ्क्षी धृतिः सा पार्थ!राजसी। यथा स्वप्नं भयं शोकं विषादं मदमेव च। न विमुञ्जति दुर्मेधा घृतिः सा पार्थ! तामसी"।
- ८ दक्षसुतारूपधर्मपत्नीभेदे
- "ददौ स दश धर्माय" इत्युपक्रमेधर्मपत्नीशब्दे उक्त वाक्ये ३८ ५७ पृ॰ दृश्यम्।
- ९ जयद्रथ-नृपस्य पौत्रे पु॰ जयद्रथस्तु राजेन्द्र! यशोदेव्याम् व्यजा-यत। ब्रह्मक्षत्रोत्तरः सत्यां विजयो नाम विश्रुतः। विजयस्य धृतिः पुत्रः" हरिवं॰ ३१ अ॰।
- १० मैथिलेराजभेदे पु॰ तदुपक्रमे
  "शुनकस्तत्सुतो जज्ञे वीति-हव्यो धृतिस्ततः" भाग॰९ ।
- ११ विश्वदेवभेदेपु॰ तन्नामोपक्रमे "बलं धृतिर्विपाप्मा च पुण्यकृत्थाबनस्तथा" भा॰ अनु॰ ९१ अ॰। सा॰ द॰ उक्ते
- १२ व्यभिचारिभावभेदे। सा च
- "सधृतिचपलनाग्लानिचिन्तावितर्काः" इत्युद्दिश्य तत्र लक्षिता यथा
- "ज्ञानाभीष्टागमाद्यैस्तुसंपूर्णस्पृहता धृतिः। सौहित्यवचनोल्लाससहासप्रतिभादिकृत्" उदाहृतं च
- "कृत्वा दीननिपीडनांनिजजने वद्ध्वा वचोविग्रहम् नैवालोच्य गरीयसी-रपि चिरादामुष्मिकीर्यातनाः। द्रव्यौघाः

परिसञ्चिताःखलु मया यस्याः कृते साम्प्रतं नीवाराञ्जलिनापिकेवलमहो मेयं कृतार्था तनुः" भा॰ द॰। "ता धृति-[Page3906-b+ 38] रस्ति गतास्मि सम्प्रतीयम्" माघः। "स्थिता कर्थंशैलजनाश्गे धृतिः" किरा॰ "अम्बरान्तधृतेः" शा॰ सु॰

## १४ गुरुत्ववतां पतनाभावे हरिदासः

"कार्य्यायोजनधृत्यादेः पदात् प्रत्ययतः श्रुतेः। वाक्यात् सङ्ख्याविशेषच्चसाध्यो विश्वविदव्ययः कुसुमा॰। धृतीति ब्रह्माण्डादिपतनप्रतिबन्धकी भूतप्रयत्नवदिधष्टितं धृतिमन्त्वात्वियति विहङ्गमधृतकाष्ठवत् धृतिश्च गुरुत्ववतां पतना-भावः" हरिदासः। मनसो भूतपञ्चकारब्धत्वात्क्षित्यंशधारणवत्त्वात् धृतिमत्त्वं बोध्यम्। धृते-र्भूमिगुणत्वञ्च भा॰ शा॰ २५

५ अ॰ उक्तं यथा "भूमेः स्थैर्य्यं गुरुत्वं च काठिन्यं प्रसवार्धता। गन्धोगुरुत्वं शक्तिश्च संथातः स्थापना धृतिः"। "स्थैर्य्यमचाञ्चल्यं गुरुत्वं पतनप्रतियोगी गुणः प्रसवोधान्याद्युत्पत्तिस्तदर्थता, गुरुत्वं प्रथिमा पिण्डपृष्टिःशक्तिर्गन्धग्रहणसामर्थ्यं सङ्घातः श्लिष्टावयवत्वम् स्था-पना मनुष्याद्याश्रयत्वं धृतिः पाञ्चभौतिके मनिस योधृत्यंशः स पार्थिवः स्थैर्य्यशब्देनैवीपात्त इति धृतिशब्दे-मात्र भूतान्तरप्रवेशस्थानत्वमुच्यते" नीलकण्ठव्याख्या। तच्छन्दसोऽष्टादशसंख्यकत्वात्तत्तुल्यसंख्यायुत्ते अष्टादश-संख्यायुक्ते च।

१६ विपुलाख्य विष्कुम्भपर्वतस्थे वनभेदेविष्कुम्भपर्वतोपक्रमे "वनं तथा चैत्तरथं विचित्रं ते-ष्वप्सरो नन्दननन्दनञ्च। धृत्याह्वयं यद् धृतिकृत् सुराणांभ्राजिष्णु वैभ्राजिमति प्रसिद्धम्" सि॰ शि॰। "विपुलशैल-मस्तके केतुवृक्षो वटो धृतिर्वनं महाह्रदः सरः" प्रमिता॰।

#### Monier - Wiliams

धृति f. holding , seizing , keeping , supporting(See. चर्षणी-, वि-) , firmness , constancy , resolution , will , command RV. etc.

धृति f. satisfaction, content, joy MBh. Ka1v. etc. ( तिं-कृ, to keep ground or stand still MBh. vii, 4540; to find pleasure or satisfaction Ratn. iv, 4/5; तिम्-बन्ध्, to show firmness Amar. 67; to fix the mind on Mn. v, 47)

धृति f. Resolution or Satisfaction personified as a daughter of दक्षand wife of धर्म( MBh. Hariv. Pur. )or as a शक्ति( Hcat. etc. )

धृति f. N. of partic. evening oblations at the अश्वमेधS3Br.

धृति f. any offering or sacrifice W.

धृति f. of sev. kinds of metre and of a class of metres consisting of 4 x 18 syllables Col.

धृति f. of the numeral 18 Var. Gan2it.

धृति f. of one of the astrol. Yogas. L.

धृति f. of a mythical garden Gol.

धृति f. of one of the 16 कलाs of the moon Pur.

धृति f. of a goddess (daughter of a कलाof प्रकृतिand wife of कपिल) ib.

धृति f. of the wife of रुद्र- मनुib.

धृति f. of the 13th of the 16 मातृकाs L.

धृति m. wish क्षत्रस्य= क्षत्र-ध्La1t2y.

धृति m. N. of one of the विश्वेदेवाs MBh.

धृति m. of a preceptor Cat.

धृति m. of the son of विजयand father of धृत-व्रतHariv. Pur.

धृति m. of a son of वीत-हव्यand father of बहुलाश्वPur.

धृति m. of a son of बभूL.

धृति m. of a वर्षांn कुश-द्वीपVP.

Different meaning of the word Dhruti can be identified according to different epics in Hindu mythology like - in Bhagvat Gita the meaning of Dhruti is 'act with determination'; whereas in Shrimadbhagavat it conveys the meaning as 'patience'. According to Devibhagavat, Devi is the energy for creation as well as the destruction of the universe. She resides in all in the form of Shakti (power and energy), amrti (memory), Dhruti (steadfastness), Buddhi (intelligence), etc. in Bhagvat Gita three types of Dhruti are mentioned – Satwiki, Rajasi and Tamasi.

In Charak Samhita Moola grantha the word Dhruti is found at 19 different places whereas in Chakrapani Tika is is found at 10 different places. In Sushruta Samhita it is observed at 8 times and 7 times in Moola Grantha and Dalhana Tika respectively.

#### 4. Medha

## Shabdakalpadruma

मेधा, स्त्री, (मेधते सङ्गच्छते अस्यामिति । मेध् + "षिद्भिदादिभ्योऽङ् ।" ३ । ३ । १०४ । इत्यङ् । टाप् ।) धारणावती बुद्धिः । इत्यमरः । १ । ५ । २ ॥ धारणाशक्तियुक्ता धीर्मेधा मेधते सङ्गच्छतेऽस्यां सर्व्वं बहुश्रुतं विषयीकरोति इति वा मेधा मेधृ- ञ सङ्गे मेधायां सेमक्तात् सरोरित्यः आपबहु- श्रुतविषयीकरणं धारणा यदुक्तं धारणा बुद्धे- गृंणविशेषः इति ॥ इति भरतः ॥ \* ॥ (यथा, मुण्डकोपनिषदि । ३ । २ । ३ । "नायमात्मा प्रवचनेन लभ्यो न मेधया न बहुना श्रुतेन । यमेवैष वृणुते तेन लभ्य- स्तस्यैष आत्मा विवृणुते तन्तं स्वाम् ॥") मेधाकरं औषधं यथा, -- "शङ्खपुष्पी वचा सोमा ब्राह्मी ब्रह्मसुवर्च्चला । अभया च गुडूची च अटरूषकवाकुची । एतैरक्षसमैर्भागैर्घृतं प्रस्थं विपाचयेत् ॥ कण्टकार्य्या रस प्रस्थं वृहत्या च समन्वितम् । एतद्ब्राह्मीघृतं नाम स्मृतिमेधाकरं परम् ॥" इति गारुडे १९८ अध्यायः ॥ \* ॥ मेधाकरगणो यथा । सतताध्ययनम् । तत्त्व- ज्ञानकथा । श्रेष्ठतन्त्रशास्त्रावलोकनम् । सिद्धु- जाचार्य्यसेवा च । इति पुराणम् ॥ (दक्षप्रजाप्पतिकन्याविशेषः । यथा, -- "कीर्त्तिलक्ष्मी धृतिर्मेघा पुष्टिः श्रद्धा क्रिया मितः ॥" इति विह्नपुराणे गणभेदनामाध्याये ॥ धनम् । इति निघण्टुः । २ । १० ॥ "मिधृ मेधृ सङ्गमे च । चकारात् हिंसामेधयोश्च । मिधिः सङ्गत्यर्थः । इति माधवः । घज् । सङ्गच्छतेऽनेन सर्व्वं तद्धता हिंस्यते वा तद्वान् चौरादिभिः घ्रन्ति चैवार्थकारणात् इति महाभारतम् ॥ यद्वा, मतौ धीयते अर्जयितव्यं रक्षितव्यं दातव्य- मिति धनवता बुद्धौ धनं धार्यते । तत्र मित- शब्द उपपदे धातोः घञर्थे कविधानम् इति कः । पृषोदरादित्वात् मितिशब्दस्य मेभावः ।" इति तद्भाष्ये देवराजयज्वा ॥)

## Amarkosha

मेधा स्त्री। धारणावत्बुद्धिः समानार्थक:मेधा 1।5।2।1।1

धीर्धारणावती मेधा सङ्कल्पः कर्म मानसम्. अवधानं समाधानं प्रणिधानमं तथैव च। चित्ताभोगा मनस्कारश्चर्चा संख्या विचारणा। विमर्शो भावना चैव वासना च निगद्यते॥

पदार्थ-विभागः : , गुणः, बुद्धिः

## Vachaspatyam

'''मेधा'''¦ स्त्री मेध--अङ्।

१ वारणावत्यां बुद्धौ यया बुद्ध्या ज्ञातस्यन विस्मरणं तत्र। नञ्दुःसुशब्दात् बहु॰ असिच्समा॰। अमेधाः दुर्मेधाः सुमेधाः इत्यादि। आधारे घञ्।

२ यागे पु॰।

#### Monier - Wiliams

मेधा f. mental vigour or power, intelligence , prudence , wisdom( pl. products of intelligence , thoughts , opinions) RV. etc.

मेधा f. Intelligence personified (esp. as the wife of धर्मand daughter of दक्ष) MBh. R. Hariv. Pur.

मेधा f. a form of दाक्षायणीin कश्मीरCat.

मेधा f. a form of सरस्वतीW.

मेधा f. a symbolical N. of the letter ध्Up.

मेधा f. = धनNaigh. ii , 10.

Literal meaning of Medha is intelligence, wisdom, memory. The word is in use since Vedic period. It is visualized as a Goddess. Goddess Medha is considered as a form of Saraswati. Medha Suktam is quite popular as a hymn to Goddess Saraswati; as a prayer seeking intelligence and capability to learn. According to Medha Suktam the meaning of Medha is "power of understanding endowed with consciousness".

#### 5. Pradnya

#### Shabdakalpadruma

प्रज्ञा, स्त्री, (प्र + ज्ञा + कः । टाप् ।) बुद्धिः । (यथा, रघुः । १ । १५ । "आकारसदृशप्रज्ञः प्रज्ञया सदृ शागमः ॥" एकाग्रता । यथा, पञ्चदश्याम् । ७ । १०६ । "तमेव धीरो विज्ञाय प्रज्ञां कुर्व्वीतब्राह्मणाः ॥") प्राज्ञी । प्रकर्षेण जानाति या । इत्यमरः ॥ सरस्वती । इति शब्दरत्नावली ॥ बुद्धिवैदिक- पर्य्यायः । केतुः १ केतः २ चेतः ३ चित्तम् ४ क्रतुः ५ असुः ६ धीः ७ शचीः ८ माया ९ वयुनम् १० अभिख्या ११ । इत्येकादशप्रज्ञा- नामानि । इति वेदनिवण्टौ ३ अध्यायः ॥

## Amarkosha

प्रज्ञा स्त्री। बुद्धिः समानार्थकः बुद्धि, मनीषा, धिषणा, धी, प्रज्ञा, शेमुषी, मित, प्रेक्षा, उपलब्धि, चित्, संविद्, प्रतिपत्, ज्ञप्ति, चेतना,संज्ञा,आत्मन्,प्रधान,प्रज्ञान 1।5।1।1।5

अवयव : वासना

वैशिष्ट्यवत् : निश्चयः धारणावत्बुद्धिः, तर्कः, निश्चयः, मोक्षोपयोगिबुद्धिः, शिल्पादिविषयकबुद्धिः, मोक्षः, शङ्का, अन्यशुभद्रेषबुद्धिः, वितर्कः

पदार्थ-विभागः : , गुणः, बुद्धिः

प्रज्ञा स्त्री। स्वयम्ज्ञात्री समानार्थक:प्राज्ञी,प्रज्ञा 2।6।12।2।4

आलिः सखी वयस्याथ पतिवत्नी सभर्तृका। वृद्धा पलिक्नी प्राज्ञी तु प्रज्ञा प्राज्ञा तु धीमती॥

पदार्थ-विभागः : , द्रव्यम्, पृथ्वी, चलसजीवः, मनुष्यः

#### Monier -Wiliams

प्रज्ञा/ प्र- P. -जानाति, to know , understand ( esp. a way or mode of action) , discern , distinguish , know about , be acquainted with( acc. ) RV. etc; to find out , discover , perceive , learn MBh. Ka1v. etc. : Caus. -ज्ञापयित, to show or point out (the way) S3Br. ; to summon , invite Lalit. 2.

प्रज्ञा/ प्र-ज्ञा f. wisdom , intelligence , knowledge , discrimination , judgement S3Br. etc.

प्रज्ञा/ प्र-ज्ञा f. device , design S3Br. S3a1n3khS3r.

प्रज्ञा/ प्र-ज्ञा f. a clever or sensible woman W.

प्रज्ञा / प्र-ज्ञा f. Wisdom personified as the goddess of arts and eloquence , सरस्वतीL.

प्रज्ञा/ प्र-ज्ञा f. a partic. शक्तिor energy Hcat.

प्रज्ञा/ प्र-ज्ञा f. (with Buddh. )true or transcendental wisdom (which is three fold Dharmas. 110 ) MWB. 126 ; 128

प्रज्ञा/ प्र-ज्ञा f. the energy of आदि-बुद्ध(through the union with whom the latter produced all things) MWB. 204.

The word 'Pradnya' can be found in various epics of Hindu mythology like Mahabharata, Riga Veda Shatpath –Brahman and Shankhayan-Shraut-Sutra etc. the references in Rigveda carries the meaning like to understand, discern, discuss, know about, be acquainted with or distinguish. In Mahabharata it is used with meanings like to perceive, learn, to find out or discover. In Shatpath-Brahman and Shankhayan-Shraut-Sutra the word 'Pradnya' denotes meaning wisdom, knowledge, intelligence, discrimination, judgement, design and device. Pradnya is name of goddess Sarasvati.

#### 6. Prama

#### Shabdakalpadruma

प्रमा, स्त्री, (प्रमीयते इति । प्र + माङ् माने + "आतश्चोपसर्गे ।" ३ । ३ । १०६ । इति अङ् । टाप् ।) यथार्थज्ञानम् । तत्पर्य्यायः । प्रमितिः २ । इत्यमरः । ३ । २ । १० ॥ प्रमा- णम् ३ । इति शब्दरत्नावली ॥ (यथा, प्रबोध- चन्द्रोदये । २ य अङ्के । "प्रत्यक्षादिप्रमासिद्धविरुद्धार्थाभिधायिनः । वेदान्ता यदि शास्त्राणि वौद्धैः किमपराध्यते ॥" यथा च ऋग्वेदे । १०। १३०। ३। "कासीत्प्रमा प्रतिमा किम् ॥" "यज्ञस्य प्रमा प्रमाणमियत्ता का कथम्भृतासीत् ।" इति तद्भाष्ये सायनः ॥) न्यायमते तद्वति तत्प्रकारकज्ञानम् । भ्रमभिन्नज्ञानम् । अस्याः कारणं गुणः । स च प्रत्यक्षे विशेष्ये विशे- षणस्य सम्बन्धः । अनुमितौ साध्यविशिष्टपक्षे परामर्शः । शाब्दबोधे योग्यतायाः तात्पर्य्यस्य वा यथार्थज्ञानम् । उपमितौ शक्ये सादृश्य- बुद्धिः । यथा, -- "दोषोऽप्रमाया जनकः प्रमायास्तु गुणो भवेत् । पित्तदूरत्वादिरूपो दोषो नानाविधः स्मृतः ॥ प्रत्यक्षे तु विशेष्येण विशेषणवता समम् । सन्निकर्षो गुणस्तु स्यादथ त्वनुमितौ पुनः ॥ पक्षे साध्यविशिष्टे च परामर्शो गुणो भवेत् । शक्ये सादृश्यबुद्धिस्तु भवेदुपमितौ गुणः । शाब्दवोधे योग्यतायास्तात्पर्य्यस्याथ वा प्रमा ॥ गुणः स्याद्भुमभिन्नन्तु ज्ञानमत्रोच्यते प्रमा । अथवा तत्प्रकारं यत् ज्ञानं तद्वद्विशेष्यकम् ॥" इति भाषापरिच्छेदे । १३१-१३५ ॥ ("दोषः इति । अप्रमां प्रति दोषः कारणं प्रमां प्रति गुणः कारणं तत्रापि पित्तादिरूपा दोषा अननुगताः तेषां कारणत्वम् अन्वयव्यतिरेका- भ्यामेव सिद्धम् । गुणस्य प्रमाजनकत्वन्तु अनु- मानात् सिद्धम् । यथा प्रमाज्ञानसाधारण-कारणभिन्नकारणजन्याजन्यज्ञानत्वात् अप्र- मावत् । न च दोषाभाव एव कारणमस्त्विति वाच्यम् । पीतः शङ्ख इति ज्ञानस्थले पित्तदोष- सत्त्वात् शङ्खप्रमानुत्पत्तिप्रसङ्गात् विनिगमना- विरहात् अनन्तदोषाभावस्य कारणत्वमपेक्ष्य गुणकारणताया न्याय्यत्वात् । न च गुणसत्त्वेऽपि पित्तप्रतिबन्धात् शङ्खे न सैत्यज्ञानमतः पित्तादि- दोषाभावानां कारणत्वमवश्यं वाच्यं तथा च किं गुणस्य हेतुत्वकल्पनयेति वाच्यं तथाप्यन्वयव्यति- रेकाभ्यां गुणस्यापि हेतुत्वसिद्धेः । एवं भ्रमं प्रति गुणाभावः कारणमित्यस्यापि सुवचत्वाच्च । तत्र दोषाः के इत्याकाङ्क्षायामाह पित्तेति । क्वचित् पीत्तादिभ्रमे पित्तं दोषः क्वचित् चन्द्रादेः स्वल्प- परिमाणभ्रमे दूरत्वं दोषः । क्वचिच्च वंशोरग- भ्रभे मण्डूकवसाञ्जनमित्येवं दोषा भ्रान्तिजनका इत्यर्थः । अथ के गुणा इत्याकाङ्क्षायां प्रत्य-क्षादौ क्रमशो गुणान् दर्शयति प्रत्यक्षेत्विति । प्रत्यक्षे

विशेषणवत् विशेष्यसन्निकर्षो गुणः अनु- मितौ साध्यवति साध्यव्याप्यवैशिष्ट्यज्ञानं गुण इति एवमग्रेऽप्यूह्यः । प्रमां निरूपमिति भ्रम- भिन्नमिति । ननु यत्र शुक्तिरजतयोरिमे रजते इति ज्ञानं जातं तत्र रजतांशेऽपि प्रमा न स्यात् तज्ज्ञानस्य भ्रमभिन्नत्वाभावात् अत आह अथवेति । तद्वद्विशेष्यकं तत्प्रकारकं ज्ञानं प्रमा इत्यर्थः । इदन्तु बोध्यम् । येन सम्बन्धेन तद्वत्ता तेन सम्बन्धेन तद्वद्विशेष्यकं तेन सम्बन्धेन प्रकारकत्वं वाच्यम् । तेन कपालादौ संयोगा- दिना घटादिज्ञाने नातिव्याप्तिः ॥" \* ॥)

#### Amarkosha

प्रमा स्त्री। प्रमाज्ञानम् समानार्थक:प्रमिति,प्रमा 3।2।10।1।6

विधा समृद्धौ स्फुरणे स्फुरणा प्रमितौ प्रमा। प्रसूतिः प्रसवे श्र्योते प्राधारः क्लमथः क्लमे॥

पदार्थ-विभागः : , गुणः, बुद्धिः

## Vachaspatyam

'''प्रमा'''¦ स्त्री प्र + मा--भावे अङ्।

१ यथार्थज्ञाने भ्रमभिन्नेज्ञाने तल्लक्षणं तदुत्पत्तौ गुणाश्च भाषा॰ उक्ता यथा(
"दोषोऽप्रमाया जनकः प्रमायास्तु गुणो भवेत्। प्रत्यक्षे तु विशेष्येण विशेषणवता समम्। सन्निकर्षोगुणस्तु स्यादथ
ह्यानुमितौ पुनः। पक्षे साध्यविशिष्टेच परामर्शो गुणो भवेत्। शाब्दबोधे योग्यतायास्तात्-पर्य्यस्याथ वा प्रमा। गुणः
स्याद्भमभिन्नस्तु ज्ञानम-त्रोच्यते प्रमा। अथ वा तत्प्रकारं यत् ज्ञानं तद्वद्विशे-ष्यकम्" भाषा॰। दोषशब्दे

६६ पृ॰ भ्रमकारणं दृश्यम्तथा च तद्वति तत्प्रकारकज्ञानत्वं प्रमात्वं प्रामाण्या-परपर्य्यायम् तच्च मतभेदेन स्वतोग्राह्यं परतोग्राह्यञ्चतच्च परतोग्राह्यशब्दे

३४ पृ॰ उक्तम्। तस्य विस्तर-स्त्वत्रोच्यते। तत्र न्यायमते "प्रमात्वं न स्वतोग्राह्यंसंशयानुपपित्ततः" भाषा॰ व्याकृतञ्च सि॰ मु॰ यथा "मीमांसका हि प्रमात्वं स्वतोग्राह्यमिति वदन्ति। तत्रगुरूणां मते ज्ञानस्य स्वप्रकाशरूपत्वात् तज्ज्ञानप्रा-माण्यं तेनैव गृह्यते इति। भट्टनां मते तु ज्ञानसती-न्द्रियम्। ज्ञानजन्या ज्ञातता प्रत्यक्षा। तया च ज्ञान-मनुमीयते। सुरारिमिश्राणां मतेऽनुव्यवसायेन ज्ञानंनृह्यते। सर्वेषामि मते तज्ज्ञानविषयकज्ञानेन तज्ज्ञा-नप्रामाण्यं गृह्यते। विषयनिरूप्यं हिं ज्ञानम्। अतोज्ञानवित्तिवेद्यो विषयः। तन्मतं दूषयति। न स्वतो-जाह्यमिति। संशयेति। यदि ज्ञानपामाण्यं स्वतोग्राह्यंस्यात् तदाभ्यासदशोत्पन्नज्ञाने तत्संशयो न स्योत्। तत्रहि यदि ज्ञानं ज्ञातं तदा प्रामाण्यं ज्ञातमेवेति कथंसंशयः। यदि तु ज्ञानं न ज्ञातं तदा धर्मिज्ञानाभावात्कथं संशयः। तस्माजज्ञानप्रामाण्यमनुमेयम्। तथा हिइद ज्ञान प्रमा संवादिप्रवृत्तिजनकत्वात् यन्नैवं तन्नैवंयथाऽप्रमा। इदं पृथिवीत्वप्रकारकं ज्ञानः प्रमा गन्ध-वति पृथिवीत्वप्रकारकज्ञानत्वात्। एवम् इदं जलज्ञानंप्रमा

स्नेहवति जलत्वप्रकारकज्ञानत्वात्। न च हतु-ज्ञानं स्वषं जातमिति वाच्छम्। पृथियीत्वप्रकारकत्वस्व[Page4477-b+ 38] स्वतोग्राह्यत्वात् तत्र गन्धवद्विशेष्यकत्वस्यापि सुग्रह-त्वात्। तत्प्रकारकत्वावच्छिन्नतद्वद्विशेष्यकत्वं परं नगृह्यते संशयानुरोधात्। न च प्रमात्वस्य साध्यस्यप्रसिद्धिः कथमिति वाच्यम् इदंज्ञानप्रमात्वस्य स्वतो-ग्राह्यत्वात्। न च प्रकारभेदेन प्रामाण्यभेदात् धटत्व-वति घटत्वप्रकारादेः कथं प्रसिद्धिरिति वाच्यम् घटत्वप्र-कारकत्वस्य स्वविशेष्यकत्वस्य च स्वतोग्राह्यत्वात्। घटस्यच पूर्वमुपस्थितत्वाद् घटविशैष्यकं घटत्वप्रकारकमितिज्ञाने प्रामाण्यस्य बाधकाभावः। व्यवसायपरन्तु प्रा-माण्यं न गृह्यते। तत्र संशयसामग्रीसत्त्वे संशयस्यै-वोपपत्तेः। किञ्चाभ्यासदशायां तृतोयानुव्यवसायादिनाप्रामाण्यस्य स्वत एव ग्रहसम्भवात् प्रथमानुव्यवसायपरंन तद्गाहकत्वमिति कल्प्यते संशयामुरोधात्। अथप्रामाण्यानुमितौ प्रामाण्यग्रहे न तस्य विषयनिश्चय-रूपत्वार्थं तत्र प्रामाण्यग्रहो वाच्यः सोऽप्यनुमित्यन्तरे-णेति फलमुखी कारणमुखी वा नानवस्थेति चेन्न अ-गृहीतप्रामाण्यग्रहकस्यैव निश्चयरूपत्वात्। यत्र चप्रामाण्यसंशयस्तत्रैव परं प्रामाण्यानुमितेरपेक्षया याव-दाशङ्कं प्रामाण्यानुमितिरिष्यत एव सर्वत्र तु न संशयःक्वचित् कोट्यनुपस्थितेः क्वचिद्विशेषदर्शनादितः क्वचिद्वि-षयान्तरसञ्चारादिति सङ्क्षेपः। ननु सर्बेषां ज्ञानानांयथार्थत्वात् प्रमालक्षणे तद्विशेष्यकत्वं विशेषणं व्यर्थम्। न च रङ्गे रजतार्थिनः प्रवृत्तिर्भ्रमजन्था न स्वात् तवमते भ्रमस्याभावादिति वाच्यम्। तत्र हि दोषाधी-नस्य पुरोवर्त्तिनि स्वतन्त्रोपस्थितरजतभेदाग्रहस्य हेतु-त्वात्। सत्यरजतस्थल तु विशिष्टज्ञानस्य सत्त्वात् तदेवकारणम्। अस्तु वा तत्रापि भेदाग्रह एव कारणमिति। न चाऽन्यथाख्यातिः सम्भवति रजतप्रत्यक्षकारणस्यरजतसन्निवर्षस्याभावात् रङ्गे रजतबुद्धेरनुपपत्तेरितिचेन्न सत्यरजतस्थले प्रवृत्तिं प्रति विशिष्टज्ञानस्य हेत्-तायाः क्रुप्तत्वात् अन्यत्रपि तत्ककल्पनात्। न च र्स-वादिप्रवृत्तौ त् भेदाग्रहः कारणमिति वाच्यम् लाघबात्प्रवृत्तिमात्रे तस्य हेतुत्वकल्पनात्। इत्थञ्च रङ्गे रजत-त्वविशिष्टबुद्ध्यनुरोधेन ज्ञानलक्षणाप्रत्यासत्तिकल्पनेऽपि नक्षतिः। फलमुखर्गारवस्यादोषत्वात्। किञ्च यद् रङ्गर-जतयोरिमे रजते इति ज्ञानं जातं न कारणबोधोऽपि। अपि च यत्र रङ्गरजतयोरिमे रजतरङ्गे इति ज्ञानंतत्रोभयत्र सुगपत्प्रवृत्तिनिवृत्ती स्वाताम्। रङ्गे रङ्ग[Page4478-a+ 38] भेदग्रहे रजते रजतभेदग्रहेऽन्यथाख्यातिभयात्। त्वन्मतेरङ्गे रङ्गभेदाग्रहस्य रजते रजतभेदाग्रहस्य च सत्त्वात्किञ्चानुमितिं प्रति भेदाग्रहस्य हेतुत्वे जलह्रदे वह्नि-व्याप्यधूमवदभेदाग्रहाद् अनुमितिर्निर्बाधा। यदि चिविशिष्टज्ञानं कारणं तदाऽयोगोलके वह्निव्याप्यधूमज्ञान-मन्मित्यन्रोधादापतितम। इत्थम् अन्यथाख्यातौ प्रत्य-क्षमेव प्रमाणम्। रङ्गं रजततया जानामीत्यनुभवा-दिति सङ्क्षेपः"। वेदान्तिमते तस्य स्वतोग्राह्यता वेदान्तपरिभाषायां व्यवस्था-पिता यथा

"एवसुक्तानां प्रमाणानां प्रामाण्यं स्वतएवउत्पद्यते ज्ञायते च तथा हि स्मृत्यनुभवसाधारणं संवा-दादिप्रवृत्त्यनुकूलं तद्वति तत्प्रकारकज्ञानत्वं प्रामाण्यंतच्च ज्ञानसामान्यसामग्रीप्रयोज्यं न त्वधिकं गुणमपेक्षतेप्रमामात्रेऽनुगतगुणाभावात्। नापि प्रत्यक्षप्रमायां भू-योऽवयवेन्द्रियसन्निकर्षः, रूपादिप्रत्यक्षे आत्मप्रत्यक्षे चतदभावात् सत्यपि तस्मिन् पीतः शङ्ख इति प्रत्यक्षस्यभ्रमत्वाच्च। अतएव न सिल्लिङपरमर्शादिकमपि अनुमि-त्यादिप्रमायां गुणः असिल्लिङ्गपरामर्शादिस्थलेऽपि विषया-बाधेनानुमित्यादेः प्रमात्वात्। न चैवमप्रमापि प्रमा स्यात्ज्ञानसामान्यसामग्र्यविशेषादितिवाच्यं दोषाभावस्यापिहेतुत्वाङ्गीकारात्। न चैवं परतस्त्वम् "आगन्तुकभावका-रणापेक्षायामेव परतस्त्वात्" ज्ञायते च प्रामाण्यं स्वतः,स्वतोग्राह्यत्वञ्च दोषाभावे सित यावत्स्वाश्रयग्राहकसा-मग्रीग्राह्यत्वम्। स्वाश्रयो वृत्तिज्ञानं तद्भाहक सा-क्षिज्ञानं तेनापि वृत्तिज्ञाने गृह्यमाणे तद्भतं प्रामाण्य-मिप गृह्यते। न चैव प्रामाण्यसंशयानुपपत्तिः तत्रसशयानुरोधेन दोषस्यापि सत्त्वेन दीषाभावघटितस्वा-श्रयग्राहकाभावेन तत्र प्रामाण्यस्यैवाग्रहात्। यद्वायावत्स्वाश्रयग्राहकग्राह्ययोग्यत्वं स्वतस्त्वं

संशयस्थलेप्रामाण्यस्योक्तयोग्यतासत्त्वेऽपि दोषवशेनाग्रहात् नसंशयानुपपित्तः। अप्रामाण्यन्तु न ज्ञानसामान्यसामग्रीप्रयोज्यं प्रमायामप्यप्रमाण्यापत्तेः किन्तु दोषप्रयोज्यंनाप्यप्रामाण्यं यावत्स्वाश्रयग्राहकग्राह्यम् अप्रामाण्य-घटकतदभाववत्त्वादेर्वृत्तिज्ञानानुपनातत्वेन साक्षिणाग्रहीतुमशक्यत्वात् किन्त विसंवादिप्रवृत्त्यादिलिङ्गकानु-मित्यादिविषय इति परत एवाप्रामाण्यमुत्पद्यते ज्ञायतेचेति"। अधिकं प्रमाणशब्दे दृश्यम्।

#### **Monier Wiliams**

प्रमा/ प्र- A1. -मिमीते(Ved. inf. प्र-मे; Pass. -मीयते) , to measure , mete out , estimate AV. S3rS. MBh. ; to form , create , make ready , arrange RV. MBh. ; to form a correct notion of( acc. ) , understand , know MaitrUp. Hariv. Hit. : Caus. -मापयित, to cause correct knowledge, afford proof or authority MW. 1.

प्रमा/ प्र-मा f. basis, foundation AV.

प्रमा/ प्र-मा f. measure, scale RV.

प्रमा/ प्र-मा f. right measure, true knowledge, correct notion Prab. Kap.Tarkas. IW. 59 etc.

प्रमा/ प्र-मा f. a kind of metre RPra1t.

The meaning of 'Prama' is valid knowledge and it is gained through tool called Pramana. It is exempted from errors.

#### 7. Smruti

## Shabdakalpadruma

स्मृतिः, स्त्री, (स्मृ + क्तिन् ।) अनुभूतविषय- ज्ञानम् । इति चण्डीटीकायां नागोजीभट्टः ॥ स्वाम्याश्रितक्रियाजन्यसंस्कारजन्यज्ञानम् । इति रसमञ्जरी ॥ अनुभव-संस्कार-जन्य-ज्ञानम् । यथा, -- "सम्बिद्धगवती द्वेधा स्मृत्यनुभवभेदिका ॥" इति कविकल्पद्रुमटीकायां दुर्गादासः ॥ किञ्च । "विभुर्ब्बुद्ध्यादिगुणवान् बुद्धिस्तु द्विविधा मता । अनुभूति स्मृतिश्च स्यादनुभूतिश्चतुर्व्विधा ॥" इति भाषापरिच्छेदः ॥

#### Amarkosha

स्मृति स्त्री। धर्मशास्त्रम् समानार्थक:स्मृति,धर्मसंहिता 1।6।6।2।1

प्रबन्धकल्पना कथा प्रवह्लिका प्रहेलिका। स्मृतिस्तु धर्मसंहिता समाहृतिस्तु संग्रहः॥

पदार्थ-विभागः : , पौरुषेयः

स्मृति स्त्री। स्मरणम् समानार्थक:चिन्ता,स्मृति,आध्यान 1।7।29।1।2

स्याच्चिन्ता स्मृतिराध्यानमुत्कण्ठोत्कलिके समे। उत्साहोऽध्यवसायः स्यात्स वीर्यमतिशक्तिभाक्.।

: कामादिजस्मृतिः

पदार्थ-विभागः : , गुणः, मानसिकभावः

# Vachaspatyam

"'स्मृति'''¦ स्त्री स्मृ--क्तिन्। अनुभूतवस्तुन उद्बोधकसहकारेणसंस्काराधीने

१ ज्ञानभेदे। स्मर्यते वेदवर्मोऽनेन करणेक्तिन्।

२ धर्मशासनशास्त्रे वेदार्थानुभवजन्ये वेदार्थानु-वादके मुनिप्रणीते वाक्यरूपे शास्त्रे। "वेदाऽखिलोधर्ममूलं स्मृतिशीले च तद्विदाम्" मनुः। ज्ञानभेदस्मृतिरूपलक्षणादिकं पात॰ सू॰ भा॰ विवरणे-षूक्तम् उक्तं यथा

"अनुभूतविषयाऽसंप्रमोषः स्मृतिः" सू॰।

"िकं प्रत्य-यस्य चित्तं स्मरित। आहोस्वित् विषयस्येति। ग्राह्यो-परक्तः प्रत्ययो ग्राह्यग्रहणोभयाकारिनर्भासः तथा-जातीयकं संस्कारमारमते स संस्कारः स्वव्यञ्जकाञ्जनंतदाकारमेव ग्राह्यग्रहणोभयात्मिकां स्मृतिञ्जनयित। तत्र ग्रहणाकारपूर्वा बुद्धिः ग्राह्याकारपूर्वा स्मृतिः। साच द्वयी, भावितस्मर्त्तव्या चाभावितस्मर्त्तव्या च खप्ने भावि-तस्मर्त्तव्या जाग्रत्समये त्वभावितस्मर्त्तव्येति। सर्वाःस्मृतयः प्रमाणविपर्य्ययिकिल्पनिद्रास्मृतीनामनुभवात्प्रभवन्ति" भा॰। "अनुभूतिवमयाऽसम्प्रमोपः स्मृतिःप्रमाणादिभिरनुभूते विमयेऽसम्प्रमोषः अस्तेयः सास्मृतिः संस्कारमात्रजन्यस्य हि ज्ञानस्थ संस्कारका-रणानुभावभासिती विषय आत्मीयस्तदिधकविषयपिर-ग्रहस्तु सम्प्रमोषः स्तेयः कस्मात् साद्वश्यात्। मृष-स्तेय इत्यस्मात् सम्प्रमोषपदव्युत्पत्तेः। एतदुक्तं भवति। [Page5374-a+38] सर्वे प्रमाणादयोऽनिधगतमर्थं सामान्यतः प्रकारतोवाधिगमयन्ति, स्मृतिः पुनर्न पूर्वानुभवमर्थ्यादामितका-मित तद्विषया तदूनविषया वा न तु तदिधकविषपासोऽयं कृत्त्यन्तराद्विशेषः स्मृतेरिति। विमृषिति किंप्रत्य-यस्येति ग्राह्यप्रवणत्वात् अनुभवस्य स्वानुभवात्तज्ञःसंस्कःरो ग्राह्यमेव स्मारयतीति। प्रतिभासयित अनुभवमात्रजनितत्वाच्चानुभवमेवेति। विमृश्यपपत्तित उभय-स्मरणमवधारयित ग्राह्यप्रवणतया ग्राह्योपरक्तः पर-मार्थतस्तु ग्राह्यग्रहणे एव उभयं तयोराकारं स्वरूपंनिर्भासयित प्रकाशयित। स्वव्यञ्जकं कारणमञ्जनमा-कारो यस्य स तथोक्तः। स्वकारणाकार इत्यर्थः। व्यञ्जक-मुद्बोधकं तेनाञ्जनं फलाभिमुखीकरणं यस्येति वेत्यर्थः। ननु यदि कारणिवचारेण बुद्धिस्मरणयाः सारूप्यंकस्तिहें भेद इत्यत आह त्तत्र ग्रहणेति। ग्रहण-मुपादानं न च गृहीतस्योपदानं सम्भवित तदनेनान-धिगतबाधनं बुद्धेरित्यक्तं ग्रहणाकारो ग्रहणरूपं पूर्वप्रधानं यस्याः सा तथोक्ता विकल्पितश्चायम् अभेदेऽपिगुणप्रधानभाव इति ग्राह्याकारः पूर्वः प्रथमो यस्याःसा तथोक्ता, इदमेव च ग्राह्याकारस्य ग्राह्यस्य पूर्वत्वंयदृत्यन्तरिवषयीकृतत्वमर्थस्य तदनेन वृत्यन्तरिवषयिकृत-गोचरा स्मृतिरित्युक्तं भवित सोऽयसम्प्रमोष इति। ननुअस्ति स्मृतेरिष सम्प्रमोषः दर्शयिति हि पित्र्यादेरतीतस्यदेशकालान्तरानुभूतस्याननुभूतचरदेशकालान्तरसम्बन्धं स्वप्रेइत्यत आह सा च द्वयीति भावितः किष्पतः स्मर्त्तव्योययासा तथोक्ता। अभावितोऽकिल्पतः पारमार्थिक इति या-वत्। नेयं स्मृतिरिष तु विपर्ययस्तल्लक्षणोपपन्नत्वात्स्मृत्याभासतया तु स्मृतिरुक्ता प्रमाणाभासिमेवेति भावः। कस्मात् पुनरन्ते स्मृतरुपन्यास इत्यत आह। सर्वाःस्मृतय इति अनुभवप्राप्तिपूर्वा वृत्तिः स्मृतिस्ततः स्मृती-नामन्ते निवेश इत्यर्थः"। धर्मशस्त्रशब्दे स्मृतिभेदादिकं ३८ ६३ पृ॰ दृश्यम्।

### Monier-Williams

स्मृति f. remembrance , reminiscence , thinking of or upon( loc. or comp. ) , calling to mind( स्मृतिम् अपि ते न यान्ति, " they are not even thought of ") , memory TA1r. ChUp. MBh. etc.

स्मृति f. memory as one of the व्यभिचारि-भावs(See. ) Das3ar.

स्मृति f. Memory (personified either as the daughter of दक्षand wife of अङ्गिरस्or as the daughter of धर्मand मेधा) Hariv. Pur.

स्मृति f. the whole body of sacred tradition or what is remembered by human teachers (in contradistinction to श्रुतिor what is directly heard or revealed to the ऋषिs; in its widest acceptation this use of the term स्मृतिincludes the 6 वेदा-ङ्गs, the सूत्रs both श्रौतand गृह्य, the law-books of मनुetc. [see next]; the इतिहासs [e.g. the महाभारतand रामा-यण], the पुराणs and

the नीतिशास्त्रs ; इति स्मृतेः, " accord. to such and such a traditional precept or legal text ") IW. 144 , 145

स्मृति f. the whole body of codes of law as handed down memoriter or by tradition ( esp. the codes of मनुयाज्ञवल्क्यand the 16 succeeding inspired lawgivers , viz. अत्रि, विष्णु, हारीत, उशनस्or शुक्र, अङ्गिरस्, यम, आपस्तम्ब, संवर्त, कात्यायन, बृहस्-पित, पराशर, व्यास, शङ्ख, लिखीत, दक्षand गौतम; all these lawgivers being held to be inspired and to have based their precepts on the वेद; See.

IW. 203 ) Gr2S3rS. Mn. Ya1jn5. etc.

स्मृति f. symbolical N. for the number 18 (fr. the 18 lawgivers above )

स्मृति f. a kind of metre L.

स्मृति f. N. of the letter ग्Up.

स्मृति f. desire, wish Pan5cat. iii , 258 ( v.l. for स्पृहा).

Smruti is the retension of perception of previous experiences. It deals with the processing of information which is already experienced, noticed, heard, gained, seen etc.

### DnyanaGrahana Prakriya

Dnyanagrahana Prakriya (acquiring the knowledge) is a multistage process; as described in Ayurveda. In Charak Samhita this process is explained in detail. It is stated that acquiring knowledge is a collaborative process of Atma, Mana, Indriya, Indriyartha and Buddhi. When the Atma (Soul) unites with Mana (mind), Mana with Indriyas (sensory organs), and Indriyas with their respective arthas (objects) then only knowledge is produced. For perception of knowledge this sequential union is needed. Presence of mind is utmost important for perception of knowledge. If the mind is absent; in spite of union of Indriya and Indriyarthas one can't perceive the knowledge. These unions are nothing but the phases or stages of acquiring knowledge. These can also be called as components of cognition process.

Apart from these major components, there are some other associated factors for perception of knowledge. These associated factors accelerate the process of knowledge production.

1. Doshas – These are; in normal condition, nothing but the producers of body, regulators of all bodily functions and destroyers in vitiated conditions. These are responsible for the physical as well as the mental functions of an individual.

A. Vata – Vata is responsible for all motor functions as well as sensory perceptions. Out of five types of Vata, Prana, Udana and Vyana are involved in Dnyana related processes. Prana Vata sustains the functions of intellect, sensory organs, heart and mind. Udana Vayu is responsible for Dhethe process of speech, effort, enthusiasium, initiating the process of grasping etc. the area of action of Vyana Vata is whole body and is responsible for the activities taking place throughout the body.

B. Pitta - Dhee and Medha are mentioned in Prakrita Pitta Karma. Sadhak Pitta is responsible for the achievement of one's own aspirations. Pitta is the prime Dosha involved in perception as well as retension of knowledge.

C. Kapha – Tarpak Kapha plays very important role of nourishment of all sensory organs.

2. Dhatu – Dhatus are nothing but the holding structures of body. They govern the Sharir (Physical) as well as Manas (mental) aspects of an individual. Dhatu Sarata can be considered as Vishuddha Dhatu stage or excellence of Dhatu. Scattered references related to Buddhi, Medha, Dhruti, Vidya etc are found in description of Rakta Sara, Twak Sara, Mamsa Sara, Majja Sara and Satwa Sara Purusha.

In nutshell, Buddhi, Medha, Pradnya and Prama can be considered as synonyms with a very little difference in characteristics. Dhi, Dhruti and Smruti can be considered as components of Buddhi. Dhi is responsible for real perception of knowledge. According to Aacharya Chakrapani because of Dhi the individual can acquire Yathartha Anubhava. Dhi can be taken as analytical power. Dhruti is meant for holding the perceived knowledge. It is nothing but the rentention power. This retension power enables the mind for logical interpretations of experiences/knowledge, brings mind upto a final decision and further more actual execution of that decision. It can be considered as governing force which abates the individual for not

following unwholesome practices. These are the Recollection of facts which were earlier experienced, heard or seen can be termed as Smruti. These terms can be easily correlated with intellect mentioned in contemporary medical sciences and the Dnyanagrahana Prakriya can be termed as cognition process mentioned in Ayurveda. Mere presence of intellect is not sufficient for the perception of knowledge but soundness of body and mind is also required for gaining the true knowledge.

#### REVIEW OF MODERN LITERATURE

The word intelligence is derived from the Latin verb 'intelligere' which means to comprehend or to perceive. Its noun form is **intelligentia** or intellectus. In middle ages this word was used for the translation of Greek word nous.

While defining intelligence various terms have been used like reasoning, planning, problem solving, creativity, understanding, critical thinking, self awareness, learning, knowledge etc. In short it can be considered as ability to perceive.

#### **Definitions**

In contemporary sciences various definitions of intelligence are quoted. Some of them are listed herewith

- 1. In 1994, total 131 researches were invited by famous wall street journal named "Mainstream science on intelligence" to finalize the definition of intelligence out of which 52 came together and finalized the definition as, "A very general mental capability that, among other things, involves the ability to reason, plan, solve problems, think abstractly, comprehend complex ideas, learn quickly and learn from experience. It is not merely book learning, a narrow academic skill, or test-taking smarts. Rather, it reflects a broader and deeper capability for comprehending our surroundings—"catching on," "making sense" of things, or "figuring out" what to do"
- 2. In 1995, one report was published by Board of Scientific Affairs of the American Psychological Association under the title 'Intelligence: Knowns and Unknowns'. It quoted the definition as, "Individuals differ from one another in their ability to understand complex ideas, to adapt effectively to the environment, to learn from experience, to engage in various forms of reasoning, to overcome obstacles by taking thought. Although these individual differences can be substantial, they are never entirely consistent: a given person's intellectual performance will vary on different occasions, in different domains, as judged by different criteria. Concepts of "intelligence" are attempts to clarify and organize this complex set of phenomena. Although considerable clarity has been achieved in some areas, no such conceptualization has yet answered all the important questions, and none commands universal assent. Indeed, when two

dozen prominent theorists were recently asked to define intelligence, they gave two dozen, somewhat different, definitions."

Besides these some other learning researchers have also postulated various definitions of Intelligence.

Table No. 1 – Various definitions of Intelligence

Researcher	Quotation
Alfred Binet	Judgment, otherwise called "good sense", "practical sense", "initiative",
	the faculty of adapting one's self to circumstances auto-critique.[1]
David Wechsler	The aggregate or global capacity of the individual to act purposefully, to
	think rationally, and to deal effectively with his environment.[2]
Lloyd Humphreys	"the resultant of the process of acquiring, storing in memory,
	retrieving, combining, comparing, and using in new contexts information
	and conceptual skills".[3]
Howard Gardner	To my mind, a human intellectual competence must entail a set of skills
	of problem solving — enabling the individual to resolve genuine
	problems or difficulties that he or she encounters and, when appropriate,
	to create an effective product — and must also entail the potential for
	finding or creating problems — and thereby laying the groundwork for
	the acquisition of new knowledge.[4]
Linda Gottfredson	The ability to deal with cognitive complexity.[5]
Robert Sternberg	Goal-directed adaptive behavior.[6]
&	
William Salter	
Reuven Feuerstein	The theory of Structural Cognitive Modifiability describes intelligence as
	"the unique propensity of human beings to change or modify the
	structure of their cognitive functioning to adapt to the changing demands
	of a life situation".[7]
Shane Legg &	A synthesis of 70+ definitions from psychology, philosophy, and AI
Marcus Hutter	researchers: "Intelligence measures an agent's ability to achieve goals in
	a wide range of environments",[8] which has been mathematically

	formalized.[9]
Alexander	$F = T \nabla S [10]$
Wissner-	"Intelligence is a force, F, that acts so as to maximize future freedom of
Gross	action. It acts to maximize future freedom of action, or keep options
	open, with some strength T, with the diversity of possible accessible
	futures, S, up to some future time horizon, τ. In short, intelligence doesn't
	like to get trapped". Human intelligence is t

# Cognition

The word is derived from the verb, 'cognosco' which means thinking and awareness. The Latin noun form is, 'cognito' which means examination, learning, knowledge.

The literal meaning of cognition is, "the mental action or process of acquiring knowledge and understanding through thought, experience, and the senses". It involves many intellectual processes like attention, formation of knowledge, memory, judgments, evaluation, reasoning, computation, problem solving, decision making, comprehension etc. it involves generation of new knowledge with the help of existing knowledge. Multiple theories of cognition process have been proposed.

#### DRUG REVIEW - YASHTIMADHU

Diversity of flora and fauna has no bounds. Hundreds of thousands of members of Plant Kingdom are spread all through the lands and oceans varying from small, unicelluar, microscopic algae to gigantic ones penetrating hundreds of meters in the sky. With the boon to relieve from diseases, they appear to man as thirty three million Gods told in oriental literature offering their blessings to him. And in the shape of wise administrator of this plethora of medicines, according to their properties and actions comes the Bhishak. Doubtless knowledge of various properties and actions of the plant, their combinations and permutations, various formulations enables him to show to the world surprising works a medicine can do.

Rasayana is very distinct branch in Ashtanga Ayurveda. Almost all the classical treaties have explained Rasayana in great detail. One of its types is Medhya Rasayana. Anything that improves intellect, memory and other functions related to Indriya, Mana and Buddhi is Medhya. Medhya Rasayanas are the herbs/ formulations which improve the intellect. Four Medhya Rasayana are mentioned in Charak Samhita; administration of Yashtimadhu Choorna along with milk is amongst them. For present study entitled, "An Open Labeled, Randomized, Two Arm Study Of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study" this formulation was taken into consideration.

## Yashtimadhu

Botanical Name – Glycyrrhiza glabra Linn

**Family** - *Papilionaceae*; *Fabaceae*.

**English Name** – liquorice, licorice root

Parts used - roots

Table no. 1. - Ganas according to various Compendia -

Sr.	Name	Period	Gana/Varga
No.			
1.	Amarkosha	5 <sup>th</sup> Cen.A.D.	Vanaushadhi Varga
2.	Sausruta Nighantu	6 <sup>th</sup> Cent. A. D.	Haridradi Gana
3	Ashtanga Nighantu	8 <sup>th</sup> Cent. A. D.	Sarivadi Gana

4.	Dhanvantari Nighantu	10 <sup>th</sup> - 13 <sup>th</sup> Cent.	Guduchyadi Varga
		A.D.	
5	Shodhala Nighantu	12 <sup>th</sup> Cent. A.D.	Guduchyadi Varga
6.	Hridayadipaka	13 <sup>th</sup> Cent. A.D.	
	Nighantu		
7.	Abhidhanaratnamala	13 <sup>th</sup> Cent. A.D.	Madhura dravya skandha.
	(Sadrasa Nighantu)		
8	Madhava-Dravyaguna	13 <sup>th</sup> Cent. A.D.	Vividh-Aushadi varga.
9	Madanpala Nighatuu	14 <sup>th</sup> Cent. A.D.	Abhayadi varga"
10	Kaiyadev Nighantu	15 <sup>th</sup> Cent. A.D.	Aushadhi Varga
	(Pathyapathya		
	Vibodhaka)		
11.	Bhavaprakasa Nighantu	16 <sup>th</sup> Cent. A.D.	Haritakyadi Varga
12.	Gunaratnamala	16 <sup>th</sup> Cent. A.D.	Haritakyadi Varga
13.	Rajanighantu	17 <sup>th</sup> Cent. A.D.	Pipalyadi Varga
	(Nighantu Raja,		
	Abhidhana chudamani)		
14.	Nighantu Adarsha	20 <sup>th</sup> Cent. A.D.	Palashadi
			Varga
15.	Priya Nighantu	20 <sup>th</sup> Cent. A.D.	Shatpushpadi Varga
16.	Charaksamhita		Kanthya Gana Jeevaniya Sandhaniya,
			Varnya, Kandughna, Mutra virajaniya,
			Shonita sthapana, Chhardi nigrahana,
			Angamarda Prashamana Snehopaga,
			Vamanopaga, Aasthapanopaga.
17	Sushruta Samhita		Vacha haridradi, Bruhatyadi, Kakolyadi,
			Ambashtadi, Nyagrodhadi, Vachadi,
			Sarivadi.Anjanadi
18	Ashtanga Hrudaya		Vamana karaka, Niruhana, Jeevaneeya,

A	Anjanadi, Haridradi, Ambastadi,
N	Nyagrodhadi, Vachadi, Sarivadi.

# Paryaya (Synonyms):

In ancient era, no special methods were available for the identification of plants. The identification was carried out by means of Pancha Dnyanendriyas i.e. by visualization, testing, touching, etc and the nomenclature of drug was done. As this was the only way available, multiple names were given to one single drug taking into consideration all aspects of that drug. These aspects include the Utpatti Sthan (habitat), Swaroop (herb, shrub etc), the appearance of leaves, flowers, fruits, thorns, stem, stem bark etc., taste-smell-touch of the drug, the historical aspect of the drug, similarity between the drug components and various structures of human body or of various animals, the specific action of the drug etc. From these observations, the probable properties and actions of the drugs were guessed. Taking inference from this knowledge, the drug was used accordingly.

Hence multiple names of Yashtimadhu are found in classical texts. All of them are listed in tabular form as follows.

Table No. 2 – Various synonyms according to various compendia

Paryaya	BP	RN	MN	DN	NA	KN	PR	AK	SuN	ShN	AsN	SdN
Klitak	<b>√</b>		<b>✓</b>		<b>✓</b>	<b>✓</b>		<b>✓</b>			<b>✓</b>	<b>✓</b>
Yashtimadhu	<b>√</b>	<b>✓</b>	<b>✓</b>	<b>V</b>	<b>✓</b>							
Yashtimadhuk	<b>√</b>		<b>✓</b>					<b>✓</b>	<b>✓</b>	<b>✓</b>		<b>✓</b>
Madhuka		<b>✓</b>	<b>~</b>	~	<b>✓</b>	<b>~</b>		<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>✓</b>	
Madhuyashti						<b>✓</b>						
Madhusrava		<b>✓</b>		<b>V</b>		<b>✓</b>						
Madhu			<b>✓</b>			<b>✓</b>						
Madhuvalli		<b>√</b>										
Yashti		<b>✓</b>		<b>~</b>							<b>✓</b>	
Yashtayaha		<b>✓</b>										<b>✓</b>
Madhulika			<b>1</b>									
Jalaja			<b>✓</b>									

Yashtik		<b>✓</b>			<b>√</b>			
Madhuyashtika		✓		<b>√</b>	✓			
Yashtika						<b>√</b>		
Kashthamadhuka					✓			
Vallimadhuka					<b>√</b>			
Parushako							✓	
Mriduphala							✓	
Dhanvanachchhad							<b>√</b>	
Madhukam								✓

[Abbrevations – **B.P.** - Bhavprakash, **R.N.**- Raj Nighantu, **M.N.**- Madanpal Nighantu, **D.N.**- Dhanwantari Nighantu, **N.A.**- Nighantu Aadarsha, **K.N.**- Kaiyadeva Nighantu, **P.R.**- Paryaya Ratnamala, **AK**- Amarkosh, **Su.N.** – Saushruta Nighantu, **Sh.N**. – Shodhala Nighantu, **AsN** – Astanga Nighantu, **SdN** – Shadrasa Nighantu(Abhidhanaratnamala)]<sup>1-24</sup>

## Vernacular Names

Assamese: Jesthimadhu, Yeshtmadhu

Bengali: Yashtimadhu

English: Liquorice root

Gujrati: Jethimadha, Jethimard, Jethimadh

Hindi: Mulethi, Mulathi, Muleti, Jethimadhu, Jethimadh

Kannada: Jestamadu, Madhuka, Jyeshtamadhu, Atimadhura

Kashmiri: Multhi

Malayalam: Irattimadhuram

Marathi: Jesthamadh

Oriya: Jatimadhu, Jastimadhu Punjabi: Jethimadh, Mulathi

Tamil: Athimadhuram

Telugu: Atimadhuramu

Urdu: Mulethi, Asl-us-sus

# **Botanical Discription**

It is a hardy herb or under shrub that attain height 2-4 feet; the leaves are multifoliolate, imparipinnate; the flowers are in axillary spikes, papilionaceous, lavender to violet in colour; the pods are compressed and contain reniform seeds. The rootstock, which is stout, throws off a large number of perennial roots. The dried, peeled or unpeeled underground stems and roots constitute the drug known in the trade as Licorice. The fruit is leguminous which contains 2 – 5 seeds. Inflorescence is in Vasanta and legumes are seen in Varsha Ritu.

Table No. 3 Images of Yashtimadhu and its useful parts



# Rasapanchaka

Rasa - Madhura

Veerya – Sheeta (cold)

Vipaka – Madhura

Guna - Guru, Snigdha

**Doshghnata** – Reduces Vata and pitta. May increase Kapha

### Rogaghnata

Yashtimadhu is widely used in therapeutics since centuries. Some properties because of which it is used in management of various diseases are listed below with the references from various nighantu.

Table No. 4 – Various properties listed in various compendia

Sr.No.	Properties	BP	RN	MN	DN	NA	KN	ShN	MD	PN
1	Pittanilhara	√	√							
2	Pittahara	1		1	1					
3	Shukravardhaka	√			1		1			
4	Shoshaghana				1					
5	Vishaghana				1					
6	Raktapittahar							1	1	
7	Grahi							1		
8	Vrisya	1	1					1		1
9	Chakshushya	1	√			1	1	1		√ √
10	Swarya	1				1		1		
11	Vranya	1		1			1	1		
12	Vranashodhan								1	
13	Krimi								1	
14	Kushthaghna								1	
15	Pipasa			1						
16	Vamana			1						
17	Balya	1	1			1	1			
18	Tridoshahar					1	1			
19	Sotha						1			
	Shamanartha									
20	Kshaya					V	√			
	Shamanarth									
21	Keshya	1				1				
22	Shosha					1				
	Shamanartha									
23	Ruchya		1							
24	Kanthya									1

25	Asrait					

<sup>i</sup>[Abbrevations – **B.P.** - Bhavprakash, **R.N.**- Raj Nighantu, **M.N.**- Madanpal Nighantu, **D.N.**- Dhanwantari Nighantu, **N.A.**- Nighantu Aadarsha, **K.N.**- Kaiyadeva Nighantu, **Sh.N**. – Shodhala Nighantu, **MD** – Madhav Dravyaguna, **PN** – Priya Nighantu]<sup>1-24</sup>

### Chemical constituents -

The principal constituent of liquorice root is glycyrrhizin (about 2 to 9%), a triterpene saponin with low haemolytic index; which is 50 times sweeter than sugar. Root contains 3.6%, a yellow amorphous powder-asparagine, a glycosideisoliquirtin-2.2%, glucose-3.8%, starch, gum, mucilage, amorphous, sulphuric acid and metallic acids, calcium and magnesium salts. It also contains potassium, Ryle and starch. Glycyrrhetinic (glycyrrhetic) acid (0.5 to 0.9%), the aglycone of glycyrrhizin is also present in the root. Other active constituents of liquorice include isoflavonoids, chalcones, coumarins, triterpenoids and sterols, lignans, amino acids, amines, gums and volatile oils.

# Pharmacological Actions mentioned in Indian Medicinal Plants Volume 1

Demulcent, expectorant, antiallergic, anti-inflammatory, spasmolytic, mild laxative, antistress, antidepressive, antiulcer, liver protective, estrogenic, emmenagogue, antidiabetic. Used in bronchitis, dry cough, respiratory infections, catarrh, tuberculosis; genitourinary diseases, urinary tract infections; abdominal pain, gastric and duodenal ulcers, inflamed stomach, mouth ulcer, adrenocorticoid insufficiency.

# **Key application**

- In catarrh of the upper respiratory tract and gastric, duodenal ulcers. (German
- Commission E, ESCOP, WHO.)
- The British Herbal Compendium indicates the use of liquorice for bronchitis, chronic gastritis, peptic ulcer, rheumatism and arthritis, adrenocorticoid insufficiency, and to prevent liver toxicity.
- *Indian Herbal Pharmacopoeia* recognizes its use as an anti-inflammatory and antiulcer agent.
- A special liquorice extract known as DGL (deglycyrrhizinated liquorice) is used in the treatment of peptic ulcer.

- Oral liquoricepreparations, containing glycyrrhetinic acid, are used for the treatment of viral infections—viral hepatitis, common cold.
- Topical preparations, containing glycyrrhetinic acid, are used for herpes, eczema, and psoriasis.
- In Japan, a preparation of glycyrrhizin, cysteine and glycine is used by injection for the treatment of acute and chronic hepatitis.

# **Dosage**

• Root powder - 2 -4 gm (Ayurved Pharmacopia of India Vol. I.)

### **Risks**

Hypokalemia is the greatest threat when liquorice preparations high in glycyrrhizin are prescribed for prolonged periods. Liquorice causes fluid retention. Patients should be placed on a high potassium and low sodium diet. Special precautions should be taken with elderly patients and patients with hypertension or cardiac, renal or hepatic disease.

### Researches done on Yashtimadhu

- 1. In a study conducted by B. Mahadev et al *Yashtimadhu* with Cow's milk and milk powder have shown remarkable effect on the learning and memory capacity in Wistar Albino Rats in both the Pharmacological Models i.e. Elevated plus maze test and Passive avoidance paradigm. Hence as propounded by *Acharya Charaka Yashtimadhu* can be used as a memory promoting drug in both healthy as well as psychologically ailed individuals of all ages without any adverse effect.<sup>25</sup>
- 2. In conceptual study done by H. Hosseinzadeh et al, the authors have summarized the phytochemical, pharmacological, and toxicological data from recent experimental and clinical studies of licorice and its bioactive constituents. They concluded that several pharmacological properties like gastro-protective, hepato-protective, neuro-protective, and cardio-protective effects of licorice have been reported. Out of these, the effects of licorice in the treatment of gastrointestinal, skin diseases, and HRT were established in human studies. They noted that the mechanisms of licorice in these clinical studies is similar to animal and in vitro studies. <sup>26</sup>
- 3. In experimental study conducted by Desai Sandhya K. et al, reduction in Acetylcholinesterase (AChE) levels in brain was observed. This suggested the anti-

- cholinesterase activity of ALE and GRE might be the probable mechanism for its memory enhancing activity.<sup>27</sup>
- 4. In clinical study done by Kultunga R.D.H. et al, statistically highly significant improvement on short and long memory impairment in senile impairment was noted. The investigators opined that Guduchyadi Medhya Rasayan has shown memory enhancing, anti depressant, anti stress and anxiolytic potential. <sup>28</sup>
- 5. In another clinical study done by Sorakte Atul S. et al, the group treated with Medhya Rasayana showed highly significant and most effective changes with respect to objective parameters i.e. short term memory test pictures and serial recall effects test using memory scope. The group treated with Yogic practices showed highly significant and most effective changes with respect to subjective and objective parameters i.e. mini mental status scale. The investigators concluded that Medhya Rasayana are quick in action and bring about improvement in memory faster as compared to Yogic practices. <sup>29</sup>
- 6. In one literature review study done by Thakur AK et al, the distribution, ethnobotany, major secondary metabolites, ethnopharmacology and potential medicinal uses of *Glycyrrhiza glabra* have been summarized. Also need for identification and analytical characterization of secondary metabolites and experimental validation of extracts of *Glycyrrhiza glabra* is highlighted.<sup>30</sup>
- 7. In experimental study conducted by Chakravarthi KK et al, spatial learning and memory enhancing activities of aqueous extract of root of *Glycyrrhiza glabra* was observed in all the selected doses. The more significant effective doses observed were of 150 and 225 mg/kg.<sup>31</sup>
- 8. In one experimental study by Chakravarthi et al, the authors reported that aqueous extract of *Glycerrhiza glabra* has shown cognitive enhancing activity at all dosages but it was more significant at 150mg/kg dose. So the same drug can be explored for the management of impaired learning, dementia, Alzimer's disease and other neurodegenerative disorders.<sup>32</sup>
- 9. In one clinical study done by Lonare M.K. et al, tab. Yashtimadhu was administered in the dose of 1gm BD for the duration of 2 months. Non verbal intelligence test and battery of intelligence tests based on Guilford's structure of intellect model prepared

- by Pradnyamanas Samshodhika Pune was used for assessment parameters. It showed that Yashtimadhu is effective in improvement of neuropharmacological activity in adolescents.<sup>33</sup>
- 10. In one experimental study done by Paramdeep Singh et al, Flavonoid rich fraction of *Glycerrhiza glabra* root extract has shown positive results against phenytoin-induced cognition deficit in pentylenetetrazol (PTZ) kindled mice by reducing seizure severity and improving cognitive functions.<sup>34</sup>
- 11. One experimental study has been conducted by Min Ji Cho et al. This study was conducted for three licorice varieties, *Glycyrhiza uralensis*, *G. glabra*, and Shinwongam (SW) on a mouse model of inflammation-induced memory and cognitive deficit. The researchers concluded that all the three licorice varieties ameliorated the inflammation-induced cognitive dysfunction by down-regulating inflammatory proteins and up-regulating BDNF. These results suggest that licorice, in particular SW, could be potential therapeutic agents against cognitive impairment.<sup>35</sup>
- 12. In one clinical study done by Dr. Kolhe et al, both Tagara and Yashtimadhu were found to be equally effective along with REBT and Satwavajaya Chikitsa. Yashtimadhu was more effective in categories like anxious mood, behavior during interview. <sup>36</sup>
- 13. For conducting this review work the authors have gone through various research studies conducted on several plants to find out the nootropic activity of them. They have tabulated several plants showing nootropic activity. For *Glycerrhiza glabra* the atthors quoted one research study in which Glabridin was isolated from the roots of *Glycyrrhiza glabra* and its effects on cognitive functions and cholinesterase activity were investigated in mice. It was noted that Glabridin appears to be a promising candidate for memory improvement and it will be worthwhile to explore the potential of glabridin in the management of Alzheimer patients.<sup>37</sup>
- 14. Another literature review work is conducted by Kulkarni Reena et al. This is an extensive review work. In it, data of multiple researches conducted on several plants having medhya effect mentioned in Ayurveda is collected and presented in review form. For *Glycerrhiza glabra* total 17 research studies were considered which explained the plant information such as chemical composition, active ingredients, medicinal uses, side effects and probable mode of action. <sup>38</sup>

15. One experimental study has been conducted by Muralidharan P. et al using root extra extract markedly improves antihypoxic effects induced by sodium nitrite in rats and the may be attributed to antioxidant activity of the extract. <sup>39</sup>										

#### **DRUG REVIEW - KSHEERA**

Ksheera is taken into account as a food supplement rich in nutrients suitable for pediatric to geriatric age. In ancient Ayurveda treaties abundant description of Ksheera qualities, usefulness in maintenance of health also as dietary and therapeutic aspect in various disease conditions is found. Due to its qualities and rich nutritive values it's considered as a serious dietary think about antenatal care described in Ayurveda (Cha.Sha.8/32). Moreover it's recommended as drug of choice in drug having Jeevaniya Karma (which provides life to individual) (Cha.Su.25/40).

Group of animals from which can be obtained is described in Ayurveda under the term of Goras Varga / Ksheera Varga / Payah etc. Eight Sources of Ksheera are mentioned namely – Goksheera (cow milk), Mahisha Ksheera (buffalo milk), Aja Ksheera (Goat milk), Ushtra Ksheera (Camel milk), Manusha Ksheera (human milk), Avika Ksheera (Eve milk), Hasti Ksheera (elephant milk), Ekshapha Ksheera (milk of single hoofed animals) (AH.Su. 5) (Su.Su.45/47)(Cha.Su.1/105,106). Amongst these, cow milk and buffalo milk are getting used widely for feeding infants and as a food supplement to children, adults and elderly.

Common enlisted properties of Ksheera as per Ayurveda are Swadupakarasa (Sweet in taste and also at the top of digestion), Snigdha (Unctus), Ojovardhana (increasres Ojas), Dhatuvardhana (increases and nourishes the body tissues), Vatapittahara (pacifies Vata and Pitta), Vrishya (aphrodisiac), Shleshmala (increases Kapha), Guru (heavy/difficult to digest), Sheetala (having cooling effect) (AH. Su. 5) (Cha.Su.1/107). Consistent with Sushrutacharya Ksheera has following qualities – Anekaushadhirasaprasada (essence of all drugs which don't contain any waste part), Pranada (which protects the life by maintaining the balance between Agni (Fire ailment) and Soma (water ailment) in body thereby liable for growth), Guru (heavy/difficult to digest), Madhura (sweet in taste), Picchila (slimy), Sheeta (having cooling effect), Snigdha(unctus), Shlakshna (smooth/fine), Sara (flowing), Mrudu (soft)(Su.Su. 45/48).

As compared to Mahisha Ksheera, Goksheera (Cowmilk) is Alpabhishyandi i.e. it creates lesser secretions in body. (Su.Su.45/50,51). Consistent with Charakacharya and Sushrutacharya Mahisha Ksheera (buffalo milk) is Gurutar (heavier to digest), Sheetatara (having more cooling effect), Snehadun (excess unctus / filled with unctus quality) as

compared to Gavya Ksheera (cowmilk). Hence it's useful in Anidra (insomnia) and Atyagni (those who have stronger digestive fire) (Cha. Su.27/215)(Su.Su.45/219)

Due to familiar composition, the Ksheera is taken into account as best suited for all quite people. It's recommended in treatment of diseases caused due to vitiation of Vata, Pitta, Rakta and in Mannasa Vikaras. It's useful in the treatment of Jeerna Jwara (chronic fever), Kasa (Cough), Shwasa(Respiratory diseases), Shosha(Emaciation), Kshaya(degenerative changes), Gulma, Unmada(Psychosomatic diseases), Udar(Ascietis), Murccha (Fainting), Bhrama (Vertigo), Mada (intoxication), Daha (burning sensation), Pipasa (excessive thirst), Hriddosha (heart diseases), Bastidosha (diseases associated with urinary system), Panduroga (Anaemia), Grahani Dosha (diseases of small intestine), Arsha (Haemorrhoids), Shoola (pain), Udavarta (reverse movement of Vata Dosha thanks to suppression or obstruction of natural urges resulting in occurance of diseases), Atisara (diarrhea), Pravahika (irritable bowel syndrome), Yoniroga (diseases of female genital system), Garbhasrava (miscarriage), Raktapitta (bleeding disorders), Shrama (tiredness), Klama (fatigue). It's Balya (imparts strength), Vrishya (Chakrapani - Shukrajanak)(aphrodisiac), Vajikar (Chakrapani - Shukrapravartak) (aphrodisiac), Rasayana (has rejuvenating property), Medhya (improves intellectual capacity), Vayasthapana (delayed ageing), Aayushya (longevity of life), Jeevan (provides life), Bruhana (imparts growth), Sandhana (cohesive property), Vamana Virechana Aasthapana (useful for straightforward conduction of purification procedures like induced emesis, induced purgation and medicated enemas), Ojovardhana (Chakrapani - due to having similarity in properties) (increases Ojas – the essence of all Dhatus). It's highly suitable for youngsters, elderly people, Kshataksheena (emaciated thanks to chronic association with disease), Kshud Vyavaya Vyayam Karshitana (those who are emaciated due to extreme hunger, excessive indulgence in sexual act, excessive exercise).(Su.Su. 45/49) (Cha.Su.1/108-113).

The description of milk in various other Ayurved treaties like Bhavprakash, Yogratnakar, Rajnighantu, Dhanwantari Nighantu, Kaiyadev Nighantu is analogous thereto of found in Brihhattrayi.

# **Drug Review - Milk**

Milk may be a nutrient-rich, white liquid food produced by the mammary glands of mammals. It's the first source of nutrition for infant mammals before they're ready to digest other sorts of food.

## Physical and Chemical properties of milk

Milk is an emulsion or colloid of butterfat globules within a water-based fluid that contains dissolved carbohydrates and protein aggregates with minerals. Because it's produced as a food source for the young, all of its contents provide benefits for growth. The principal requirements are energy (lipids, lactose, and protein), biosynthesis of non-essential amino acids supplied by proteins (essential amino acids and amino groups), essential fatty acids, vitamins and inorganic elements, and water.

### pН

The pH of milk ranges from 6.4 to 6.8 and it changes over time. Milk from other bovines and non-bovine mammals varies in composition, but features a similar pH.

# Lipids

Initially milk fat is secreted within the sort of a fat globule surrounded by a membrane. Each fat globule consists almost entirely of triacylglycerols and is surrounded by a membrane consisting of complex lipids like phospholipids, along side proteins. These act as emulsifiers which keep the individual globules from coalescing and protect the contents of those globules from various enzymes within the fluid portion of the milk. Although 97–98% of lipids are triacylglycerols, small amounts of di- and monoacylglycerols, free cholesterol and cholesterol esters, free fatty acids, and phospholipids also are present. Unlike protein and carbohydrates, fat composition in milk varies widely within the composition due to genetic, lactational, and nutritional factor difference between different species The fat-soluble vitamins A, D, E, and K along side essential fatty acids like linoleic and omega-6 fatty acid are found within the milk fat portion of the milk.

#### **Proteins**

Normal bovine milk contains 30–35 grams of protein per liter of which about 80% is arranged in casein micelles. Total proteins in milk represent 3.2% of its composition.

Milk contains dozens of other types of proteins beside caseins and including enzymes. These other proteins are more water-soluble than caseins and do not form larger structures. Because the proteins remain suspended in whey remaining when caseins coagulate into curds, they are collectively known as whey proteins. Lactoglobulin is the most common whey protein by a large margin.

## Salts, minerals, and vitamins

Minerals or milk salts are traditional names for a variety of cations and anions within bovine milk. Calcium, phosphate, magnesium, sodium, potassium, citrate, and chloride are all included as minerals and they typically occur at concentration of 5–40 mM. The milk salts strongly interact with casein, most notably calcium phosphate. It is present in excess and often, much greater excess of solubility of solid calcium phosphate.

#### Vitamins

Milk may be a good source of the many other vitamins. Vitamins A, B6, B12, C, D, K, E, thiamine, niacin, biotin, riboflavin, folates, and pantothen are all present in milk.

### Carbohydrates

Milk contains several different carbohydrate including lactose, glucose, galactose, and other oligosaccharides. The lactose gives milk its sweet taste and contributes approximately 40% of whole cow's milk's calories. Lactose may be a disaccharide composite of two simple sugars, glucose and galactose. Bovine milk averages 4.8% anhydrous lactose, which amounts to about 50% of the entire solids of skim milk. Levels of lactose are dependent upon the type of milk as other carbohydrates can be present at higher concentrations than lactose in milks.

The composition of milk differs widely among species. Factors like the sort of protein; the proportion of protein, fat, and sugar; the amount of varied vitamins and minerals; and therefore the size of the butterfat globules, and the strength of the curd are among people who may vary.

- Human milk contains, on average, 1.1% protein, 4.2% fat, 7.0% lactose (a sugar), and supplies 72 kcal of energy per 100 grams.
- Cow's milk contains, on average, 3.4% protein, 3.6% fat, and 4.6% lactose, 0.7% minerals and supplies 66 kcal of energy per 100 grams.
- Donkey and horse milk have the lowest fat content, while the milk of seals and whales may contain more than 50% fat.

Table No. 1 - Analysis of composition of milk according to species

Sr.No	Constituents	Units	Cow	Buffalo	Goat	Sheep
1	Water	g	87.8	81.1	88.9	83
2	Protein	g	3.2	4.5	3.1	5.4
3	Fat	g	3.9	8.0	3.5	6.0
4	Saturated fatty acids	g	2.4	4.2	2.3	3.8
5	Monounsaturated fatty acids	g	1.1	1.7	0.8	1.5
6	Polyunsaturated fatty acids	g	0.1	0.2	0.1	0.3
7	Carbohydrate	g	4.8	4.9	4.4	5.1
8	Cholesterol	mg	14	8	10	11
9	Calcium	mg	120	195	100	170
10	Energy	kcal	66	110	60	95
	2	kJ	275	463	253	396

In dairy industry, milk is processed by 2 major methods pasteurization and sterilization.

1. Pasteurisation: It involves the process of heating every particle of milk of different classes to at least 63°C and holding at such temperature continuously for at least 30 minutes or heating it to at least 71.5°C and holding at such temperature continuously for at least 15 seconds or an approved temperature time combination that will serve to give a negative Phosphatase Test. It is expected that all pasteurised milk of different classes shall be cooled immediately to a temperature of 10°C, or less.

2. Sterilisation: It means heating milk in sealed container continuously to a temperature of either 115°C for 15 minutes or at least 130°C for a period of one second or more during a continuous flow then packed under aseptic condition in hermetically sealed containers to make sure preservation at temperature for a period not but 15 days from the date of manufacture.

# Types of Milk

#### **Boiled Milk**

Boiled Milk means milk which has been delivered to boil.

#### **Mixed Milk**

Mixed Milk means a mixture of milk of cow, buffalo, sheep, goat or the other milch animal and should be a mixture of any of those milk which has been made and conforms to the fat at 4.5% and solids-not-fat (SNF) at 8.5%

#### **Recombined Milk**

Recombined Milk means the homogenised product prepared from milk fat, non-fat-milk solids and water. Recombined milk shall be pasteurised and shall show a negative Phosphatase test. It conforms to the fat at 3% and solids-not-fat (SNF) at 8.5%

## **Skimmed Milk**

It is prepared from milk from which almost all the milk fat has been removed using cream separator. The quantity of fat left is approximately 0.05 to 0.1% and solids-not-fat (SNF) at 8.7%

### **Toned Milk**

Toned Milk is prepared by admixture of cow or buffalo milk or both with fresh skimmed milk; or by admixture of cow or buffalo milk or both that has been standardised to fat at 3% and solids-not-fat (SNF) at 8.5% by adjustment of milk solids. It involves pasteurization and when it shows a negative Phosphatase test, the criterion is fulfilled. Its nutritive value is similar to that of fresh cow milk.

## **Double Toned Milk**

Double Toned Milk is prepared by admixture of cow or buffalo milk or both with fresh skimmed milk, or by admixture of cow or buffalo milk or both that has been standardised to fat not less than 1.5% and solids-not-fat(SNF) at 8.5% by adjustment of milk solids. It is pasteurized and shall show a negative Phosphatase Test. Its nutritive value is almost same as that of toned milk except for lower fat and Vitamin A content.

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# Drug Review - Yashtimadhu

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http://niimh.nic.in/ebooks/eNighantu/ashtanganighantu/?mod=search&searchText=yaS hTImadhu

17. Dhanwantari Nighantu –

http://niimh.nic.in/ebooks/eNighantu/dhanvantarinighantu/?mod=search&searchText= yaShTImadhu

18. Bhavprakash Nighantu –

 $\underline{\text{http://niimh.nic.in/ebooks/eNighantu/bhavaprakashanighantu/?mod=search\&searchTex}}\\ \underline{\text{t=yaShTImadhu}}$ 

19. Madanpal Nighantu –

http://niimh.nic.in/ebooks/eNighantu/madanapalanighantu/?mod=search&searchText= yaShTImadhu

20. Raj Nighantu –

http://niimh.nic.in/ebooks/eNighantu/rajanighantu/?mod=search&searchText=yaShTI
madhu

21. Shivkosha –

http://niimh.nic.in/ebooks/eNighantu/shivakosha/?mod=search&searchText=yaShTIm
adhu

22. Shodhal Nighantu –

http://niimh.nic.in/ebooks/eNighantu/shodhalanighantu/?mod=search&searchText=yaS
hTImadhu

23. Saraswati Nighantu –

http://niimh.nic.in/ebooks/e-Nighantu/sarasvatinighantu/?mod=read&h=madhu 24. Siddhasara Nighantu –

http://niimh.nic.in/ebooks/e-Nighantu/siddhasaranighantu/?mod=search

25. Saushruta Nighantu – <a href="http://niimh.nic.in/ebooks/e-Nighantu/soushrutanighatu/?mod=read&h=madhuka">http://niimh.nic.in/ebooks/e-Nighantu/soushrutanighatu/?mod=read&h=madhuka</a>

26. Hridaydipak Nighantu – <a href="http://niimh.nic.in/ebooks/e-Nighantu/hrdudayadipakanighantu/?mod=search">http://niimh.nic.in/ebooks/e-Nighantu/hrdudayadipakanighantu/?mod=search</a>

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#### AIMS AND OBJECTIVES

## Aim

To evaluate the effect of consumption of Yashtimadhu Choorna along with milk on health and cognitive parameters in healthy volunteers.

# **Objectives**

# **Primary Objectives**

- 1. To evaluate the effect of consumption of Yashtimadhu Choorna along with milk on cognitive parameters in healthy volunteers in study group on the basis of
  - 1. DLST (Digit Letter Substitution Test)
  - 2. SLCT(Six Letter Cancellation Test)
- 2. To evaluate the cognitive parameters in healthy volunteers in control group on the basis of
  - 1. DLST (Digit Letter Substitution Test)
  - 2. SLCT(Six Letter Cancellation Test)

# **Secondary Objectives**

- 1. To compare the cognitive parameters in healthy volunteers in either groups on the basis of
  - 1. DLST (Digit Letter Substitution Test)
  - **2.** SLCT(Six Letter Cancellation Test)
- 2. Assessment of health status on the basis of episodes, severity and duration of illnesses in both groups.
- 3. Assessment of difference in absent days in school due to illness in both groups.
- 4. Assessment of change in energy levels, strength and stamina in both groups.
- 5. Assessment of growth parameters like height and weight in both groups.

#### MATERIAL AND METHODS

The present research topic entitled, "An Open Labeled, Randomized, Two Arm Study of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study" was planned with following research question and Hypotheses keeping in mind.

#### **Research Question**

Whether consumption of Yashtimadhu Choorna along with milk has any effect on health and cognitive parameters in healthy volunteers?

## **Hypothesis**

Consumption of Yashtimadhu Choorna along with milk has effect on health and cognitive parameters in healthy volunteers.

# Null Hypothesis – H<sub>0</sub>

Consumption of Yashtimadhu Choorna along with milk does not have any effect on health and cognitive parameters in healthy volunteers.

# Alternate Hypothesis – H<sub>1</sub>

Consumption of Yashtimadhu Choorna along with milk has beneficial effect on health and cognitive parameters in healthy volunteers.

Study Design: Open label, Randomized, Multi center, Prospective, Two arm Clinical Study

**Study Site:** Mahatma Phule Vidyaniketan Institution's Dnyanaprabodhini Madhyamik and Kanishtha Mahavidyalaya, Sasanenagar, Hadapsar Pune 28

**Ethical Clearance:** Permission from Institutional Ethics committee of Tilak Maharashtra Vidyapeeth was taken before commencement of clinical study.

**CTRI Registration:** Study is registered with clinical trial registry of India. The registration number is CTRI/2018/07/014909 [Registered on: 17/07/2018]

# Drug used for the study:

**Collection of raw material** - Medically useful parts (Upyuktanga - roots) were collected from local market for drug preparation.

**Authentication** - This sample raw material was subjected to authentication from Agharkar Research Institute (An autonomous body under Department of science and Technology, Government of India).

# S.O.P. (Standard operating procedure) for preparation of Choorna -

- 1. 10 kg. Dried roots of Yashtimadhu were purchased from the market.
- 2. With the help of disintegrator fine powder of Yashtimadhu roots i.e. Yashtimadhu Choorna was prepared having mesh size 60-80-100.
- 3. The *Choorna* was subjected to Analytical study. Analytical study was conducted at Central Research Laboratory, College of Ayurved and Research Centre, Nigadi, Pradhikaran, Pune. Moisture percentage, Total Ash, Acid soluble and insoluble Ash, Water soluble and insoluble Ash, Aqueous and Methanol Extractive Value and TLC were conducted during the Analytical study.
- 4. After obtaining Analytical study report the Choorna was packed into packets.
- 5. Each packet had 160 gm of Yashtimadhu Choorna.
- 6. Packets were duly sealed and labelled. Information of date of manufacturing, date of expiry, instructions for consumption etc. was printed on labels.

# Analytical Study Reports-

The Authentication and Analytical study reports are mentioned in Annexures

Table no. 1 – Images of raw material used and final product, packing and dispenser used



#### Methods followed for clinical study

Firstly the study design was explained to the school officials including teachers. After obtaining their consent, parent meeting was called. With the help of power point presentation, the study was explained in detail to the parents. Each and every possible effort was taken to answer study related queries. Parents' attendance was also recorded. The parents who were willing for participation were called on next day with their ward for participation eligibility screening.

# **Activities performed on Screening Visit**

Written informed consent was obtained from the parent /LAR of subjects prior to screening for possible inclusion in the study. During Informed consent process, the parents were given enough time to read the Informed Consent Form (ICF) & Patient Information Sheet (PIS)

which was printed in the languages best understood by them. They were given freedom to ask the questions and all questions were answered up to their satisfaction. If he/she agreed to participate in the study, a written informed consent for the same was obtained from him/her.

After signing Consent by the parent/LAR, assent procedure was conducted in subjects. For Assent, the study was explained to subjects in the language best understood to them. Then specially prepared Assent form was shared with them for reading purpose. The subjects were given enough time to read the Assent form which was printed in the languages best understood by them. They were given freedom to ask the questions and all questions were answered up to their satisfaction. If he/she agreed to participate in the study, a written informed Assent was obtained from him/her. After obtaining the assent from child and consent from parent study related activities were conducted.

Detailed physical and systemic examination was performed. Detailed past and present illness as well as medicinal history was taken to rule out any existing disease. This screening phase was designed to confirm that the subject fulfills all inclusion criteria and don't meet exclusion criteria. After finalization of inclusion in study, subjects were asked to come for baseline visit.

# **Activities performed on Baseline Visit**

Detailed physical and systemic examination was performed. Detailed past and present illness as well as medicinal history was taken to rule out any existing disease. Subject's medical history including number of episodes, severity (mild, moderate and severe) and duration of illness (days) during last month was recorded in CRF. Clinical symptoms, if observed any were noted in the CRF. The assessment parameters evaluation i.e. Digit Letter Substitution Test and Six Letter Cancellation Test was conducted in one to one manner. Their teachers were contacted to get information about their number of absent days due to illness, energy level, physical fitness, attentiveness in class and social behavior in class in last month.

According to randomization, the children were included in respective groups. Investigational drug i.e. Yashtimadhu Choorna was dispensed to subjects in group A. They were given 160gms of Yashtimadhu Choorna in sealed and duly labeled packet. They were instructed to empty the packet in clean and dry container at home. They were also advised to bring the container on next follow up visit to check the accountability. The group A subjects were advised to follow their regular routine which they were already following along with consumption of Yashtimadhu Choorna 2.5 gm along with 50 ml of milk, twice in a day for the

duration of 1 month. The subjects in group B were advised to follow their regular routine which they were already following along with consumption of 50 ml of milk twice in a day, for the duration of 1month. The subjects and their parents were informed to record the number of episodes of illnesses, severity (mild, moderate and severe) and duration of illness (days) during the month and provide the information in timely manner. Contact details were also shared with them and they were instructed to contact in emergency situation. There class teachers were contacted and requested to observe the students' about their number of absent days due to illness, energy level, physical fitness, attentiveness in class and social behavior in class during this month and share their observations at the end of the month.

One follow up card and one accountability sheet was issued to each participant. The participants were instructed to tick on the accountability sheet after consumption of Yashtimadhu Choorna along with milk on daily basis.

# Activities performed on Visit I (30<sup>th</sup> Day)

Detailed physical and systemic examination was performed. Subject's medical history including number of episodes, severity (mild, moderate and severe) and duration of illness (days) during last month was recorded in CRF. Clinical symptoms, if observed any; were noted in the CRF. Subjects were asked for any AE/SAE occurred. If subjects had AE/SAE, the details of the incidence were documented in the CRF. Their teachers were contacted to get information about their number of absent days due to illness, energy level, physical fitness, attentiveness in class and social behavior in class in last month.

The container/ Accountability sheet was checked to access the drug compliance. Investigational product i.e. Yashtimadhu Choorna was dispensed to subjects in group A. They were given 160gms of Yashtimadhu Choorna in sealed and duly labeled packet. They were instructed to empty the packet in clean and dry container at home. They were also advised to bring the container on next follow up visit to check the accountability. The group A subjects were advised to follow their regular routine which they are already following along with consumption of Yashtimadhu Choorna 2.5 gm along with 50 ml of milk, twice in a day for the duration of 1 month. The subjects in group B were advised to follow their regular routine which they are already following along with consumption of 50 ml of milk twice in a day, for the duration of 1 month. The subjects and their parents were informed to record the number of

episodes of illnesses, severity (mild, moderate and severe) and duration of illness (days) during the month and provide the information in timely manner. One accountability sheet was issued to each participant. The participants were instructed to tick on the accountability sheet after consumption of Yashtimadhu Choorna along with milk on daily basis. There class teachers were contacted and requested to observe the students' about their number of absent days due to illness, energy level, physical fitness, attentiveness in class and social behavior in class during this month and share their observation at the end of the month.

# Activities performed on Visit II (60th Day)

Detailed physical and systemic examination was performed. Subject's medical history including number of episodes, severity (mild, moderate and severe) and duration of illness (days) during last month was recorded in CRF. Clinical symptoms, if observed any were noted in the CRF. Subject were asked for any AE/SAE occurred. If subject had AE/SAE, the details of the incidence were documented in the CRF. Their teachers were contacted to get information about their number of absent days due to illness, energy level, physical fitness, attentiveness in class and social behavior in class in last month.

The container/ Accountability sheet was checked to access the drug compliance. Investigational product i.e. Yashtimadhu Choorna was dispensed to subjects in group A. they were given 160gms of Yashtimadhu Choorna in sealed and duly labeled packet. They were instructed to empty the packet in clean and dry container at home. They were also advised to bring the container on next follow up visit to check the accountability. The group A subjects were advised to follow their regular routine which they are already following along with consumption of Yashtimadhu Choorna 2.5 gm along with 50 ml of milk, twice in a day for the duration of 1 month. The subjects in group B were advised to follow their regular routine which they are already following along with consumption of 50 ml of milk twice in a day, for the duration of 1 month. The subjects and their parents were informed to record the number of episodes of illnesses, severity (mild, moderate and severe) and duration of illness (days) during the month and provide the information in timely manner. One accountability sheet was issued to each participant. The participants were instructed to tick on the accountability sheet after consumption of Yashtimadhu Choorna along with milk on daily basis. There class teachers were contacted and requested to observe the students' about their number of absent

Methodology

days due to illness, energy level, physical fitness, attentiveness in class and social behavior in

class during this month and share their observation at the end of the month.

Activities performed on Visit III (90th Day)

Detailed physical and systemic examination was performed. Subject's medical history

including number of episodes, severity (mild, moderate and severe) and duration of illness

(days) during last month was recorded in CRF. Clinical symptoms, if observed any were noted

in the CRF. Subjects were asked for any AE/SAE occurred. If subject had AE/SAE, the details

of the incidence were documented in the CRF. The assessment parameters evaluation i.e. Digit

Letter Substitution Test and Six Letter Cancellation Test was conducted in one to one manner.

Their teachers were contacted to get information about their number of absent days due to

illness, energy level, physical fitness, attentiveness in class and social behavior in class in last

month.

The container/ Accountability sheet was checked to access the drug compliance.

**Total Duration of Study:** 1 to 1 ½ years.

Study intervention: Yashtimadhu Choorna

**Dosage:** 2.5gm BD (early morning, on empty stomach and after evening meal)

**Anupana** – 50 ml of milk

**Duration of Therapy:** 3 months.

**Study Groups:** 

Group A (Study Group): the students in this group were advised to follow their regular

routine which they are already following along with consumption of Yashtimadhu Choorna

2.5 gm along with 50 ml of milk, twice in a day for the duration of 3 months.

Group B (Control group): the students in this group were advised to follow their regular

routine which they are already following along with consumption of 50 ml of milk twice in a

day, for the duration of 3 months.

**Sample Size:** 

Considering 10% dropout rate, enrollment of minimum110 participants to get 100 completers in each group was proposed.

# **Toal Sample size - 239**

#### **Study Visits:**

Screening Visit (Day 0), Baseline Visit (Day 0), Visit I (Day 30), Visit II (Day 60), Visit III (Day 90),

#### Selection criteria:

#### **Inclusion Criteria:**

- 1) Apparently healthy volunteers i.e. students of secondary school
- 2) No significant medical or surgical illness at the time of screening
- 3) Volunteers and their parents ready for the study and willing for treatment
- 4) Volunteers of the age group 10 to 14 yrs (both inclusive)
- 5) Selection was irrespective of religion, gender, socioeconomic status, class and standard.
- 6) Willing to undergo study related procedures.

# **Exclusion Criteria:**

- 1) Presence of significant medical or surgical illness at the time of screening requiring long term treatment.
- 2) Volunteers having history of delayed milestones in infancy/childhood
- 3) K/C/O growth retardation, mentally retarded children.

#### Withdrawal Criteria:

- 1) If volunteer develop any adverse effect owing to use of intervention.
- 2) Any other serious condition or any serious adverse event which requires urgent treatment occurs.
- 3) If volunteer refuses to continue with the treatment and wish to be withdrawn

#### **Criteria for Assessment**

- 1. Digit Letter Substitution Test (DLST) was conducted at baseline visit and at the end of the study.
- 2. Six Letter Cancellation Test(SLCT) was conducted at baseline and at the end of the study.
- 3. Overall Improvement was assessed at the end of the study

# Methodology for assessment parameters

# 1. Digit Letter Substitution Test (DLST)

- a. Digit letter substitution test includes visual scanning, mental flexibility, sustained attention and psychomotor speed of information processing.
- b. The DLST worksheet consists of an array of random digits,1-9, in 8 rows and 12 columns.
- c. The coding sheet has instructions about the test with example of substituting a specific letter for each digit 1-9, the same coding applying to an entire test group.
- d. Subjects were instructed to make their own choice of letter substitution strategy, whether horizontally, vertically, or selecting a particular digit randomly in the array one at a time.
- e. They were instructed to substitute as many target digits as possible in the specified time of 90 seconds.

# 2. Six Letter Cancellation Test (SLCT)

- a. Cancellation tests require visual selectivity and a repetitive motor response. A six letter cancellation test is administered to assess functions such as selective and focused attention, visual scanning, and the activation and inhibition of rapid responses.
- b. The six letter cancellation task worksheet consists of an array of random alphabets, A-Z, in 14 rows and 22 columns.
- c. Subjects were instructed to seat with the worksheet turned over until the start of the test. All participants to be tested were given instruction sheet (coding sheet) indicating the six target letters to be cancelled. The instructions were given regarding cancellation of as many target digits as possible in the specified time of 90 seconds.
- d. They were given the choice of cancellation strategy to do it horizontally, vertically, or selecting a particular letter one at a time randomly in the array.

e. Finally, after ensuring that they have understood the test by answering all their queries they were asked to turn over the worksheet and start the test as the bell rings.

#### **Common SOP followed for conduction of assessment tests**

- 1. Both of these tests were conducted on the same day
- 2. Both tests were conducted in one to one manner.
- 3. First instructions regarding Digit Letter Substitution Test (DLST) were given. After ensuring that the subject has understood how to perform the test, he/she was allowed to do so.
- 4. After completion of Digit Letter Substitution Test (DLST), that worksheet was taken and Six Letter Cancellation Test (SLCT) was issued.
- 5. First instructions regarding Six Letter Cancellation Test (SLCT) were given. After ensuring that the subject has understood how to perform the test, he/she was allowed to do so.
- 6. After completion of Six Letter Cancellation Test (SLCT), that worksheet was taken.
- 7. The invigilators were sat quietly and minimized movements to avoid distracting the participant during these tests.
- 8. Also peaceful surroundings were maintained to avoid distracting the participant during these tests.

# 3. Overall improvement

- a. Discussion with school teacher was done.
- b. For teacher the points under discussion will be absenteeism due to illness, attentiveness, energy level, physical fitness, social behavior in class.
- c. For parents/subjects the points under discussion will be episodes, severity and duration of illness, energy levels, physical fitness, stamina, social behavior at home

# **Study Design Flow Chart**

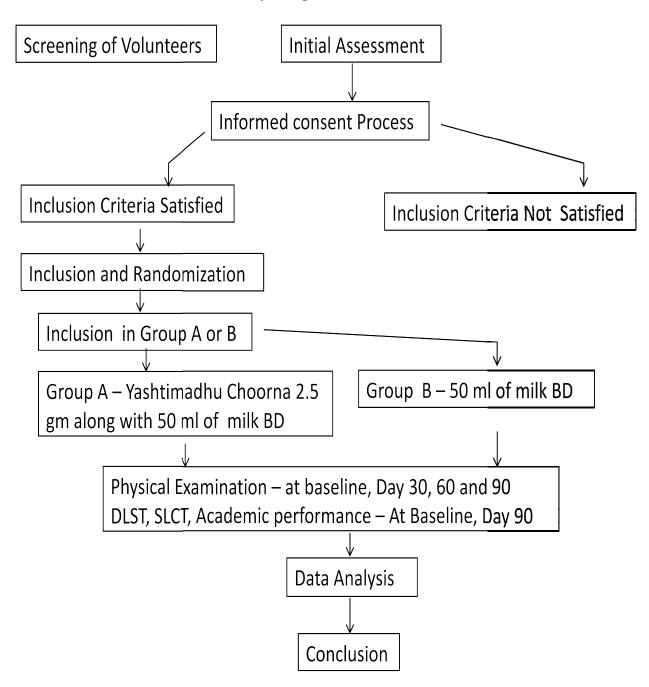


Table No. 2 Schedule of activities conducted during the study

Activity	Screening Visit	Baseline Visit	Visit I	Visit II	Visit III
Written Informed Consent	√	X	X	X	X
Assessment of Inclusion/ Exclusion Criteria	V	1	X	X	X
Demographic Data and History	X	√	X	X	X
Prakriti evaluation	X	1	X	X	X
Examinations (Vitals, Systemic, height, weight Clinical)	V	<b>V</b>	<b>√</b>	<b>V</b>	√
Evalation of Assessment parameters - DLST, SLCT	X	V	X	X	<b>√</b>
CGI Scale Assessment	X	√	X	X	√
Teachers Narrative	X	V	√	√	V
Drug Dispensing	X	<b>√</b>	√	√	X
Drug Compliance	X	X	√	√	V
Safety assessment and ADR/Adverse Events	X	√	√	<b>V</b>	<b>√</b>

#### **OBSERVATIONS AND RESULTS**

The data generated during the study was grouped under three headings for convenience of statistical analysis.

- 1. Analysis of demographic data of subjects included in study.
- 2. Analysis of assessment parameters
- 3. Analysis of adverse events

For statistical analysis SPSS (version 23) and Microsoft Excel were used. For analysis of objective data before and after treatment within group paired t test was used, while for analysis of data between groups unpaired t test was used. Multiple measurements were analysed using one way analysis of variance (ANOVA). The results obtained after statistical analysis were interpreted at confidence level of 95%.

### **Analysis of Demographic Data of Subjects Included in Study**

After obtaining informed consent and baseline screening total 239 subjects were included in both groups. In group A 119 subjects were included, while in group B 120 subjects were included. For analysis of demographic data all subjects included in study were considered.

# Age Wise Distribution (n = 239)

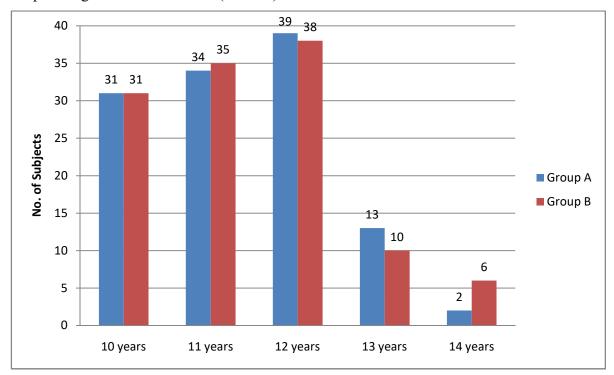
According to the inclusion criteria subjects between age group of 10 to 14 years (both years inclusive) were included in the study. Out 239 subjects included maximum (32.22 %) were of 12 years, while minimum (3.35 %) subjects belonged to 14 years of age. Out of remaining subjects 25.94 % belonged to 10 years, 28.87 % belonged to 11 years and 9.62 % belonged to 13 years of age (Table 1, Graph 1).

Table 1: Age Wise Distribution (n = 239)

Sr.	Age	Group A		Gro	Group B		Total (Group A + B)	
No		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	
1.	10 years	31	26.05	31	25.83	62	25.94	
2.	11 years	34	28.57	35	29.17	69	28.87	

3.	12 years	39	32.77	38	31.67	77	32.22
4.	13 years	13	10.92	10	8.33	23	9.62
5.	14 years	2	1.68	6	5.00	8	3.35
	Total	119	100.00	120	100.00	239	100.00

Graph 1: Age Wise Distribution (n = 239)



Mean age and standard deviation (SD) of subjects included in group A was  $11.355 \pm 1.178$  years, while for group B it was  $11.356 \pm 1.121$  years. Baseline comparison of age between groups showed statistically insignificant results (p > 0.05) indicating that both groups did not differ from each other as far as age is concerned. (Table 2).

Table 2: Between Group Analysis of Age at Baseline

	Group A Age (in years)	Group B Age (in years)	Statistics	
N	119	120	T	Sig. (2-tailed)
Mean Age	11.355	11.356	-0.006	0.995
Std. Error of Mean	0.107	0.102		(p > 0.05)
Std. Deviation	1.178	1.121		

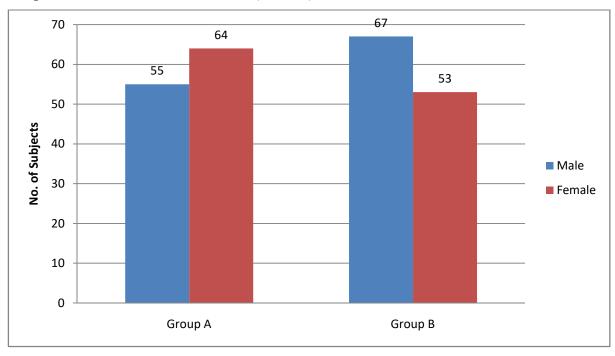
# Gender Wise Distribution (n = 239)

Gender wise distribution showed that 51.05 % subjects were male while 48.95 % subjects were female (Table 3, Graph 2). It indicates that nearly equal number of male and female subjects was included in the study and there was no bias in inclusion as far as gender is concerned.

Table 3: Gender Wise Distribution (n = 239)

Sr.	Gender	Group A		Gro	Group B		Total (Group A + B)	
No.		Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Male	55	46.20	67	55.8	122	51.05	
2.	Female	64	53.80	53	44.2	117	48.95	
	Total	119	100.0	120	100.0	239	100.00	

**Graph 2: Gender Wise Distribution (n = 239)** 



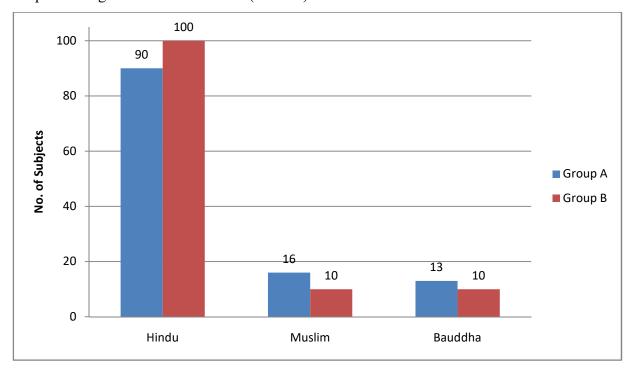
# Religion Wise Distribution (n = 239)

It was observed in the study that 79.50 % subjects were Hindu, 10.88 % were Muslims, while 9.62 % were followers of Buddhism. (Table 4, Graph 3)

Table 4: Religion Wise Distribution (n = 239)

Sr.	Religion	Group A		Gro	Group B		Total (Group A + B)	
No.		Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Hindu	90	75.6	100	83.3	190	79.50	
2.	Muslim	16	13.4	10	8.3	26	10.88	
3.	Bauddha	13	10.9	10	8.3	23	9.62	
	Total	119	100.0	120	100.0	239	100.00	

Graph 3: Religion Wise Distribution (n = 239)



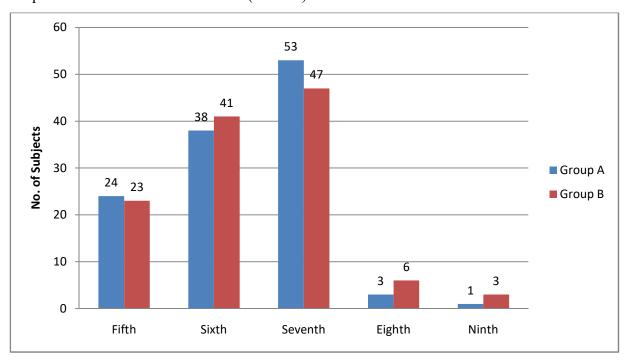
# Standard Wise Distribution (n = 239)

Standard wise distribution of subjects showed that maximum (41.84 %) students were studying in seventh standard. Students studying in fifth, sixth and eighth standard were 19.67 %, 33.05 % and 3.77 % respectively, while 1.67 % of subjects were studying in ninth standard (Table 5, Graph 4)

Table 5: Standard Wise Distribution (n = 239)

Sr.	Standard	Group A		Gro	Group B		Total (Group A + B)	
No.		Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Fifth	24	20.2	23	19.2	47	19.67	
2.	Sixth	38	31.9	41	34.2	79	33.05	
3.	Seventh	53	44.5	47	39.2	100	41.84	
4.	Eighth	3	2.5	6	5.0	9	3.77	
5.	Ninth	1	0.8	3	2.5	4	1.67	
	Total	119	100.0	120	100.0	239	100.00	

Graph 4: Standard Wise Distribution (n = 239)



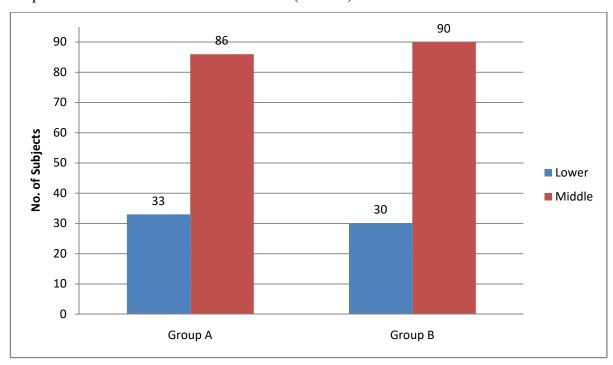
# Financial Status Wise Distribution (n = 239)

Financial status of the parents of subjects included in the study revealed that maximum families belonged to middle class (73.67 %), while remaining families (26.36 %) belonged to lower financial status. None of subject was from higher classes of society. It indicates that all the subjects belonged to majority class of people (Table 6, Graph 5).

Table 6: Financial Status Wise Distribution (n = 239)

Sr.	Financial	Group A		Gro	Group B		Total (Group A + B)	
No.	Status	Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Lower	33	27.7	30	25.0	63	26.36	
2.	Middle	86	72.3	90	75.0	176	73.67	
3.	Higher	00	0.00	00	0.00	00	00.00	
	Total	119	100.0	120	100.0	239	100.00	

Graph 5: Financial Status Wise Distribution (n = 239)



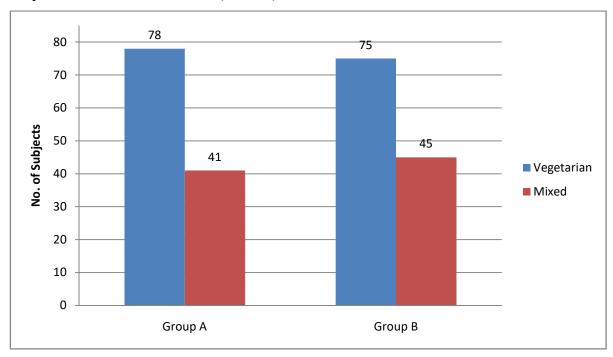
# Diet Wise Distribution (n = 239)

It was observed in the study that majority of the subjects (64.02 %) were following vegetarian diet practices, while 35.98 % subjects were having mixed diet (Table 7, Graph 6).

Table 7: Diet Wise Distribution (n = 239)

Sr.	Diet	Group A		Gro	Group B		Total (Group A + B)	
No.	Pattern	Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Vegetarian	78	65.5	75	62.5	153	64.02	
2.	Mixed	41	34.5	45	37.5	86	35.98	
	Total	119	100.0	120	100.0	239	100.00	

Graph 6: Diet Wise Distribution (n = 239)



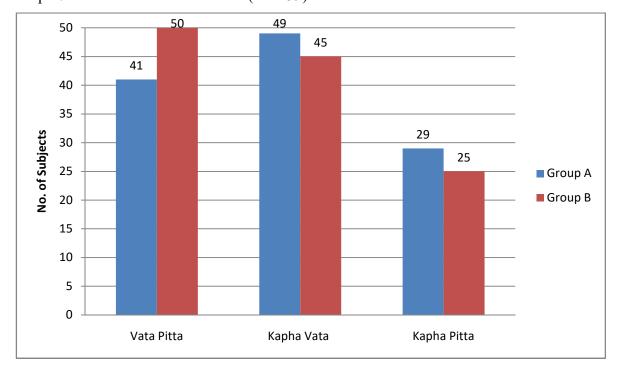
# Prakruti Wise Distribution (n = 239)

Out of 239 subjects included in the study 39.33 % belonged to Kapha Vata Pradhan Prakruti, 38.08 % of subjects were found to have Vata Pitta Pradhan Prakruti, while remaining (22.59 %) belonged Prakruti with Kapha Pitta dominance. Prakruti is very basic consideration for Ayurvedic way of examination and the distribution of patients in present study is fairly comparable between groups as well (Table 8, Graph 7).

Table 8: Prakruti Wise Distribution (n = 239)

Sr.	Prakruti	Group A		Gro	Group B		Total (Group A + B)	
No.		Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Vata Pitta	41	34.5	50	41.7	91	38.08	
2.	Kapha Vata	49	41.2	45	37.5	94	39.33	
3.	Kapha Pitta	29	24.4	25	20.8	54	22.59	
	Total	119	100.0	120	100.0	239	100.00	

Graph 7: Prakruti Wise Distribution (n = 239)



# Agni Wise Distribution (n = 239)

Agni is the digestive fire that transforms everything that is ingested into Dhatu (~body tissues). According to variations of Agni observed 35.15 % of subjects were having Teekshna Agni, 33.89 % subjects were having Vishama Agni, while 17.15 % were fitting into the criteria of Manda Agni. Minimum subjects (13.81 %) were having desired type of Agni i.e. Sama Agni (Table 9, Graph 8).

Table 9: Agni Wise Distribution (n = 239)

Sr.	Agni	Group A		Gro	Group B		Total (Group A + B)	
No.		Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Sama	19	16.0	14	11.7	33	13.81	
2.	Vishama	41	34.5	40	33.3	81	33.89	
3.	Teekshna	44	37.0	40	33.3	84	35.15	
4.	Manda	15	12.6	26	21.7	41	17.15	
	Total	119	100.0	120	100.0	239	100.00	

44 45 41 40 40 40 35 30 No. of Subjects 26 25 Group A 19 20 ■ Group B 15 14 15 10 5 0 Vishama Teekshna Sama Manda

Graph 8: Agni Wise Distribution (n = 239)

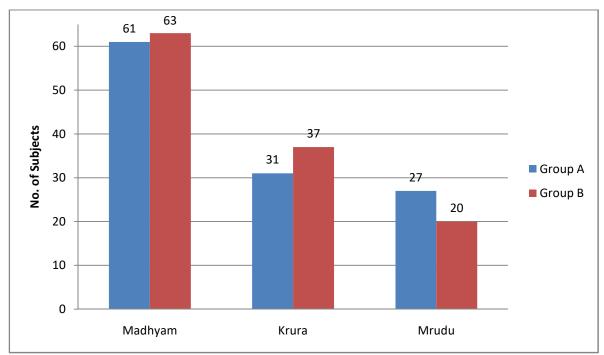
# Koshtha Wise Distribution (n = 239)

According to the types of Koshtha, maximum subjects (51.88 %) were belonging to Madhyam Koshtha. Subjects belonging to Krura Koshtha were 28.45 %, while remaining (19.67 %) belonged to Mrudu Koshtha category (Table 10, Graph 9).

Table 10: Koshtha Wise Distribution (n = 239)

Sr.	Koshtha	Group A		Gro	Group B		Total (Group A + B)	
No.		Frequency	Percent	Frequency	Percent	Frequency	Percent	
1.	Madhyam	61	51.3	63	52.5	124	51.88	
2.	Krura	31	26.1	37	30.8	68	28.45	
3.	Mrudu	27	22.7	20	16.7	47	19.67	
	Total	119	100.0	120	100.0	239	100.00	

Graph 9: Koshtha Wise Distribution (n = 239)



# Baseline Comparison of Assessment Parameters (n = 239)

In this study primary assessment parameters were Digit Letter Substitution Test (DLST) and Six Letter Cancellation Test (SLCT) which were conducted before and after study. Comparison of mean values of DLST, SLCT, and basic physical characters such as height, weight and body mass index (BMI) was done at baseline. The analysis revealed that there was no significant difference between groups (p > 0.05). Hence the groups are comparable to each other (Table 11).

Table 11: Comparison of Growth parameters, DLST and SLCT between Group A and Group B at Baseline

Assessment	Group	N	Mean	SD	SE	t	Sig. (2-	
Parameter	Group		wican	SD	J SL		tailed)	
Height Baseline	A	119	1.386	0.076	0.007	-0.336	0.737	
Height Daseinic	В	120	1.389	0.078	0.007	-0.550	0.737	
Weight Baseline	A	119	31.286	8.479	0.777	-0.134	0.894	
Weight Baseinie	В	120	31.424	7.487	0.683	-0.134	0.074	
BMI Baseline	A	119	16.099	3.189	0.292	-0.081	0.936	
Divil Daseinic	В	120	16.131	2.866	0.262	-0.031	0.730	
DLST Total	A	119	32.017	9.729	0.892	-0.697	0.486	
Baseline	В	120	32.858	8.918	0.814	-0.097	0.400	
DLST Wrong	A	119	1.168	3.482	0.319	0.245	0.807	
Baseline	В	120	1.083	1.481	0.135	0.243	0.007	
DLST Net	A	119	30.849	10.380	0.952	-0.723	0.471	
Baseline	В	120	31.775	9.418	0.860	-0.723	0.471	
SLCT Total	A	119	21.067	6.712	0.615	1.100	0.273	
Baseline	В	120	20.117	6.651	0.607	1.100	0.273	
SLCT Wrong	A	119	0.588	1.123	0.103	-1.276	0.203	
Baseline	В	120	0.808	1.514	0.138	-1.2/0	0.203	
SLCT Net	A	119	20.479	6.548	0.600	1.407	0.161	
Baseline	В	120	19.308	6.318	0.577	1.70/	0.101	
[Foot Note: * - me	an differer	nce is sig	gnificant at 0	.05 level]	1			

# Analysis of Total Number of Subjects Included in Study

Total 239 subjects were randomised in two study groups (n = 119 in group A, n = 120 in group B). Out of these 4 subjects from group A and 5 subjects from group B did not complete the study. Out of 4 dropouts in group A subjects 1 subject changed school, 1 was lost to follow up and 2 refused to take study medicine hence withdrawn from the study. Out of 5 dropouts from group B, 2 subjects changed school during study period hence could not complete the

study, while 3 were lost to follow up. Hence total 230 subjects (n = 115 in each group) completed the study. The details are outlined in flow chart.

# **Analysis of Effect on Assessment Parameters (n = 115 in each group)**

Primary efficacy variables were DLST and SLCT conducted at baseline and after treatment.

# **Digit Letter Substitution Test (DLST)**

**Group A:** In group A, that received Yashtimadhu (*Glycerriza glabra* Linn.) powder with milk mean and SD of total DLST score at baseline and after treatment was  $31.478 \pm 9.291$  and  $41.565 \pm 10.634$  respectively. The mean and SD scores of wrong substitutions of digits with letters in DLST at baseline and after treatment was  $1.139 \pm 3.497$  and  $0.548 \pm 2.507$  respectively, while for net score of DLST it was  $30.339 \pm 9.999$  and  $41.017 \pm 10.958$ . The increase in means of total DLST score and net DLST score was statistically significant (p < 0.001), while the decrease in means of wrong substitutions after treatment was insignificant (p > 0.05) (Table 12).

Table 12: Within Group Analysis of Effect on DLST in Group A (n = 115)

Pair	Parameter		Statistics	Paired D	ifference	+	Sig. (2-
raii	rarameter		Statistics	Mean	SD	t	tailed)
DI ST To	DLST Total	Mean	31.478				
	Baseline	SD	9.291		7.756	-13.947	0.000*
Pair 1		SE	0.866	-10.087			
		Mean	41.565	10.007			0.000
	DLST Total AT	SD	10.634				
		SE	0.992				
	DLST Wrong	Mean	1.139				0.067
	Baseline	SD	3.497				
Pair 2	Dascinic	SE	0.326	0.591	3.433	1.847	
1 411 2		Mean	0.548	0.371	J. <del>1</del> JJ	1.07/	0.007
	DLST Wrong AT	SD	2.507				
		SE	0.234				

		Mean	30.339				
	DLST Net Baseline	SD	9.999				
Pair 3		SE	0.932	-10.678	8.060	-14.208	0.000*
Tan 3	DLST Net AT	Mean	41.017	10.070	0.000	11.200	0.000
		SD	10.958				
		SE	1.022				
[Foot No	ote: * - mean difference	is significar	nt at 0.05 leve	i]	1	1	

**Group B:** It was standard control group that continued consumption of milk. In this group mean and SD of total DLST at baseline and after treatment was  $32.756 \pm 9.068$  and  $38.139 \pm 9.298$  respectively. The mean and SD scores of wrong substitutions at baseline and after treatment were  $1.130 \pm 1.495$  and  $0.991 \pm 1.673$  respectively. The net DLST scores at baseline and after treatment (mean and SD) were  $31.626 \pm 9.566$  and  $37.104 \pm 9.433$  respectively. Statistical analysis showed that there was significant increase in total and net DLST scores as compared to baseline (p < 0.001), while decrease in mean and SD of wrong substitutions was insignificant (p > 0.05) (Table 13).

Table 13: Within Group Analysis of Effect on DLST in Group B (n = 115)

Pair	Parameters		Statistics	Paired D	ifference	t	Sig. (2-
1 an	1 arameters			Mean	SD		tailed)
		Mean	32.756				
	Pair  DLST Total Baseline  DLST Total AT	SD	9.068			-10.564	
Pair		SE	0.846	-5.382	5.473		0.000*
1		Mean	38.139	-5.562	J. <del>4</del> /J		
		SD	9.298				
		SE	0.867				
		Mean	1.130				
Pair	DLST Wrong Baseline	SD	1.495	0.139	2.313	0.645	0.520
2		SE	0.139	0.137	2.313	0.043	0.520
	DLST Wrong AT	Mean	0.991				

		SD	1.673				
		SE	0.155				
		Mean	31.626				
	DLST Net Baseline	SD	9.566				
Pair		SE	0.892	-5.478	6.244	-9.409	0.000*
3		Mean	37.104	-3.476	0.244	-7.407	0.000
	DLST Net AT	SD	9.433				
		SE	0.880				
[Foot]	Note: * - mean difference	is significa	nt at 0.05 leve	1]	1		1

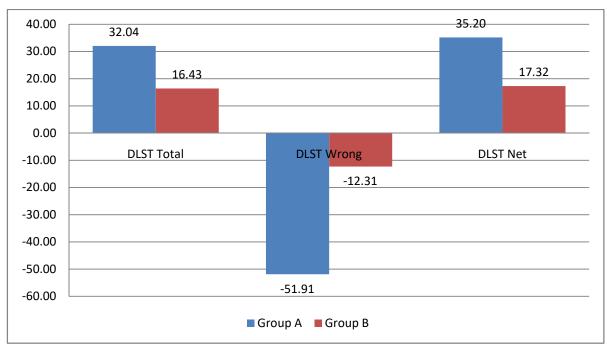
**Between Group Analysis:** Comparison of both groups showed that increase in mean scores of total and net DLST scores in group A was significantly higher than group B (p < 0.05). Comparison of means of wrong substitutions in DLST between both groups was insignificant (p > 0.05) (Table 14).

Table 14: Between Group Analysis of Effect on DLST (n = 115 in each group)

Daramatar	Group		Statistic	Mean	Std. Error	Т	Sig. (2-
Parameter	Group		Statistic	Difference	Difference	1	tailed)
		Mean	41.565				
	A	SD	10.634		1.317		0.010*
DLST		SE	0.992	3.426		2.601	
Total AT		Mean	38.139	3.420			
	В	SD	9.298				
		SE	0.867				
	A	Mean	0.548				0.116
DLST		SD	2.507	-	0.281	-1.578	
Wrong		SE	0.234	-0.443			
AT		Mean	0.991	0.443	0.201	-1.576	0.110
AI	В	SD	1.672				
		SE	0.156				
DLST Net	A	Mean	41.017	3.913	1.348	2.902	0.004*
AT		SD	10.958	3.713	1.570	2.702	0.004

[Foot Note: \* - mean difference is significant at 0.05 level]

Further comparison showed that improvement in total and net DLST score in group A was 32.04 % and 35.20 %, while improvement in group B was nearly half as compared to group A (16.43 % and 17.32 % respectively). It shows better effect of treatment in group A as compared with group B (Graph 10).



Graph 10: Change in percentage of means in DLST before and after treatment

## **Six Letter Cancellation Test (SLCT)**

**Group A:** In group A, mean and SD score of total SLCT before treatment was  $20.826 \pm 6.619$  that increased to  $26.130 \pm 7.766$  after treatment. The mean and SD of wrong cancellation of letters before treatment was  $0.600 \pm 1.138$ , while after treatment it was  $0.426 \pm 0.909$ . The mean of net score thus achieved by the subjects at baseline was  $20.226 \pm 6.440$ , while after treatment it was  $25.704 \pm 7.545$ . Increase in means of total and net SLCT score was statistically significant as compared to baseline (p <

0.001), while the decrease in wrongly attempted SCLT after treatment was insignificant as compared to baseline (p > 0.05) (Table 15).

Table 15: Within Group Analysis of Effect on SLCT in Group A (n = 115)

Pair	Parameter		Statistics	Paired D	ifference	Т	Sig. (2-
1 an	Tarameter		Statistics	Mean	SD	1	tailed)
	SLCT Total	Mean	20.826				
	Baseline	SD	6.619				
Pair	Busenne	SE	0.617	-5.304	6.607	-8.610	0.000*
1		Mean	26.130	-3.304	0.007	-0.010	
	SLCT Total AT	SD	7.766				
		SE	0.724				
	SLCT Wrong	Mean	0.600				
	Baseline	SD	1.138				0.171
Pair	20000000	SE	0.106	0.174	1.352	1.379	
2	SLCT Wrong	Mean	0.426	0.174	1.332	1.579	
	AT	SD	0.909				
	711	SE	0.085				
	SLCT Net	Mean	20.226				
	Baseline	SD	6.440				
Pair	Busenne	SE	0.601	-5.478	6.496	-9.044	0.000*
3		Mean	25.704	-3.770	0.470	-2.077	0.000
	SLCT Net AT	SD	7.545				
		SE	0.704				
[Foot]	Note: * - mean diffe	erence is si	ignificant at (	0.05 level]	ı	1	1

**Group B:** In group B, mean and SD of total SLCT score at baseline and after treatment was  $20.113 \pm 6.750$  and  $24.122 \pm 6.163$ . At baseline, the mean and SD of wrong cancellation was  $0.843 \pm 1.537$ , while after treatment it reduced to  $0.661 \pm 1.401$ . The net SLCT score at baseline was  $19.270 \pm 6.404$ , which was found increased to  $23.461 \pm 5.955$  after treatment. Analysis of these mean and SD showed that total and net SLCT scores improved significantly from baseline to the end of treatment (p < 0.001), while decrease in wrong substitutions was insignificant (p > 0.05) (Table 16).

Table 16: Within Group Analysis of Effect on SLCT in Group B (n = 115)

SI Pair	Carameter SLCT Total Baseline SLCT Total AT	Mean SD SE Mean	20.113 6.750 0.629	Mean	SD	T	tailed)
Pair Ba	Baseline	SD SE	6.750 0.629				
Pair Ba	Baseline	SE	0.629				
Pair 1							
	LCT Total AT	Mean	21122	-4.009	6.065	-7.088	0.000*
Sl	SLCT Total AT		24.122	-4.009	0.003	-7.000	0.000
SLCT Total AT	SD	6.163					
		SE	0.575				
SI	SLCT Wrong	Mean	0.843				
	Baseline	SD	1.537			0.955	
Pair	Juscinic	SE	0.143	0.183	2.050		0.342
2		Mean	0.661	0.103	2.030		
SI	SLCT Wrong AT	SD	1.401				
		SE	0.131				
		Mean	19.270				
SI	SLCT Net Baseline	SD	6.404				
Pair		SE	0.597	-4.191	5.712	-7.868	0.000*
3		Mean	23.461	-7.171	3.712	-7.000	0.000
SI	SLCT Net AT	SD	5.955				
		SE	0.555				

[Foot Note: \* - mean difference is significant at 0.05 level]

**Between Group Analysis:** Statistical analysis showed that increase in total and net SLCT score observed in group A was significantly higher as compared to group B (p < 0.05), while decrease in wrong cancellation of letters was statistically similar (p > 0.05) (Table 17).

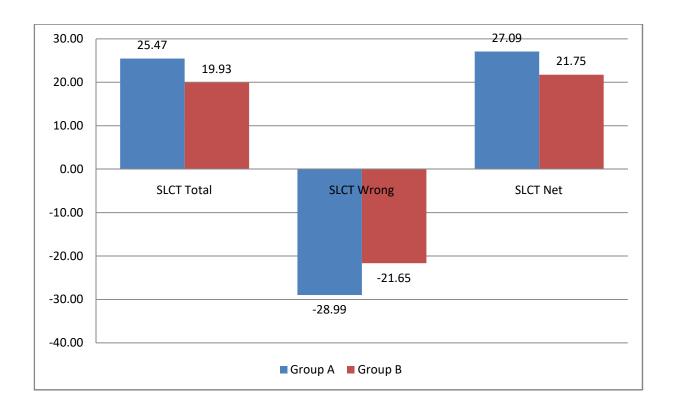
Table 17: Between Group Analysis of Effect on SLCT (n = 115 in each group)

Parameter	Group		Statistic	Mean Difference	Std. Error Difference	Т	Sig. (2- tailed)
SLCT	A	Mean	26.130	2.009	0.925	2.173	0.031*

Total AT		SD	7.766				
		SE	0.724				
		Mean	24.122				
	В	SD	6.163				
		SE	0.575				
		Mean	0.426				
SLCT Wrong	A	SD	0.909				
		SE	0.085	-0.235	0.156	-1.508	0.133
AT		Mean	0.661	-0.233	0.130	-1.500	
711	В	SD	1.401				
		SE	0.131				
		Mean	25.704				
	A	SD	7.545				
SLCT Net		SE	0.704	2.243	0.896	2.503	0.013*
AT		Mean	23.461	2.243	0.070	2.303	0.013
	В	SD	5.955				
		SE	0.555				
[Foot Note:	* - mean	differen	ce is signifi	cant at 0.05 le	vel]		

Further comparison in percentage of change in means showed that for total SLCT score improved by 25.47 % in group A and 19.93 % in group B, while net SLCT score improved by 27.09 % in group A and 21.75 % in group B. It shows better improvement in group A as compared to group B (Graph 11).

Graph 11: Change in percentage of means in SLCT before and after treatment



# Analysis of Effect on Growth Parameters – Height, Weight and Body Mass Index (n = 115 in each group)

Height, weight and body mass index (BMI) were examined at baseline and at the end of each month, till three months.

**Group A:** In trial group (A) the mean and SD of height at baseline was  $1.383 \pm 0.075$  meter (m), while, at the end of first, second and third month it was  $1.396 \pm 0.076$  m,  $1.399 \pm 0.075$  m and  $1.460 \pm 0.076$  m respectively. Mean and SD of weight measured at baseline was  $31.261 \pm 8.580$  kilogram (kg), while at first, second and last follow up it was  $31.922 \pm 8.763$  kg,  $31.871 \pm 8.872$  kg and  $32.072 \pm 8.901$  kg respectively. About BMI, the mean and SD at baseline were  $16.142 \pm 3.222$  kg/m². At the end of first month it was  $16.186 \pm 3.188$  kg/m², while at the end of second and third month it was  $16.078 \pm 3.251$  kg/m² and  $16.009 \pm 3.198$  kg/m², respectively. The within group analysis done using one way ANOVA showed that there was significant difference in height, weight and BMI. (For height – Wilks' Lambda = 0.136, F (3, 112) = 236.430, p < 0.001 and  $\eta^2 = 0.864$ . For weight – Wilks' Lambda = 0.611, F (3, 112) = 23.729, p < 0.001 and  $\eta^2 = 0.389$ . For BMI – Wilks' Lambda = 0.869, F (3, 112) = 5.647, p < 0.05 and  $\eta^2 = 0.131$ ) (Table 18).

Table 18: Within Group Analysis of Effect on Height, Weight and BMI in Group A (n = 115)

Parameters	Mean	SD		Multiva	ariate Test: Wilks	s' Lambda	
1 arameters	Wican	SD	Value	F	Hypothesis df	Error df	Sig.
Height Baseline	1.383	0.075					
Height FU1	1.396	0.076	0.136	236.430	3.000	112.000	0.000*
Height FU2	1.399	0.075	0.130				0.000*
Height AT	1.406	0.076					
Weight Baseline	31.261	8.580					
Weight FU1	31.922	8.763	0.611	23.729	3.000	112.000	0.000*
Weight FU2	31.871	8.872				112.000	
Weight AT	32.037	8.901					
BMI Baseline	16.142	3.222					
BMI FU1	16.186	3.188	0.860	5.647	3.000	112.000	0.001*
BMI FU2	16.078	3.251	0.869	3.047	3.000	112.000	0.001
BMI AT	16.009	3.198	•				
[Foot Note: Mea	suring uni	its – heigl	ht – mete	r. weight	– kilogram, BM	$II - kg/m^2$ .	* - mean

[Foot Note: Measuring units – height – meter, weight – kilogram, BMI – kg/m², \* - mean difference is significant at 0.05 level]

Pair wise comparison of all parameters showed that there was significant difference all pairs associated with height (p < 0.001). Significant difference in weight was observed when all follow up values were compared individually with baseline (p < 0.001) while for BMI there was no significant difference when baseline BMI was compared individually with each follow up (p > 0.05). Other pair wise comparisons though found significantly different from each other at some levels do not possess clinical importance (Table 19).

Table 19: Pair Wise Analysis of Effect on Height, Weight and BMI in Group A (n = 115)

Parameter 1	Parameter 2	Mean Difference	SE	Sig. <sup>a</sup>
		(Parameter1- Parameter2)		
Height Baseline	Height FU1	-0.012*	0.001	0.000
	Height FU2	-0.016*	0.001	0.000

	Height AT	-0.023*	0.001	0.000
	Height Baseline	0.012*	0.001	0.000
Height FU1	Height FU2	-0.003*	0.000	0.000
	Height AT	-0.010*	0.001	0.000
	Height Baseline	0.016*	0.001	0.000
Height FU2	Height FU1	0.003*	0.000	0.000
	Height AT	-0.007*	0.001	0.000
	Height Baseline	0.023*	0.001	0.000
Height AT	Height FU1	0.010*	0.001	0.000
	Height FU2	0.007*	0.001	0.000
	Weight FU1	-0.661*	0.085	0.000
Weight Baseline	Weight FU2	-0.610*	0.097	0.000
	Weight AT	-0.776*	0.105	0.000
	Weight Baseline	0.661*	0.085	0.000
Weight FU1	Weight FU2	0.050	0.060	1.000
	Weight AT	-0.115	0.083	1.000
	Weight Baseline	0.610*	0.097	0.000
Weight FU2	Weight FU1	-0.050	0.060	1.000
	Weight AT	-0.165	0.076	0.189
	Weight Baseline	0.776*	0.105	0.000
Weight AT	Weight FU1	0.115	0.083	1.000
	Weight FU2	0.165	0.076	0.189
	BMI FU1	-0.043	0.044	1.000
BMI Baseline	BMI FU2	0.065	0.050	1.000
	BMI AT	0.133	0.055	0.108
BMI FU1	BMI Baseline	0.043	0.044	1.000
	BMI FU2	0.108*	0.033	0.008
	BMI AT	0.176*	0.047	0.002
BMI FU2	BMI Baseline	-0.065	0.050	1.000
DIVIT I UZ	BMI FU1	-0.108*	0.033	0.008

	BMI AT	0.068	0.042	0.660
	BMI Baseline	-0.133	0.055	0.108
BMI AT	BMI FU1	-0.176*	0.047	0.002
	BMI FU2	-0.068	0.042	0.660

[Foot Note: Measuring units – height – meter, weight – kilogram, BMI – kg/m², a – adjustment for multiple comparisons: Bonferroni, \* - mean difference is significant at 0.05 level]

**Group B:** In this group the mean and SD of height at baseline was  $1.390 \pm 0.078$  m, at the end of first month it increased to  $1.403 \pm 0.078$  m, at the end of second month it was  $1.407 \pm 0.079$  m, while after treatment it increased up to  $1.412 \pm 0.081$  m. Mean and SD of weight at baseline was  $31.517 \pm 7.503$  kg, while at first, second and last follow up, it was observed as  $32.143 \pm 7.645$  kg,  $32.226 \pm 7.768$  kg and  $32.454 \pm 7.873$  kg respectively. About BMI, the mean and SD at baseline was  $16.158 \pm 2.871$  kg/m². It changed to  $16.181 \pm 2.862$  kg/m² at the end of first month, while at the end of second month and after treatment it was recorded as  $116.130 \pm 2.880$  kg/m² and  $16.122 \pm 2.951$  kg/m², respectively. Statistical analysis within group B showed that increase in height and weight were significant (p < 0.001), while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda = 0.165, F (3, 112) = 189.459, p < 0.001 and  $10.120 \pm 1.000$  m, while wilks' Lambda =  $10.120 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda =  $10.160 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda =  $10.000 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda =  $10.000 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda = 0.165, F (3, 112) =  $10.000 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda =  $10.000 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda =  $10.000 \pm 1.000$  m, while change in BMI was insignificant (p > 0.05). (For height – Wilks' Lambda = 0.165, F (3, 112) =  $10.000 \pm 1.000$  m, while change in BMI was insignificant (p > 0.000 m).

Table 20: Within Group Analysis of Effect on Height, Weight and BMI in Group B (n = 115)

		SD	Multivariate Test: Wilks' Lambda					
Parameter	Mean		Value	F	Hypothesis df	Error df	Sig.	
Height Baseline	1.390	0.078						
Height FU1	1.403	0.078	0.165	189.459	3.000	112.000	0.000*	
Height FU2	1.407	0.079	0.102	103.123	2.000	112.000	0.000	
Height AT	1.412	0.081						
Weight Baseline	31.517	7.503	0.623	22.573	3.000	112.000	0.000*	
Weight FU1	32.143	7.645						

Weight FU2	32.226	7.768					
Weight AT	32.454	7.873					
BMI Baseline	16.158	2.871					
BMI FU1	16.181	2.862	0.981	0.720	3.000	112.000	0.542
BMI FU2	16.130	2.880	0.501	0.720	2.000	112.000	0.512
BMI AT	16.122	2.915					

[Foot Note: Measuring units – height – meter, weight – kilogram, BMI – kg/m², Multivariate test used for analysis is Wilks' Lambda, \* - mean difference is significant at 0.05 level]

Pair wise comparison of each mean of height, weight and BMI showed that, there was significant difference in all pairs of height (p < 0.001). There was significant difference in weight when all follow up values were compared individually with baseline (p < 0.001) while for BMI there was no significant difference when baseline BMI was compared individually with each follow up (p > 0.05). Comparisons of other pairs of means though found significantly different from each other at some levels do not possess clinical importance (Table 21).

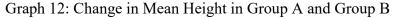
Table 21: Pair Wise Analysis of Effect on Height, Weight and BMI in Group B (n = 115)

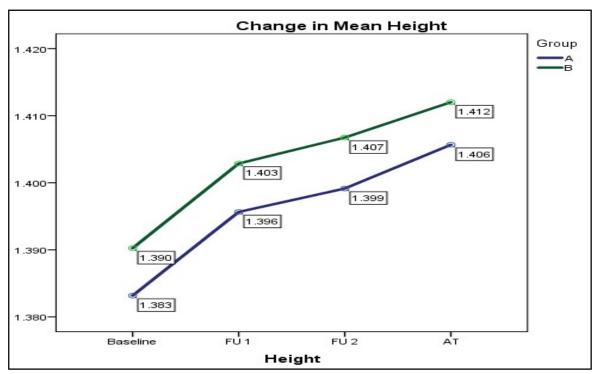
Parameter 1	Parameter 2	Mean Difference (Parameter1- Parameter2)	SE	Sig. <sup>a</sup>
	Height FU1	- 0.013*	0.001	0.000
Height Baseline	Height FU2	- 0.016*	0.001	0.000
	Height AT	- 0.022*	0.001	0.000
	Height Baseline	0.013*	0.001	0.000
Height FU1	Height FU2	- 0.004*	0.001	0.000
	Height AT	- 0.009*	0.001	0.000
	Height Baseline	0.016*	0.001	0.000
Height FU2	Height FU1	0.004*	0.001	0.000
	Height AT	- 0.005*	0.001	0.000
Height AT	Height Baseline	0.022*	0.001	0.000

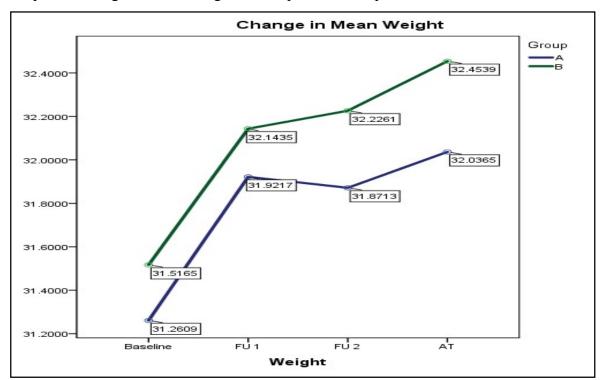
	Height FU1	0.009*	0.001	0.000
	Height FU2	0.005*	0.001	0.000
	Weight FU1	- 0.627*	0.087	0.000
Weight Baseline	Weight FU2	- 0.710*	0.104	0.000
	Weight AT	- 0.937*	0.120	0.000
	Weight Baseline	0.627*	0.087	0.000
Weight FU1	Weight FU2	- 0.083	0.072	1.000
	Weight AT	- 0.310*	0.092	0.006
	Weight Baseline	0.710*	0.104	0.000
Weight FU2	Weight FU1	0.083	0.072	1.000
	Weight AT	- 0.228*	0.081	0.034
	Weight Baseline	0.937*	0.120	0.000
Weight AT	Weight FU1	0.310*	0.092	0.006
	Weight FU2	0.228*	0.081	0.034
	BMI FU1	- 0.023	0.046	1.000
BMI Baseline	BMI FU2	0.027	0.051	1.000
	BMI AT	0.036	0.057	1.000
	BMI Baseline	0.023	0.046	1.000
BMI FU1	BMI FU2	0.050	0.036	1.000
	BMI AT	0.059	0.049	1.000
BMI FU2	BMI Baseline	- 0.027	0.051	1.000
	BMI FU1	- 0.050	0.036	1.000
	BMI AT	0.008	0.041	1.000
BMI AT	BMI Baseline	- 0.036	0.057	1.000
	D) (I FILI	0.050	0.049	1.000
BMI AT	BMI FU1	- 0.059	0.049	1.000

[Foot Note: Measuring units – height – meter, weight – kilogram, BMI – kg/m², a – adjustment for multiple comparisons: Bonferroni, \* - mean difference is significant at 0.05 level]

**Between Group Analysis:** Statistical analysis of growth parameters between group A and group B showed that there was no significant difference between groups for height, weight and BMI. It shows that changes observed in height, weight or BMI were similar in both groups. (For height – Wilks' Lambda = 0.991, F (3, 226) = 0.672, p > 0.05 and  $\eta^2$  = 0.009. For weight – Wilks' Lambda = 0.987, F (3, 226) = 0.985, p > 0.05 and  $\eta^2$  = 0.013. For BMI – Wilks' Lambda = 0.986, F (3, 226) = 1.048, p > 0.05 and  $\eta^2$  = 0.014) (Table 22, Graph 12, Graph 13, Graph 14).

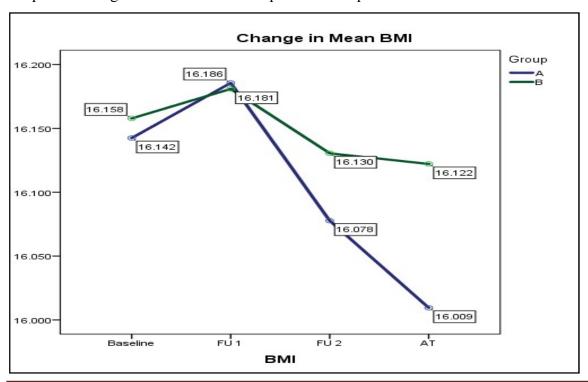






Graph 13: Change in Mean Weight in Group A and Group B





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Table 22: Between Group Analysis of Effect on Height, Weight and BMI (n = 115 in each group)

					Multivar	iate Test: Wilks	' Lambda	
Parameter	Group	Mean	SD	Value	F	Hypothesis df	Error df	Sig.
Height	A	1.383	0.075					
Baseline	В	1.390	0.078					
Height FU1	A	1.396	0.076					
Treight FOT	В	1.403	0.078	0.991 <sup>a</sup>	0.672	3.000	226.000	0.570
Height FU2	A	1.399	0.075	0.551	0.072	3.000	220.000	0.570
Tieight 1 02	В	1.407	0.079					
Height AT	A	1.406	0.076					
Tieight A1	В	1.412	0.081					
Weight	A	31.261	8.580					
Baseline	В	31.517	7.503				226.000	
Weight FU1	A	31.922	8.763			3.000		
Weight 101	В	32.143	7.645	0.987 <sup>b</sup>	0.985			0.400
Weight FU2	A	31.871	8.872	0.507	0.703			0.400
Weight 1 02	В	32.226	7.768					
Weight AT	A	32.037	8.901					
Weight 111	В	32.454	7.873					
BMI	A	16.142	3.222					
Baseline	В	16.158	2.871					
BMI FU1	A	16.186	3.188					
BWILLOL	В	16.181	2.862	0.986°	1.048	3.000	226.000	0.372
BMI FU2	A	16.078	3.251	0.700	1.048	5.000	220.000	0.572
DIVITIO2	В	16.130	2.880					
BMI AT	A	16.009	3.198					
	В	16.122	2.915					

[Foot Note: Measuring units – height – meter, weight – kilogram, BMI – kg/m², a – Analysis of Height\*Group, b – Analysis of Weight\*Group, c – Analysis of BMI\*Group]

### Analysis of Effect on Physical Stamina (n = 115 in each group)

Analysis of physical stamina was done by sports teacher associated with school. The teacher observed physical stamina of each subject during regular physical training activities and assigned grades to each of them according to clinical global impression (CGI) scale at each follow up.

**Group A:** In treatment group (A) 49 subjects were in grade (+3), 38 subjects were in grade (+2), while 8 subjects were in grade (+1). At the end of study number of subjects in grade (+3) increased to 63, 27 subjects were in grade (+2), while 8 subjects were in grade (+1). It indicates that many subjects changed grade from good physical stamina to better physical stamina. Similarly number of subjects in lowest grade of physical stamina (-3) reduced from 5 at baseline to 2 at the end of study.

**Group B:** In control group (B), 55 subjects were in grade (+3), 36 subjects were in grade (+2) and 3 subjects were in grade (+1) at baseline. Similar number of subjects were observed in these grades at the end of study i.e. 57 in grade (+3), 35 in grade (+2) and 3 in grade (+1). Hence it can be seen that better effect was seen in physical stamina in treatment group (A) as compared to control group (B). (Table 23)

Table 23: Effect on Physical Fitness

Physical		Grou	p A		Group B				
Fitness	At	At FU1	At FU2	AT	At Baseline	At FU1	At FU2	AT	
	Baseline								
Grade(+ 3)	49	59	58	63	55	62	63	57	
Grade (+ 2)	38	29	32	27	36	29	30	35	
Grade (+1)	8	8	7	8	3	4	5	3	
Grade 0	2	2	1	0	1	1	1	0	
Grade(-1)	0	1	3	0	1	1	1	3	
Grade(-2)	12	11	10	15	12	12	11	12	
Grade(-3)	5	5	4	2	5	5	3	3	

Total	114	115	115	115	113	114	114	113
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### Analysis of Effect on Energy Level (n = 115 in each group)

Similar to physical stamina, analysis of energy level was done by sports teacher at each follow up on the basis of CGI scale.

**Group A:** In this parameter at baseline, total 54 subjects were in grade (+3), which increased to 67 at the end of study. Number of subjects in grade (+2) decreased from 24 at baseline to 13 at the end of study indicating that many subjects migrated from lower to highest grade. Number of subjects in grade (+1) increased from 11 at baseline to 18 to the end of the study.

**Group B:** In this treatment arm drastic increase in number of subjects was seen in grade (+3) from baseline (50) to the end of study (72), similarly sharp decrease was seen in grade (+2), from 32 at baseline to 13 at the end of study. It indicates that more number of subjects migrated from (+2) to (+3) grade in group B as compared to group A. (Table 24).

Table 24: Effect on Energy Level

Energy		Grou	p A			Group	В	
Level	At	At FU1	At FU2	AT	At Baseline	At FU1	At FU2	AT
	Baseline							
Grade(+ 3)	54	61	63	67	50	55	59	72
Grade (+ 2)	24	19	18	13	32	28	28	13
Grade (+1)	11	10	17	18	7	7	10	15
Grade 0	8	8	0	1	10	10	4	0
Grade(-1)	1	1	2	1	3	3	3	2
Grade(-2)	11	11	11	10	4	4	6	6
Grade(-3)	5	5	4	5	7	7	4	5
Total	114	115	115	115	113	114	114	113

### Analysis of Effect on Attentiveness in Class (n = 115 in each group)

Attentiveness in class was observed by class teachers of each class and was reported according to CGI scale at each follow up from baseline.

**Group A:** In group A, number of subjects in highest grade (+3) increased from 46 at baseline to 57 at the end of study. Number of subjects in grade (+2) and (+1) changed from 43 and 5 at baseline to 36 and 7 at the end of study respectively.

**Group B:** In this group number of students in grade (+3) at baseline was 46 at baseline which showed minimal increase (50 subjects) in grade (+3) at the end of study. Number of subjects in grade (+2) were 45 at baseline which reduced to 40 at the end of study, while for grade (+1) number of subjects increased from 1 at baseline to 7 at the end of study (Table 25).

Table 25: Effect on Attentiveness in Class

Attentiveness		Group	A			Group 1	В	
in Class	At	At FU1	At FU2	AT	At	At FU1	At FU2	AT
	Baseline				Baseline			
Grade(+3)	46	56	54	57	46	56	50	50
Grade (+ 2)	43	35	37	36	45	37	43	40
Grade (+1)	5	5	5	7	1	2	5	7
Grade 0	5	4	4	0	5	4	3	0
Grade(-1)	4	3	5	5	6	6	4	6
Grade(-2)	5	6	5	6	7	7	8	9
Grade(-3)	6	6	5	4	3	2	1	1
Total	114	115	115	115	113	114	114	113

#### Analysis of Effect on Social Behaviour (n = 115 in each group)

Effect on social behaviour of a subject was observed by class teacher of each class and was reported according to CGI scale at each follow up.

**Group A:** In group A number of subjects in grade (+3) at baseline was 59 which increased to 69 at the end of study. Subjects in grade (+2) reduced from 32 at baseline to 23 at the end of study, while the number increased for grade (+1) from 5 at baseline to 9 at the end of the study.

**Group B:** At baseline number of subjects in grade (+3) was 59 at baseline, which increased to 67 at the last follow up. Number of subjects in grade (+2) decreased from 39 at baseline to 26 at the end of study, while subjects in grade (+1) increased from 5 at baseline to 10 at the end of study (Table 26).

Table 26: Effect on Social Behavior

Physical		Group	A			Gro	ир В	
Fitness	At	At FU1	At FU2	AT	At	At FU1	At FU2	AT
	Baseline				Baseline			
Grade(+ 3)	59	73	70	69	59	76	63	67
Grade (+ 2)	32	20	25	23	39	21	35	26
Grade (+1)	5	4	5	9	5	6	5	10
Grade 0	5	5	2	1	1	2	2	0
Grade(-1)	4	5	9	4	2	1	1	2
Grade(-2)	6	5	3	6	5	6	7	6
Grade(-3)	3	3	1	3	2	2	1	2
Total	114	115	115	115	113	114	114	113

Comparison of percent of subjects increasing in grade (+3) after treatment shows that for physical stamina there was increase of 11.80% subjects in group A, as compared to 1.77% in group B, however subjects with increased in energy level was better in group B (19.47%) as compared to group A (10.89%). Subjects showing improvement in attentiveness in class were 9.21% in group A while for group B these were 3.45%. Improvement of subjects in social behaviour had a little difference for both the groups, i.e. 8.25% for group A and 7.08% in group B (Table 27). Overall it was observed that there was very little change in number of subjects having grades 0 or less from baseline to the end of study. The observation remains factual for both the groups.

Table 27: Number of Students Shifting to Highest Grade (+ 3) after Treatment as Compared to Baseline

Sr.	Parameter	Group	ρA	Grou	p B
No.		Number of Percentage		Number of	Percentage
		Students		Students	
1	Physical Fitness	14	11.80	2	1.77
2	Energy Level	13	10.89	22	19.47
3	Attentiveness in Class	11	9.21	4	3.54

4	Social Behavior	10	8.25	8	7.08

### **Analysis of Adverse Events**

According to the ICH GCP guidelines adverse events are defined as – "Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product<sup>1</sup>."

According to this definition all the untoward or unintended observations seen in subjects were recorded from baseline till last follow up. At baseline detailed history of past illnesses or any illness from which the subject usually suffers was taken. Along with it, history of absenteeism from school for any health conditions, number of episodes, intensity of illness and need to take treatment for such illnesses was also recorded. Detail physical examination was conducted to ensure that the subject was not suffering from any illness at the time of inclusion. At each follow up, details of any heath related complaint that the subject suffered after last follow up or abnormal observation found during clinical examination were recorded. Detailed information of such events, such as, absenteeism from school for health related complaints, number of episodes, intensity of illness and need to take treatment for such illnesses was also recorded. Hence with an intention analyse effect of the treatment on immunity related parameters, further analysis of the data was done.

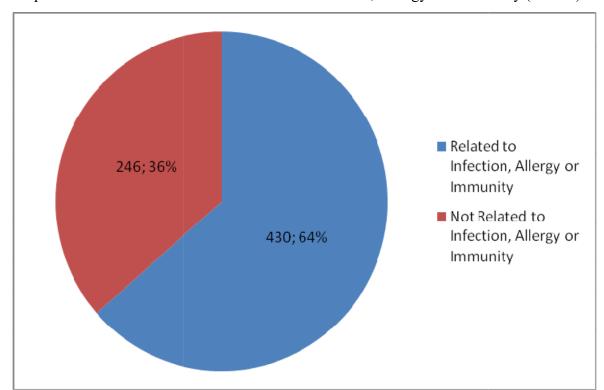
### Association of Adverse Events with Infection, Allergy and Immunity (n = 676)

Collected data about all adverse events was categorised according to its association of the adverse event with infection, allergy and immunity. Total 676 adverse events were observed in the study in both groups. Out of these, 430 (63.61 %) events were associated, while 246 (36.39 %) events were not associated with infection, allergy and immunity (Graph 15).

<sup>1</sup> E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1): Guidance for Industry, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), March 2018, page 3.111

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Graph 15: Association of Adverse Events with Infection, Allergy and Immunity (n= 676)

In group A, total 201 (29.73 %) were associated while 119 (17.60 %) were not associated with infection, allergy and immunity, while in group B the numbers were 229 (33.88 %) and 127 (18.79 %) respectively (Table 28).

Table 28: Association of Adverse Events with Infection, Allergy and Immunity (n = 676)

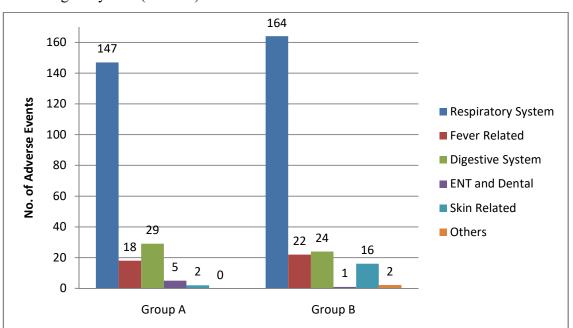
Sr.	Association	Group A		Gro	oup B	Total		
No.	with	No. of Percentage		No. of	Percentage	No. of	Percentage	
	Immunity	Events		Events		Events		
1	Associated	201	29.73	229	33.88	430	63.61	
2	Not Associated	119	17.60	127	18.79	246	36.39	
	Total	320	47.34	356	52.66	676	100.00	

## Number of Adverse Events According to System in Group A and Group B (n = 430)

Adverse events associated with infection, allergy and immunity were further classified according to system involved. It was observed that maximum (311, 72.33%) adverse events were associated with respiratory system, out of which 147 (34.19 %) were seen in group A and 164 (38.14 %) were seen in group B. Fever related adverse events were 40 (9.30 %) out of which 18 (4.19 %) were observed in group A, while, 22 (5.12 %) were observed in group B. Adverse events related with digestive system were 53 (12.33 %). Among these, 29 (6.74 %) were seen in group A and 24 (5.58 %) were seen in group B. Adverse events related with other systems were very few (Table 29, Graph 16).

Table 29: Number of Adverse Events According to System in Group A and Group B (n = 430)

Sr.		Gr	oup A	Gr	oup B	·	Γotal
No		Events	Percentage	Events	Percentage	Events	Percentage
1.	Respiratory System	147	34.19	164	38.14	311	72.33
2.	Fever Related	18	4.19	22	5.12	40	9.30
3.	Digestive System	29	6.74	24	5.58	53	12.33
4.	ENT and Dental	5	1.16	1	0.23	6	1.40
5.	Skin Related	2	0.47	16	3.72	18	4.19
6.	Others	0	0.00	2	0.47	2	0.47
	Total	201	46.74	229	53.26	430	100.00



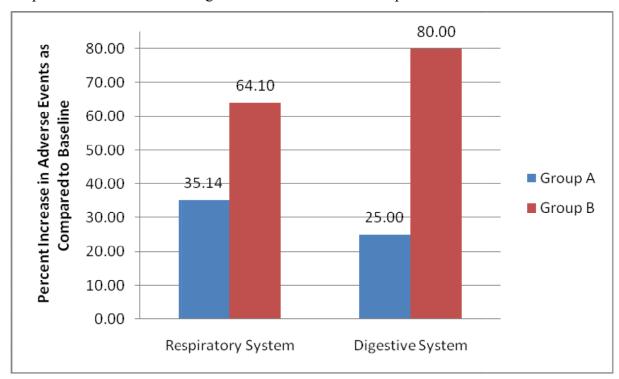
Graph 16: Number of Adverse Events Associated with Infection, Allergy and Immunity According to System (n = 430)

# Analysis of Adverse Events Related to Infection, Allergy and Immunity According to Visit (n = 430)

Further analysis revealed that specific adverse events associated with infection or allergies were observed in varying frequencies at all visits in both groups. In relation with respiratory system adverse events seen were – common cold, cough, rhinitis, upper respiratory tract infection (URTI), pharyngitis. Adverse events associated with fever were dengue, fever with chills, viral fever, while illnesses associated with digestive system were gastritis, jaundice, vomiting due to infection and pain in abdomen. Adverse events associated with skin were boils, urticaria, herpes zoster, tinea, skin rash and ring worm. Also, subjects were seen suffering from otalgia, toothache due to dental caries, conjunctivitis and urinary tract infection (UTI) (Table 30)

Increase in number of adverse events was seen in respiratory system in both groups – in group A, 37 adverse events were noted at baseline that increased up to 50 during last month of study, while for group B the incidences were 39 at baseline and 64 at the end of study. However, the rate of increase in group A was 35.14 %, while it was 64.10 % in group B. Similar observation can be highlighted for adverse events related to digestive system. At baseline number of

adverse events associated with digestive system in group A was 8, while in group B it was 5. During last month of study the number increased to 10 in group A and 9 in group B. The rate of increase thus observed was 25 % in group A and 80 % in group B (Graph 17).



Graph 17: Increase in Percentage of Adverse Events as Compared to Baseline

Observations associated with other systems are displayed in table 30.

Table 30: Analysis of Adverse Events Related to Infection, Allergy and Immunity in Group A and Group B According to Visit (n = 430)

System and	At Ba	seline	At F	U 1	At I	FU 2	A	T
<b>Adverse</b> Event	Group	Group	Group	Group	Group	Group	Group	Group
Term	A	В	A	В	A	В	A	В
		R	espiratory	System				
Common Cold	2	0	12	12	2	5	18	19
Cough	2	3	12	11	7	7	11	10
Rhinitis	11	12	2	1	3	5	3	11

URTI	15	15	5	7	14	6	16	14
Pharyngitis	7	9	0	2	3	5	2	10
Sub Total	37	39	31	33	29	28	50	64
			Fever Re	lated				
Dengue	1	3	0	0	0	0	0	0
Fever	1	2	6	9	4	2	3	5
Fever with Chills	0	0	1	0	0	0	0	0
Viral Fever	0	1	0	0	2	0	0	0
Sub Total	2	6	7	9	6	2	3	5
		Г	Digestive S	System				
Gastritis	0	0	1	3	1	1	2	2
Vomiting (related	0	0	3	1	0	1	0	1
to infection)								
Pain in Abdomen	8	5	5	1	1	2	8	6
Jaundice	0	0	0	1	0	0	0	0
Sub Total	8	5	9	6	2	4	10	9
,			-		I	l	1	1
			ENT and l	1	I	T	ı	1
Otalgia	2	1	1	0	0	0	0	0
Toothache due to	0	0	1	0	0	0	1	0
Dental Caries								
Sub Total	2	1	2	0	0	0	1	0
			Skin Rel	ated				
Boil	0	1	1	0	0	0	0	2
Ring Worm	0	1	0	2	0	1	0	2
Urticaria	0	1	0	0	0	0	0	0
Herpes Zoster	0	0	0	0	0	0	1	0

Skin Rashes	0	0	0	1	0	2	0	1			
Tinea	0	0	0	0	0	0	0	2			
Sub Total	0	3	1	3	0	3	1	7			
			1	1		I	1	1			
	Others										
Conjunctivitis	0	0	0	1	0	0	0	0			
UTI	0	0	0	0	0	0	0	1			
Sub Total	0	0	0	1	0	0	0	1			
Grand Total	49	54	50	52	37	37	65	86			

# Absenteeism in School Due to Adverse Events Associated with Infection, Allergy and Immunity (n = 602)

Detailed record of absenteeism in school of each subject was procured from respective class teacher and same was confirmed with parents of the subject. It was observed in the study that out of total absent days (602) during study period, subjects in group A were absent for 267 days (44.35 %) while subjects in group B were absent for 335 days (55.65 %). The difference thus observed was statistically significant (p < 0.05). Thus it can be said that absenteeism in school due to illness was significantly less in group A as compared to group B (Table 31, Table 32, Graph 18).

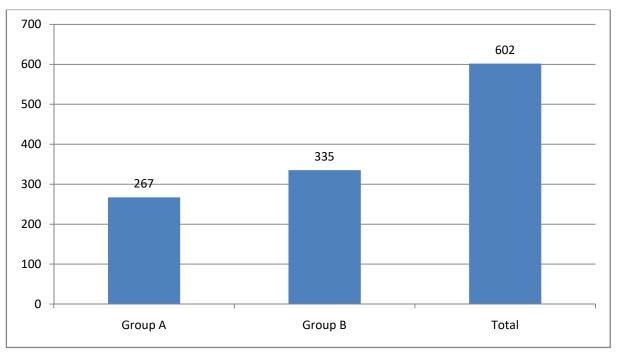
Table 31: Absenteeism in School Due to Adverse Events Associated with Infection, Allergy and Immunity (n = 602)

Sr.	Time Line	Group A		Group B		Total	
No.		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
1	Baseline to	89	47.59	98	52.41	187	100.00
2	FU1 to FU2	87	41.63	122	58.37	209	100.00
3	FU2 to AT	91	44.17	115	55.83	206	100.00
	Total	267	44.35	335	55.65	602	100.00

Table 32: Between Group Analysis of Absenteeism in School Due to Adverse Events Associated with Infection, Allergy and Immunity

Parameter	Group .	Group	В	t	Sig (2-tailed)	
	Mean SD		Mean SD			
Absenteeism	89.000	1.633	111.667	10.077	-3.140	0.035

Graph 18: Absenteeism in School Due to Adverse Events Associated with Infection, Allergy and Immunity (n = 602)



Total Duration of Adverse Events Associated with Infection, Allergy and Immunity (n = 1258)

Parents of subjects who suffered from illness associated with infection, allergy and immunity were enquired to capture data about total duration of illness. It was observed that out of 1258 days of total illness associated with infection, allergy and immunity, subjects in group A were ill for 525 (41.73 %) days, while subjects in group B were ill for 733 (58.27 %) days. However the difference in means failed to achieve statistical significance (p > 0.05). But it is worth to note that duration of illness was less by 16.54 % in group A as compared to group B (Table 33, Table 34, Graph 19).

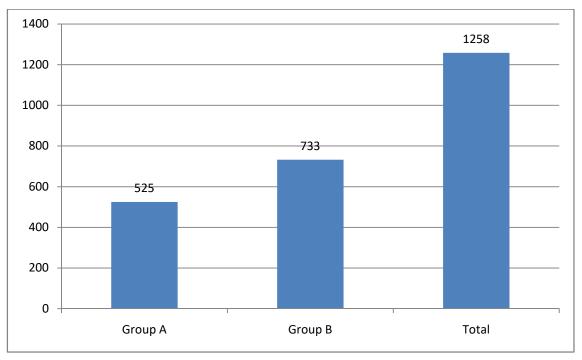
Table 33: Total Duration of Adverse Events Associated with Infection, Allergy and Immunity in Days (n = 1258)

Sr.	Time Line	Group A		Gro	up B	Total	
No.		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
1	Baseline to FU1	141	41.47	199	58.53	340	100.00
2	FU1 to FU2	118	48.16	127	51.84	245	100.00
3	FU2 to AT	266	39.52	407	60.48	673	100.00
	Total	525	41.73	733	58.27	1258	100.00

Table 34: Between Group Analysis of Duration of Adverse Events Associated with Infection, Allergy and Immunity

Parameter	Group .	A	Grou	bB	T	Sig (2-tailed)
	Mean SD		Mean SD			
Duration of Illness	175.000	65.028	244.333	118.719	-0.724	0.509

Graph 19: Total Duration of Adverse Events Associated with Infection, Allergy and Immunity in Days (n = 1258)



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## Episodes of Adverse Events Associated with Infection, Allergy and Immunity (n = 327)

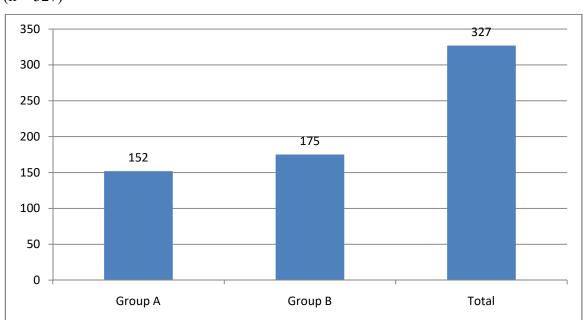
Total number of episodes of adverse events associated with infection, allergy and immunity were 327 in both groups. In group A, total episodes were 152 (46.48 %), while in group B they were 175 (53.52). Statistical analysis showed that the difference is insignificant (p > 0.05) (Table 35, Table 36, Graph 20)

Table 35: Number of Episodes of Adverse Events Associated with Infection, Allergy and Immunity (n = 327)

Sr.	Time Line	Group A		Gro	Group B		Total	
No.		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	
1	Baseline to FU1	50	49.02	52	50.98	102	100.00	
2	FU1 to FU2	37	50.00	37	50.00	74	100.00	
3	FU2 to AT	65	43.05	86	56.95	151	100.00	
	Total	152	46.48	175	53.52	327	100.00	

Table 36: Between Group Analysis of Number of Episodes of Adverse Events Associated with Infection, Allergy and Immunity

Parameter	Group A		Gre	oup B	t	Sig (2-tailed)
	Mean SD		Mean SD			
Number of Episodes	50.667 11.441		58.333 20.499		-0.462	0.668



Graph 20: Total Episodes of Adverse Events Associated with Infection, Allergy and Immunity (n = 327)

### Number of Subjects Suffering from Adverse Events in Mild and Moderate Intensity

The total number of subject suffering from adverse events in mild intensity were 278, out of which 139 (50.00 %) were from group A and 139 (50.00 %) were from group B. The total number of subject suffering from adverse event with moderate intensity were 39, out of these 13 (26.53 %) were belonging to group A and 36 (73.47 %) belonged to group B. The mean difference for mild intensity was insignificant (p > 0.05), but for moderate intensity it was significant (p < 0.05). Hence, it can be claimed that subjects in group A suffered from illnesses with lesser severity. No subject suffered from any adverse event with severe intensity (Table 37, Table 38, Table 39, Graph 21)

Table 37: Number of Subjects Suffering from Adverse Events in Mild Intensity (n = 278)

Sr.	Time Line	Grou	p A	Gro	ир В	Total	
No.		Frequency Percentage		Frequency	Percentage	Frequency	Percentage
1	Baseline to	47	52.22	43	47.78	90	100.00
	FU1						
2	FU1 to FU2	33	55.00	27	45.00	60	100.00
3	FU2 to AT	59	46.09	69	53.91	128	100.00

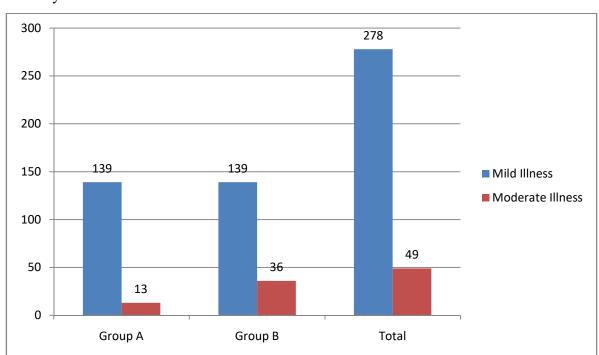
Total	139	50.00	139	50.00	278	100.00

Table 38: Number of Subjects Suffering from Adverse Events in Moderate Intensity (n = 49)

Sr.	Time Line	Group A		Gro	ир В	Total	
No.		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
1	Baseline to	3	25.00	9	75.00	12	100.00
	FU1						
2	FU1 to FU2	4	28.57	10	71.43	14	100.00
3	FU2 to AT	6	26.09	17	73.91	23	100.00
	Total	13	26.53	36	73.47	49	100.00

Table 39: Between Group Analysis of Intensity of Adverse Events

Parameter		Group A		Group B		t	Sig (2-tailed)
		Mean	SD	Mean	SD		
Episodes with M	ild	46.333	10.625	46.333	17.308	0.000	1.000
Intensity							
Episodes w	ith	4.333	1.247	12.000	3.559	-2.875	0.045
Moderate Intensity							



Graph 21: Number of Students Suffering from Adverse Events in Mild and Moderate Intensity

## **Number of Adverse Events Requiring and Not Requiring Treatment**

The total number of adverse events requiring treatment was 189. Group wise division of the number shows that in group A 89 (47.09 %) adverse events required some treatment, while 100 (52.91 %) adverse events required treatment. Number of adverse events that did not require any treatment for remission were 138, out of which 63 (45.65 %) belonged to group A, while remaining (75, 54.35 %) belonged to group B. Statistical analysis showed that mean difference between groups was insignificant (p > 0.05) (Table 40, Table 41, Table 42, Graph 22)

Table 40: Number of Adverse Events Requiring Treatment (n = 189)

Sr.	Time Line	Grou	рА	Gro	ир В	Total	
No.		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
1	Baseline to FU1	26	42.62	35	57.38	61	100.00
2	FU1 to FU2	25	59.52	17	40.48	42	100.00
3	FU2 to AT	38	44.19	48	55.81	86	100.00
	Total	89	47.09	100	52.91	189	100.00

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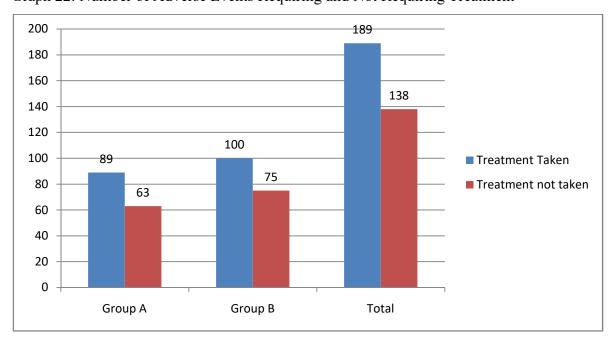
Table 41: Number of Adverse Events Not Requiring Treatment (n = 138)

Sr.	Time Line	Grou	рА	Gro	ир В	Total	
No.		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
1	Baseline to	24	58.54	17	41.46	41	100.00
	FU1						
2	FU1 to FU2	12	37.50	20	62.50	32	100.00
3	FU2 to AT	27	41.54	38	58.46	65	100.00
	Total	63	45.65	75	54.35	138	100.00

Table 42: Between Group Analysis about Requirement of Treatment

Parameter	Group A		Group B		t	Sig (2-tailed)	
	Mean	SD	Mean	SD			
Treatment Taken	29.667	5.907	33.333	12.710	-0.370	0.730	
Treatment Not Taken	21.000	6.481	25.000	9.274	-0.500	0.643	

Graph 22: Number of Adverse Events Requiring and Not Requiring Treatment



## Adverse Events Not Related with Infection, Allergy and Immunity (n = 246)

Adverse events which were not associated with infection, allergy and immunity were also captured. As these were associated with factors other than immunity further analysis to highlight the efficacy of treatment was not done. The details of it are outlined in table 43.

Table 43: Details of Adverse Events Not Related to Infection, Allergy and Immunity (n = 246)

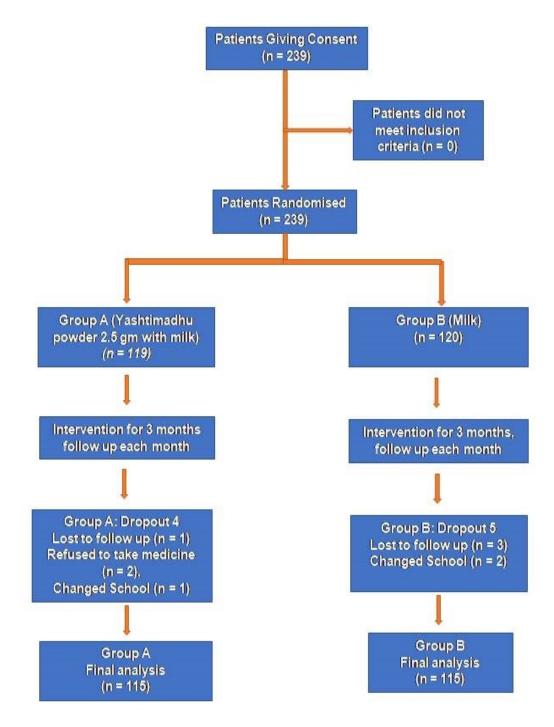
Adverse Event	Baseline		At FU 1		At FU 2		AT	
Term	Group	Group	Group	Group	Group	Group	Group	Group
	A	В	A	В	A	В	A	В
Acidity	0	1	1	0	0	0	0	1
Backache	0	0	0	0	0	0	0	1
Body ache	1	0	0	2	0	0	0	0
Burn Injury	0	0	1	1	0	0	0	0
Chalasion	0	0	0	0	0	0	1	0
Chest Pain	0	0	0	0	0	0	1	1
CLW	2	2	2	2	0	2	2	1
Costochondritis	1	0	0	0	0	0	1	0
Dental Caries	5	7	5	3	5	4	5	1
Dental Tartar	1	0	1	0	1	0	1	0
Diminished	3	5	0	1	1	1	0	0
Vision								
Excessive	1	0	1	0	0	0	0	0
Sweating								
Eye Pain	3	5	1	4	0	0	4	1
Fracture of left	0	0	0	0	0	1	0	0
radius								
Graying of Hair	1	0	1	0	1	0	1	0
Headache	3	3	2	0	2	7	3	5
Insect Bite	0	0	1	0	0	0	0	0
Leg Pain	3	0	1	1	1	1	2	1
Mouth Ulcer	0	0	0	0	0	0	0	1

Pallor	1	4	4	3	0	0	0	0
Spider Bite	0	0	0	0	0	0	1	0
Sprain	0	0	0	0	0	0	1	0
Stammering	1	0	1	0	1	0	1	0
Tonsillar	10	11	7	14	12	15	2	6
Hypertrophy								
Vertigo	0	0	0	1	0	1	0	2
Vomiting (Related	0	1	2	1	0	1	1	0
to Faulty Diet)								
White Patches on	1	0	0	0	0	0	0	1
Skin								
Total	37	39	31	33	24	33	27	22

### Safety of Treatment in Group A and Group B

No serious adverse events or adverse drug reactions were noted in either group throughout the study period. Only one subject from group A complained of vomiting after consumption of Yashtimadhu powder with milk. Further enquiry revealed that vomiting was observed immediately after taking medicine on first day only. No further episodes of vomiting were observed on subsequent days and the subject completed study. Hence it can be concluded that though the episode of vomiting was observed after consumption of study medicine it is not associated with it. Hence it can be claimed from the data in this study that consumption of Yashtimadhu (*Glycerriza glabra* Linn.) powder with milk is safe.

## **CONSORT Diagram**



#### DISCUSSION

Excellence and intelligence in medical sciences that continues to exist in India is Ayurveda. It has a glorious tradition of over thousands of years, just enough to prove its efficacy in serving mankind for effective treatment of many health ailments. Apart from treatment of different diseases, various treatments are explained for imperative aspect of health sciences which is prevention of diseases. Rasayana is a pivotal branch of Ashtanga Ayurveda that mainly helps in improving the status of Dhatu and helps in keeping the body healthy. Optimum status of Dhatu prevents pathology of disease from being completed though there is vitiation of Dosha due to seasonal variation, diet, occupation etc. Hence, Rasayana play important role in maintaining health. Along with optimum status of Dhatu a person always longs for excellent memory, intelligence, grasping power and alertness of mind and sense organs. According to oriental philosophy these functions are dependent on Indriya, Mana, Buddhi and also, Vayu that plays important role in Dnyana Grahana. As status of Indriya, Mana and Buddhi are indirectly dependent upon status of Dhatu, optimum status of Dhatu doesn't always ensure high intelligence. Hence a different class of Rasayana called as Medhya Rasayana is explained by ancient researchers that are specifically advocated for direct beneficial effect on functions of Indriya, Mana and Buddhi. Four Medhya Rasayana are explained, namely - fresh juice of Mandukaparni, paste of Shankhapushpi, juice of roots and leaves of Guduchi and Choorna of Yashtimadhu with milk. Out of these the first three Rasayana medicines are always needed fresh, while powder of Yashtimadhu can be stored due to longer shelf life. This makes the combination of Yashtimadhu Choorna more practical option as Medhya Rasayana.

In today's era of fast moving world, change in diet and working culture, industrialisation, excess use of chemical and synthetic based medicines/ food items, different addictions and stress, life of a human has become more miserable and full of health ailments than ever. With constant advancement in all sectors, newer and newer diseases are also emerging. Hence necessity of Rasayana is more than any other time period of history of human race. Advancement in science and technology has also brought about unfinished race in all classes. Students taking education are under constant stress to score more and more marks in examinations. As to the race becomes more and more stiff, demand of some remedy that can

improve functions of Buddhi – Dhee, Dhruti and Smruti is increasing. Hence an offering that is quoted as a Medhya Rasayana in classical Ayurvedic texts, easy to administer, cost effective is need of the day. Though Shankhapushpi is considered to have better Medhya effect, due to obvious difficulty in getting it fresh daily, combination Yashtimadhu powder and milk was considered. Many experimental studies and some human studies are already done on this topic, but major drawbacks of the studies are samples from specific gender, change of form of Yashtimadhu from powder to Ghanavati, variation in duration of study, use of less specific assessment parameters. Also, Medhya effect can be best assessed in school going children. Hence the proposed study entitled - An Open Labeled, Randomized, Two Arm Study Of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study is undertaken.

Review of literature reveals that oriental sciences recognise intelligence as 'Buddhi' that literally means power of forming and retaining conceptions and general notions<sup>i</sup>. Though Buddhi is considered as a single entity, its different aspects have been recognised by different names in oriental sciences. 'Dhi' is ability of a person to perceive or understand<sup>ii</sup>. 'Dhruti' is firmness about a thing that is understood<sup>iii</sup>. 'Medha' is wisdom or prudence<sup>iv</sup>. 'Pradnya' is to understanding of modus operandi of anything<sup>v</sup>. 'Prama' is ability to measure or estimate<sup>vi</sup>, while, 'Smruti' is ability to remember<sup>vii</sup>. Each of these words, which are many a time used as synonyms, actually depicts different facets of Buddhi. Modern sciences explain all these different aspects in one word – intelligence. This difference found in both philosophies about the description of same entity highlight how meticulous the ancient Acharya were in detailing different aspects of Buddhi.

In ancient times, different types of examinations or parameters might have been used for assessment of various aspects of Buddhi. Shalaka Pariksha, Sambhasha are some of the examples of such possible assessment scales. However, intelligence itself is not assessed as a separate entity, but it can be measured with reference of some activity. Hence, scales or examinations or task based assessments which were used for assessment in different streams of knowledge might also have been used for assessment of 'Buddhi'. In modern times a lot of different scales are developed used to understand intelligence, decision making, memory,

psychology etc. Many complex, gadget based test are now available. Digit letter substitution test (DLST) and Six Letter Cancellation Test (SLCT) are scales which are subset of Wechsler scale and can be effectively used in school going children. The literature search shows that both the tests have been used previously in clinical interventional studies in adults as well as school going children. Pradhan B (2013) has reported use of DLST and SLCT in assessing effect of Kapalbhati in adults viii. Elst W V D et al (2006) have assessed results of DLST in 1,858 adults between 24 and 81 years adults ix. Pradhan B and Nagendra H R (2009) have reported results of DLST in 843 school going children between 8 to 16 years of age, which the authors claim as Indian normative data is. Similarly various scholars around the world have tested and validated SLCT. Pradhan B and Nagndra H R (2008) have reported normative data of SLCT for Indian school going children in different psychological or neurological conditions. Sala S D (1992) have reported results about reliability of cancellation test in assessing attention deficits in Alzeimer's disease xii.

DLST and SLCT are both used as a screening tool in many studies conducted for brain dysfunction as well as cognition. Though these are considered as nonspecific tests for diagnosis of brain dysfunction, they are better suited for assessment of cognition. A response received in either of the tests is an outcome of complex neuro-psychological process that includes visual scanning, mental flexibility, sustained attention, psycho-motor speed and speed of processing an information xiii. If the same complex neuro-psychological process is perceived from Ayurveda's point of view, it reflects process of Dnyana Grahana. Visual scanning is perception of information (Indriva Vishaya) by Dnyanedriva through its Adhishthana. Sustained attention is defined as ability to focus on an activity or stimulus over a long period of time, which in other words called as 'Concentration', It reflects the function of Manas that connects the perceived information with Buddhi. Mental flexibility is ability to shift course of thought or action according to the changing demands of situation xv. Mental flexibility along with speed of processing information can be very well understood as functions Manas, Buddhi that processes the information received and takes rational decision under given circumstances. Psycho-motor speed is the time required for motor effects of the mental activity, which according to Ayurveda is governed by Buddhi through Manas, Karmendriya and Karmendriya Adhishthana. Hence, the responses received for DLST and SLCT indicate involvement of all components of Medha, Dhruti, Smruti and Dhee, hence can be used as assessment tools to quantify Medhya effect (improvement in cognition) of a treatment or therapy. (Figure 1)

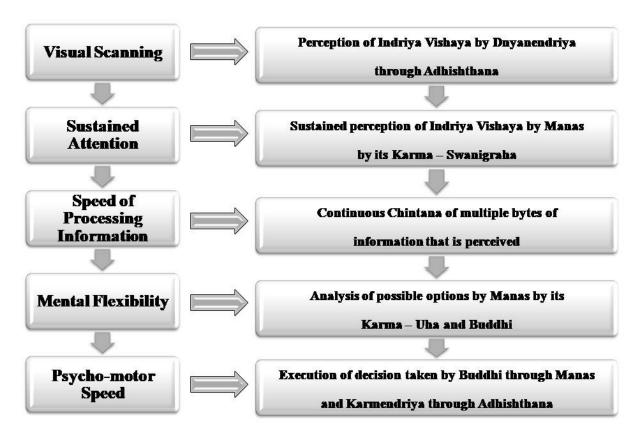


Figure 1: Comparison of DLST and SLCT with Ayurvediya Dnyanagrahana Process

Children have short attention period ranging from 4 to 6 minutes at the age of 2 years up to 28 to 42 minutes at the age of 14 years<sup>xvi</sup>. Hence, in studies that involve children in broad age range it is difficult to implement lengthier assessment scales and get real estimate of their cognition. In such studies, DLST and SLCT are simple tests which are completed in lesser time. Hence probability of getting true results increases. Due to these reasons, DLST and SLCT were chosen for assessment of treatment.

The current study was planned as per AYUSH GCP guideline<sup>xvii</sup>. The study was started after getting approval from ethics committee of the study centre and after registering the trial in clinical trials registry of India (CTRI). All subjects and their parents underwent informed consent process before enrolment. After procuring consent from parents and oral or written ascent from children, they were enrolled in the study. To avoid bias, group allocation of the participants was done according to computerised block randomisation method, with each block containing six participants and as per chronological order of baseline visit after informed consent process.

Analysis of demographic data of 239 subjects showed that baseline data of both groups when compared for age, gender, DLST and SLCT was insignificantly different, indicating that the samples were homogenous and comparable. As far as class of students is concerned maximum students belonged to seventh standard (44.84%), followed by sixth standard (33.05%). Though students from all standards that could be included as per inclusion criteria were invited for participation, maximum response was received from parents and students of sixth and seventh standard. Maximum (73.67%) subjects belonged to middle income class. It indicates the stratum of students attending the school.

Maximum (64.02%) subjects were following vegetarian diet practice. Though it is generally believed that plant based or vegetarian diet is associated with better cognitive functions, a review of 205 articles (Medawar E et al, 2019) failed to establish relationship between vegetarian diet and cognition<sup>xviii</sup>. Agrawal U et al (2015) have concluded that vegetarian diet is associated with improvement in depression, anxiety and productivity<sup>xix</sup>. Similar results are reported by Breezhold B et al (2015) as well<sup>xx</sup>. However, in view of reports depicting exact opposite results (Hibbeln JR, et al, 2018)<sup>xxi</sup> more studies are needed to reach any conclusive results.

Assessment of Prakruti showed that maximum subjects belonged to Kapha Vata (39.33%) and Vata Pitta (38.08%) Prakruti. Nyahalse V B et al (2019) have reported association of Prakruti and intelligence quotient (IQ) that higher IQ is associated with Pitta Vata followed by Pitta Kapha Prakruti xxii. The researchers claim properties of Pitta as the basis of better IQ.

Nandvadekar V et al (2016) have reported that better IQ is associated with Kapha Prakruti<sup>xxiii</sup>. However, due to small sample size, single centric study and different scales used in assessment of Prakruti and IQ, results of these studies need to be confirmed by larger studies. In present study due to variation in number of subjects of different Prakruti assessment of effect of study medicine as per Prakruti was inconclusive. Assessment of Agni showed that maximum subjects had Teekshna (35.15%) and Vishama (33.89%) Agni, while analysis of Koshtha showed maximum subjects (51.88%) had Madhyam Koshtha. However, any correlation between cognition and Agni or Koshtha has not yet been reported.

The subjects were divided in two groups. Group A received Yashtimadhu (Glycerrhiza glabra Linn) Churna with milk twice daily for 90 days, while group B received only milk twice daily for 90 days. Primary efficacy variables DLST and SLCT were conducted before and at the end of study. Before conducting the tests instructions were given to subjects as per standard operating procedure and were conducted separately for all subjects. Assessment of DLST in group A revealed that mean score of total substitutions increased by 32.04% while in group B it was 16.43%. Though the mean differences in both groups were statistically significant when compared with baseline, it is clear that improvement in group A is twice as compared to group B. It is also evident in inter group analysis. In group A, 105 subjects showed improved score in total substitutions, nine subjects showed decreased score, while it remained same in one subject. In group B, 98 subjects showed improved score in total substitutions, 16 subjects scored less while one subject performed same number of substitutions as baseline. In both groups, mean scores of wrong substitutions declined as compared to baseline. However, decrease in wrong substitutions was not significant within group or between groups. The net score of substitutions increased by 35.20%, while in group B it increased by 17.32%. Though net substitutions increased significantly in both groups when compared with baseline, it can be appreciated that increase in net score was double in group A as compared to group B. In group A, 106 subjects showed improved score in total substitutions, seven subjects showed decreased score, while it remained same in two subjects. In group B, 98 subjects showed improved score in net substitutions, 12 subjects scored less while five subjects performed same number of substitutions as baseline.

Assessment of cancellation test showed that, in group A, mean of total cancellations improved by 25.47%, while in group B it improved by 19.93%. In 93 subjects in group A, total cancellation score improved, in three subjects it remained same while in 20 subjects it decreased than baseline. In group B, 83 subjects showed improvement in total cancellation score, seven subjects scored same, while 25 subjects scored less as compared to baseline score. It is also evident that in group A there is significant decline in total cancellation score than group B. Similar trend was seen in net cancellation score. In group A, mean of net cancellation score improved by 27.09%, while in group B it improved by 21.75%. In group A, 91 subjects showed improvement in net cancellation score, in three subjects it remained same while in 21 subjects it decreased. In group B, 85 subjects showed improvement in net cancellation score; eight subjects scored same while 22 subjects scored less than baseline. Group A showed significant improvement than group B in score of net cancellations.

Both the scales have been used as assessment parameters in many studies evaluating effects of Yoga. Improvement in SLCT is also reported by researchers following yoga based relaxation techniques (Sarang SP and Telles S, 2007) xxiv. Similarly improvement in DLST is also reported in cognitive function after following Chandra Anga Pranayam (Shanthanam Kumar SS et al, 2020) xxv. Gulati K et al (2019) have reported improved DLST and SLCT scores in school going children after intervention of different Yoga procedures for 4.5 months xxvi. Yogic breathing such as Bramari Pranayama has shown beneficial effects in Braille version of SLCT in visually impaired subjects as well (Pradhan B et al, 2018) xxviii. Though, evaluation of Yoga techniques by teenagers on performance of DLST and SLCT have shown improved DLST scores, contrary results are seen in SLCT in same samples (Pradhan B and Nagendra HB, 2009) xxviii. Similar results are seen in another study evaluating effect of Kapalbhati on performance of DLST and SLCT (Pradhan B, 2013) xxix. In current study, though significant improvement was observed in DLST as well as SLCT, the quantum of improvement in DLST was much more than SLCT.

Diet and exercises have also been evaluated on the basis of results obtained in DLST and SLCT. Natu V. M. and Agarwal A. K. (1997) have reported significant increase in scores of DLST and SLCT after administering hot coffee as compared with placebo<sup>xxx</sup>. The report

suggests that stimulant effect of caffeine as the reason for improved psychomotor performance. It is further claimed by Araujo LF et al (2016) that higher coffee consumption was associated with better performance in DLST, better executive function and lower incidences of lacunar infarcts \*\*xxxi\*\*. Other factors showing positive effect on cognition are also identified. Structured and unstructured physical exercises have shown beneficial effects on cognitive functions in school going children (Subramanian S. K. et al, 2015)\*\*xxxii\*\*. It has also been demonstrated that healthy diet at midlife preserves global cognitive function, especially verbal memory (Kesse-Guyot E et al, 2012)\*\*xxxiii\*\*. Protective role of antioxidants has also been claimed against age related decline in cognition in a systematic review (Rafnsson S. B. et al, 2013)\*\*xxxiiv\*\* In Ayurveda, diet has been called as 'Maha Bhaishajya' – the supreme medicine, as healthy diet is responsible for keeping of Dhatu and Indriya at optimum state. Healthy diet avoids collection of Dosha and helps to keep the body free from diseases. If Dhatu Bala is optimum all the Gati of Vata are Anuloma. Vayu is responsible for perception of senses and controls Indriya and their Adhishthana. Hence role of healthy diet pattern is justifiable from Ayurveda's point of view as well.

Role of some antidepressant medicines, namely, sertraline and desvenlafaxine has also been established in improvement, while fluoxetine has been linked with decline of psychomotor function (Mendhe P. P. et al, 2017)<sup>xxxv</sup>. But in another study by Jaykaran et al (2009) fluoxetine has also shown improved cognitive functions<sup>xxxvi</sup>. However, their action according to Ayurveda cannot be explained, but it can be appreciated that medicines can show improvement in higher brain functions.

In definition of a Swastha, healthy state of Atma, Indriya and Manas has been given a special emphasis xxxvii. In Ayurveda a lot of medicines are explained for treatment of diseases and also for maintenance of health. Treatments which predominantly take care in maintenance of health are called as Rasayana. Medhya Rasayana is a separate class of Rasayana that has positive effects in maintaining functions of Manas, Buddhi and their functions. Yashtimadhu is Sheeta, Guru, Snigdha, Madhura, Chakshushya, increases Bala, Varna and Shukra xxxviii. Due to its Snigdha, Madhura and Guru property it is capable of imparting nutrition to all Dhatu from Rasa to Shukra. It is well known that Vata which is responsible for optimum functioning of

Indriya remains Anuloma if Dhatu are Snigdha. Chakshushya (beneficial to eyes) effect shows that Yashtimadhu has capacity to reach Indriya and their Adhishthana, which is not possible by many other medicines. It highlights possible positive effect on functioning of Indriya which is important factor of Medhya activity (Figure 2). However, due to lack of clear cut explanation Acharyas have preferred to explain the effect as 'Prabhava'.

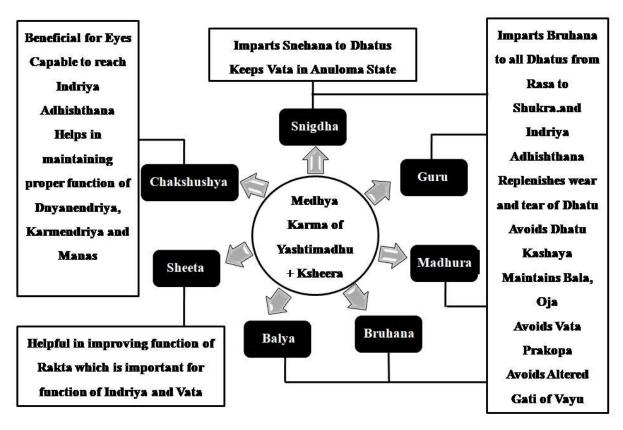


Figure 2: Possible explanation of Medhya Karma by Yashtimadhu and Ksheera on the basis of their Guna and Karma

The classical method explained as Medhya Rasayana has also been evaluated by Mahadevan B et al (2016). In this experimental study it was seen that Yashtimadhu with cow's milk or milk powder show remarkable effect on the learning and memory capacity in Wistar Albino Rats in two pharmacological models, namely, elevated plus maze test and passive avoidance paradigm. Hence, as propounded by Acharya Charaka, Yashtimadhu can be used as a memory promoting drug xxxix. Kolhe et al (2013) have reported beneficial effect of Yashtimadhu Ghanavati and Tagara Ghanavati with psychotherapy in management of mental adjustment disorder in young adults xl.

The current study the study medicine, Yashtimadhu (Glycerrhiza glabra) has been extensively evaluated for its nootropic effects. Yashtimadhu contains glycyrrhizine, glicophenone, glicoisoflavanone xli, glycyrrhetenic acid xlii and six phenolic compounds xliii. Yashtimadhu is known to possess anxiolytic and antidepressant activity in animal models. Ravichandran V et al (2007) have demonstrated significant improvement in spatial learning, retention memory and reversal of amnesia caused by scopolamine induction in rats xliv. Yashtimadhu extracts have free radical scavenging activity, inhibitory effect against lipid peroxidation and deoxyribose, thus proving its antioxidant effect<sup>xlv</sup>. Researchers claim that the improvement in psychomotor function after administration of Yashtimadhu can be attributed to its antioxidant effect. Murlidharan P et al (2009) have evaluated cerebro-protective effect aqueous extract of Yashtimadhu in hypoxic rats xlvi. They have reported restoration of reduced levels of antioxidant enzymes, namely, superoxide dismutase, glutathione peroxidase, glutathione reductase and catalase, to normal levels after administration of Yashtimadhu. In an interesting experimental study Zhan C and Yang J (2006) have evaluated protective effects of isoliquiritigenin, a flavonoid from root of Yashtimadhu, against focal cerebral ischemia in rats<sup>xlvii</sup>. They have reported significant reduction in volume of cerebral infarct and oedema and neurological deficit after administration of isoliquiritigenin. Further evaluation showed that isoliquiritigenin increased brain ATP content, energy charge and total adenine nucleotides. It inhibited increase of brain malondialdehyde content and prevented the activities of brain superoxide dismutase, catalase and glutathione peroxidise. It brings forward pharmacodynamics of Yashtimadhu by protecting brain against ischemic assaults. It is very well known that different cognitive skills depend on status of nerve cells. Decrease in living nerve cells due to aging or any other pathological condition such as cerebro-vascular accident leads to reduced cognitive skills. Keeping the brain healthy through nutrition and physical activity is necessary to protect from cognitive decline due to cerebro-vascular accidents xlviii. Rathee P et al (2008) have claimed increased blood circulation in central nervous system and balancing of sugar levels in blood vlix. Dhingra D et al (2004) have claimed beneficial effect on learning and memory in mice<sup>1</sup>. This effect might be seen due to facilitation of cholinergictransmission. All these studies highlight major role of Yashtimadhu in maintaining and improving functions of brain and may throw light on its possible Medhya effect.

Ksheera (milk) is considered as one of the most suitable food supplement from paediatric to geriatric age. It is a general belief that milk is one of the best tonics and everyone; especially children are provided with milk in many homes. Different products that make tastier and can add nutritive value are also available in market. In different programs initiated to promote nutrition in children, pregnant women, elderly or in specific diseases milk is always added in diet plan. Ayurveda also advocates use of Ksheera in healthy individuals and also in management of different diseases. Combinations of different medicines with milk are extensively explained in Ayurveda as Ksheera Paka and are extensively used by Ayurvedic practitioners. Combination of Yashtimadhu with Ksheera is one such combination advocated as Medhya Rasayana. Properties of different milk are explained in classical treatises, but cow's milk is considered as the best. However, in current scenario, cow's milk as well as buffalo's milk is used for daily needs. In current study, subjects were advised to take milk that was available at home. Ksheera is Madhura, Snigdha, Dhatu Vardhana and Oja Vardhana, Vata Pitta Hara, Guru and Sheeta<sup>li</sup>. Acharya Sushruta has explained Khseera as essence of all drugs which don't contain any waste part lii. Hence beneficial effect of milk in improving Medha can be justified by its Dhatu Vivardhana, Oja Vivardhana, Bruhana and Snigdha properties.

Milk is primary source of nutrition for infant mammals before they are able to digest other types of food. In almost all ethnicities it continues to remain important source of nutrition. It contains – water, fats, fatty acids, proteins, carbohydrates and calcium in varying proportions. However, effect of regular intake of milk on cognitive functions is still debatable. Chrichton et al (2012) have reported relation between intake of dairy food and cognition through a Maine-Syracuse Longitudinal Study<sup>liii</sup>. The authors have claimed that frequent dairy food intake was associated with better cognitive performance. On the contrary, a cohort study of sample size 13751 concluded that regular intake of milk is associated with cognitive decline over a period of 20 years (Petruski-Ivleva N et al 2017)<sup>liv</sup>. Scholars have suspected role of lactose which is present in milk as causative factor for the cognitive decline. In view of the conflicting results outcome of meta-analysis which can be considered as a reliable source reach to a conclusion.

Lee et al (2018)<sup>lv</sup> have concluded that results of meta-analysis are inconclusive. It underlines the need for further study in this regards.

Analysis of height, weight and BMI showed significant improvement in both groups as compared with baseline. However, between group analysis showed insignificant difference. It suggests that Yashtimadhu did not make significant difference as far as physical growth is concerned. However, no data is available in this regards to compare results of present study. Analysis of physical stamina was done on the basis of standard scale. The within group analysis revealed that physical stamina increased significantly in group A, while group B did not show significant improvement. Between group analysis showed insignificant increase. In group A, 14 subjects were added in highest grade, while in group B showed only two subjects shifted to highest grade at the end of study as compared with baseline. Similar observations were seen in energy level. At the end of study, in group A, number of subjects in highest grade increased by 13, while in group B it increased by 22 as compared to baseline. Height, weight, BMI, physical stamina and energy level are physical parameters. As, Yashtimadhu and milk, both have nutritive potential, increasing trend was seen in these parameters in both groups.

Attentiveness in class was observed by class teachers of each class and was reported according to CGI scale at each follow up from baseline. It is expected that attentiveness is directly related with increase in cognition. But, in present study insignificant improvement between groups was observed about attentiveness. Similar observation was seen about social behaviour. Both the parameters were dependant on data received from class teachers. In a government aided public school, number of students per class is more. Teachers are needed to perform a lot of other duties apart from teaching. Hence, possibility of manual errors could not be ruled out. Hence, though objective parameters such as DLST and SLCT showed significant difference between groups, same might not have been observed about attentiveness and social behaviour.

Various Rasayana mentioned in Ayurveda have been evaluated for their immune booster effects (Masram P et al 2014)<sup>lvi</sup> (Deshpande VS and Deshpande SV, 2018)<sup>lvii</sup>. Famous Ayurvedic medicine – Chyavanprash is known to have positive effects on health of school

going children (Gupta A et al, 2017) lviii. In current study number of adverse events observed were categorised on the basis of their association with infection, allergy and immunity. Further categorisation of adverse events was done as per infected system, duration of illness, number of episodes per group, intensity of illness and requirement of concomitant medicine for infection, allergy and immunity. Between groups analysis of adverse events suggests that there was insignificant difference in number of episodes related with infection, allergy and immunity, duration of illness and requirement of concomitant medicine. However, absenteeism of subjects in group A due to illness was significantly less. Also, majority of episodes related with infection, allergy and immunity were of mild intensity in group A. Out of total episodes of moderate illnesses 75% episodes were seen group B and while remaining 25% episodes were seen in group A. If both the parameters are considered together, it can be said that subjects in group A missed the school significantly less times due to less severe illnesses. Absenteeism in school adversely affects academic performance, class participation, coordination with teachers and peers (Khalid and Mehmood, 2017) lix. Children commonly suffer from different respiratory, gastro-intestinal or skin infections or allergies. Some students are chronic sufferers of these conditions. Absenteeism due to recurrent health ailment can cause negative impact on school performance and is also associated with morbidity (Nichol K. L. et al, 2005)<sup>lx</sup>. However, current study suggests possible positive effect of Yashtimadhu with milk on improving immunity and reducing severity of the allergy or infection.

No serious adverse events or adverse drug reactions were noted in either group throughout the study period. Single episode of vomiting was observed in one subject after consumption of first dose of study medicine. But no further episodes were observed in any of the subjects. Hence the episode was unassociated with study medicine. Hence, it can be claimed that consumption of Yashtimadhu with milk is safe in school going children.

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#### SUMMARY AND CONCLUSION

#### **Summary**

- The present study entitled An Open Labeled, Randomized, Two Arm Study of Effect of Yashtimadhu Choorna with Milk on Health and Cognitive Parameters in Healthy Volunteers – A School Based Study is presented in two main sections – conceptual and interventional.
- Conceptual study was done using available literature like Brihattrayi with various commentaries, encyclopaedias like Shabdakalpadruma, Vachaspatyama, Amarkosha, Monier Williams's dictionary etc.
- Study intervention: Yashtimadhu Choorna
- **Dosage:** 2.5gm BD (early morning, on empty stomach and after evening meal)
- Anupana 50 ml of milk
- **Duration of Therapy:** 3 months
- Sample size 239
- Study Groups:

**Group A (Study Group):** the students in this group were advised to follow their regular routine which they were already following along with consumption of Yashtimadhu Choorna 2.5 gm along with 50 ml of milk, twice in a day.

**Group B** (Control group): the students in this group were advised to follow their regular routine which they were already following along with consumption of 50 ml of milk twice in a day.

#### • Assessment Parameters

- 1. Digit Letter Substitution Test (DLST) was done at baseline visit and at the end of the study.
- 2. Six Letter Cancellation Test (SLCT) was done at baseline and at the end of the study.
- Statistical Analysis For statistical analysis SPSS (version 23) and Microsoft Excel were used. For analysis of objective data before and after treatment within group paired t test was used, while for analysis of data between groups unpaired t test was used. Multiple measurements were analysed using one way analysis of variance (ANOVA). The results obtained after statistical analysis were interpreted at confidence level of 95%.

#### Conclusion

Administration of Yashtimadhu Choorna with milk in school going children has shown promising results in improving the score of post test results of DLST, SLCT and health status related parameters, without causing any untoward effects. So Yashtimadhu Choorna with milk is effective on health and cognitive parameters in healthy children between the age of 10-14yrs.

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## <u>अनुमतीपत्र</u>

शीर्षक - स्वस्थ मुलांमध्ये मेध्य रसायनाचे विशेषतः यष्टीमधु चूर्णाचे दुधासोबत सेवन केल्याने आरोग्य व बौद्धीक पातळीवर होणारा परिणाम विद्यालयातील विद्यार्थ्यावर आधारीत अभ्यास

मला या अभ्यासासंदर्भात पुरेशी माहिती पुरवण्यात आली आहे.मी माहितीपत्रक काळजीपूर्वक पूर्ण वाचले आहे ( मला वाचून दाखवण्यात आले आहे) व मला ती माहिती समजलेली असून माझ्या पाल्याने या अभ्यासात स्वेच्छेने सहभागी होण्यास माझी अनुमती आहे.माझ्या प्रश्नांची उत्तरे मला समाधानकारकिरत्या मिळालेली आहेत.या अभ्यासात भविष्यात मला काही प्रश्न उद्भवल्यास प्रमुख अभ्यासक अथवा त्यांचे सहकारी त्याची उत्तरे देतील सदर अभ्यासातील माझ्या पाल्याचा सहभाग ऐच्छिक असून कुठलेही कारण न देता या अभ्यासातून तो कधीही बाहेर पडू शकतो / शकते याची मला पूर्ण जाणिव आहे.

स्वाक्षरी /डाव्या हाताचा अंगठा	
पालकाचे नाव	
दिनांक	
स्वाक्षरी	
साक्षीदाराचे नाव	
दिनांक	
स्वाक्षरी	
अभ्यासकाचे नाव	
दिनांक	
दिनांक	



## Pune District Education Association's

# College of Ayurved & Research Centre

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Central Research Laboratory

Ref No. CARC CRL/ 152 / 22 / 07 / 2018

Date: 26/07/2018

## **Analytical Report**

Name of the student	:	Dr. Vaishali S. Deshpande
Name of the guide	:	Dr. Abhijit Joshi
Title of the study	:	An open labeled randomized, two arm study of effect of Yashtimadhu choorna with milk on health and cognitive parameters in healthy volunteers a school based study
Samples	:	Yashtimadhu choorna
Date of sample received	:	22/07/2018
Tests performed	:	Moisture percentage, Total Ash, Acid soluble & insoluble Ash, Water Soluble & insoluble Ash, Aqueous and methanol Extractive value & TLC

Test	Yashtimadhu choorna	API values
Moisture %	4.092%	-
Ash %	7.06 %	Not more than 10%
Color of Ash	Off white	-
Acid insoluble Ash	1.96	Not more than 2.5 %
Aq. Ext. %	17.06	Not less than 20 %
Color of extract	Dark Brown	
Odor	Sweet characteristic smell	
Appearance	Turbid	-

Test	Yashtimadhu choorna	API values
Taste	Madhur kashay	
Meth. Ext. %	17.07	Not less than 10%
Color of meth. Extract	Dark brown	<b>H</b>
Odor	Sweet characteristic smell	-
Appearance	Clear	

Sample- aqueous extract and methanol extract of Yashtimadhu roots

Solvent system -Toluene: Ethyl acetate: formic acid (5:4:1)

Solvent front- 15 cm.

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H.O.D OF DEPARTMENT OF RESEARCH DR.YOGINI R. KULKARNI

H.O.B.

Besearch Methodology College of Ayunyed And Research Centre Akurdl Pani - 411 044

PRINCIPAL DR. RAGINI R. PATIL

Principal

P.D.E.A'S

College of Ayurved And Research

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# टिळक महाराष्ट्र विद्यापीठ Tilak Maharashtra Vidyapeeth

(Declared as Deemed University under section 3 of UGC Act 1956 vide Notification No.F-9-19/85-U-3 dated 24 April 1987 by the Government of India). Vidyapeeth Bhavan, Mukundnagar, Gultekdi, Pune-411037.

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Ref No.Ayu/18/59

Date: 26/06/2018

## **Institutional Ethics Committee Approval Letter**

To,
Dr.Vaishali Deshpande
Ph.D. Scholar,
The Late P.G. Nanal Dept. of Ayurveda,
Tilak Maharashtra Vidyapeeth, Pune

Subject: Report of IEC meeting held on 22/06/2018

Ph.D. student,

The research topic "An Open Labeled, Randomized, Two Arm Study Of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study" has been reviewed by the hon. Members' of the Institutional Ethics Committee.

Following documents were reviewed:

Sr. No	Document
1	Clinical Study Protocol
2	Case Report Form
3	Informed Consent Document (English and Marathi)
4	Consent Form (English and Marathi)
5	Assent (English and Marathi)

The proposal for clinical study has been unanimously accepted by the *Institutional Ethics Committee for Biomedical Research*, *Tilak Maharashtra Vidyapeeth*, *Pune – 411037*.

Sincerely yours,

Prof. Dr. Abhijit H. Joshi Member Secretary,

IEC for Biomedical Research, Tilak Maharashtra Vidyapeeth, Pune

### माहितीपूर्ण संमतीपत्रक मराठी

**नाव** - स्वस्थ मुलांमध्ये मेध्य रसायनाचे विशेषतः यष्टीमधु चूर्णाचे दुधासोबत सेवन केल्याने आरोग्य व बौद्धीक पातळीवर होणारा परिणाम विद्यालयातील विद्यार्थ्यावर आधारीत अभ्यास

उद्देश - सदर अभ्यासात विद्यालयातील स्वस्थ विद्यार्थ्यांमध्ये मेध्य रसायनाचे विशेषतः यष्टीमधु चूर्णाचे दुधासोवत सेवन केल्याने आरोग्य व बौद्धीक पातळीवर होणारा परिणाम अभ्यासणे अपेक्षित आहे .

प्रिकेया - ह्या अभ्यासासाठी सर्वप्रथम टिळक महाराष्ट्र विद्यापीठाच्या इथिक्स किमटीकडून मान्यता मिळवली जाईल याची नोंदणी क्लिनीकल ट्रायल रिजस्ट्री ऑफ इंडियाच्या संकेतस्थळावर केली जाईल त्यांनंतर विद्यालयातील प्रशासकीय व्यक्तींना यासंदर्भात भेटून संपूर्ण महिती दिली जाईल त्यांच्या परवानगीनंतर पालकांशी व विद्यार्थ्याशी संवाद साधला जाईल पालकांच्या परवानगीने व विद्यार्थ्याच्या स्वेच्छेने त्यांचा यात समावेश केला जाईल सहभागी विद्यार्थ्याची रॅन्डमली दोन अ व ब गटात विभागणी केली जाईल त्यापैकी अ गटाला अभ्यासाचे औषध म्हणजे यण्टीमधू चूर्ण १ ग्रॅम अर्था कप दुधासोबत ५० मिली दिवसातून दोन वेळा ९० दिवसांसाठी सेवन करण्यास सांगीतले जाईल व ब गटाला केवळ अर्धा कप दुधाचे ५० मिली दिवसातून दोन वेळा ९० दिवसांसाठी सेवन करण्यास सांगीतले जाईल ही विभागणी करतांना प्रत्येक विद्यार्थ्याला प्रत्येक गटात समाविष्ट होण्याची समान शक्यता असेल पूर्ण शारीरिक तपासणी केल्यानंतरच विद्यार्थ्याचा अभ्यासातील सहभाग निश्चित केला जाईल औषधाचा परिणाम अभ्यासण्यासाठी विद्यार्थ्यांना प्रश्न विचारले जातील तसेच डीजिट लेटर सर्वस्टिटयुशन टेस्ट (डी एल एस टी) व सिक्स लेटर कॅन्सलेशन टेस्ट (एस एल सी टी ) या चाचण्या केल्या जातील विद्यार्थ्याच्या शिक्षकांशी चर्चा करून त्यांच्या आजारपणामुळे असलेल्या अनुपस्थिती वर्गातील अध्यापनाच्या काळातील लक्षपूर्वकता शैक्षणिक प्रगती इ चा आढावा घेतला जाईल त्यांच्या उत्तरांच्या व या चाचण्यांच्या आधारे निष्कर्ष काढले जातील .

#### अभ्यासकांची माहिती -

अभ्यासातील असुरक्षित व प्रतिकुल बाबी - व्यावहारीक दृष्टया या अभ्यासात भाग घेणा-यास कोणत्याच असुरक्षित व प्रतिकुल बाबी नाहीत अभ्यासात भाग घेणा-यास फायदे - दुध हे शरीरासाठी पोषक आहे. जेष्ठमध हे वेगवेगळया असंख्य आजारांमध्ये औषथ स्वरूपात वापरले जाते. यामुळे प्रतिकारश्क्ती वाढणे आरोग्याचा व बौद्यीक स्तर सुधारणे अभिप्रेत आहे.

काही विपरीत परिणाम झाल्यास - सामान्यतः यामुळे कोणताही विपरीत परिणाम होण्याची शक्यता नाही हे फार पूर्वीपासून ज्ञात असून अशा प्रकारच्या परिस्थितीमध्ये उपचाराकरता वापरावे असा उल्लेख आहे . तसेच पुरातनकालीन साहित्यात हे वाईट परिणामकारक घटकांच्या यादीत नाही . तरीसुध्दा जर काही विपरीत परिणाम आढळला तर आवश्यकता भासल्यास विद्यार्थ्याला अभ्यासातून वगळण्यात येईल आणि अभ्यासकाच्या व विकित्सकाच्या सल्ल्याप्रमाणे व सूचनेप्रमाणे त्याची यथावश्यक विकित्सा केली जाईल .

गुप्तता - विद्यार्थ्याची सर्व वैद्यकीय माहिती गुप्त ठेवण्यात येईल आणि त्याची ओळख कोणत्याही प्रकाशनात प्रकाशित केली जाणार नाही . पुढील माहितीसाठी संपर्क -

#### Informed consent form

**Title** – An Open Labeled, Randomized, Two Arm Study Of Effect Of Medhya Rasayana W.S.R. To Yashtimadhu Choorna Along With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study

I have been explained about this clinical study. I have read the informed consent document (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate. All my questions have been answered. If I have any questions, in future about the study, the investigator listed above or his/her staff will answer them. I also fully understand that I am free to withdraw from the trial any moment during the course of the trial.

Signature/Left hand thumb impression	
Name of Parent	
Date	
Signature	
Name of Witness	
Date	
Signature	
Name of Investigator	
Date	

#### **Informed Consent Document - English**

**Title** - An Open Labeled, Randomized, Two Arm Study Of Effect Of Medhya Rasayana W.S.R. To Yashtimadhu Choorna Along With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study.

**Objective** – To study the effect of medhya rasayana i.e. yashtimadhu choorna along with milk on health and cognitive parameters in healthy school going students.

Methodology –initially permission from Ethics Committee of Tilak Maharashtra Vidyapeeth will be obtained. The study will be registered with Clinical Trial Registry of India (CTRI). Firstly the study design will be explained to the school officials including teachers. After obtaining their consent, the study will be explained in detail to the parents and students. Only after obtaining consent from parent and willingness of student, inclusion in the study will be done. With the help of randomization, the included students will be divided into two groups. Students in group A will be advised to take Yashtimadhu Choorna 1 gm with 50 ml of milk and students in group B will be advised to take 50 ml of milk two times in a day for 90 days. During randomization, every student will have equal opportunity to fall in either group. Inclusion in study will be confirmed only after performing thorough clinical examination. To evaluate the drug effect, the students will be inquired and tests like Digit Letter Substitution Test (DLST) and Six Letter Cancellation Test (SLCT) will be done. Discussion with students' teachers will be carried out to get information regarding absenteeism due to illness, attentiveness in class, academic performance etc. conclusion will be drawn on the basis of these tests and discussions.

#### **Investigator's information -**

**Foreseeable risks** – Yashtimadhu and milk are in human use since decades. There are no specific safety concerns for the use of these drugs.

**Expected benefits** – Milk is considered as nutrient for body. Yashtimadhu is used as a medicine for various diseases. By participating the student may be benefited by improvement in immunity status, health and intelligence.

What if anything goes wrong? – Generally, there are no safety concerns about usage of these drugs. Both the drugs are in human use since decades. In case, if your child comes across any adverse effect, the child will be withdrawn from the study if required and treated according to the investigator.

**Confidentiality** – Your child's all medical record will be kept confedential and identity will not be revealed in any publication.

For further information, contact -

Assent Form - Marathi Subject ID Group A/B

#### बालकांचे संमतीपत्रक

**नाव** - स्वस्थ मुलांमध्ये मेध्य रसायनाचे विशेषतः यष्टीमधु चूर्णाचे दुधासोवत सेवन केल्याने आरोग्य व बौद्धीक पातळीवर होणारा परिणाम विद्यालयातील विद्यार्थ्यावर आधारीत अभ्यास

उद्देश - सदर अभ्यासात विद्यालयातील स्वस्थ विद्यार्थ्यांमध्ये मेध्य रसायनाचे विशेषतः यष्टीमधु चूर्णाचे दुधासोबत सेवन केल्याने आरोग्य व बौद्यीक पातळीवर होणारा परिणाम अभ्यासणे अपेक्षित आहे .

सर्वप्रथम तुमच्या पालकांशी या अभ्यासाबाबत संवाद साधला जाईल त्यांना माहितीपूर्ण संमतीपत्रक वाचण्यासाठी दिले जाईल पालकांच्या परवानगीने व युमच्या स्वेच्छेने तुमचा यात समावेश केला जाईल पालकांचा पारवानगीने व युमच्या स्वेच्छेने तुमचा यात समावेश केला जाईल पालकांचा योग्यता असल्यास अभ्यासातील सहभाग निश्चित केला जाईल व दोनपैकी एका गटात तुमचा समावेश केला जाईल हे दोन गट रॅडमली केले जातील त्यापैकी अ गटाला अभ्यासाचे औषध म्हणजे यष्टीमधू चूर्ण १ग्रॅम अर्धा कप दुधासोवत ५० मिली दिवसातून दोन वेळा ९० दिवसांसाठी सेवन करण्यास सांगीतले जाईल व व गटाला केवळ अर्धा कप दुधाचे ५० मिली दिवसातून दोन वेळा ९० दिवसांसाठी सेवन करण्यास सांगीतले जाईल व व गटाला केवळ अर्धा कप दुधाचे ५० मिली दिवसातून दोन वेळा ९० दिवसांसाठी सेवन करण्यास सांगीतले जाईल व विचारले जातील प्रत्येक गटात समाविष्ट होण्याची समान शक्यता असेल औषधाचा परिणाम अभ्यासण्यासाठी तुम्हाला प्रश्न विचारले जातील तसेच डीजिट लेटर सबस्टिटयुशन टेस्ट (डा.एल.एस.टी) व सिक्स लेटर कॅन्सलेशन टेस्ट (एस.एल.सी.टी.) या चाचण्या केल्या जातील तुमच्या शिक्षकांशी चर्चा करून तुमची आजारपणामुळे असलेली अनुपस्थिती वर्गातील अध्यापनाच्या काळातील लक्षपूर्वकता शैक्षणिक प्रगती इ.चा आढावा घेतला जाईल या उत्तरांच्या व या चाचण्यांच्या आधारे निष्कर्ष काढले जातील .

षा अभ्यासात सहभागी झाल्यामुळे तुम्हाला प्रतिकारश्क्ती वाढणे आरोग्याचा व बौद्धीक स्तर सुधारणे हे फायदे होऊ शकतात. जर काही विपरीत परिणाम आढळला तर आवश्यकता भासल्यास तुम्हाला या अभ्यासातून वगळण्यात येईल आणि अभ्यासकाच्या व चिकित्सकाच्या सल्ल्याप्रमाणे व सूचनेप्रमाणे त्याची यथावश्यक चिकित्सा केली जाईल. तुमची सर्व वैद्यकीय माहिती गुप्त ठेवण्यात येईल आणि तुमची ओळख कोणत्याही प्रकाशनात प्रकाशित केली जाणार नाही.

सहभागी होण्याचा निर्णय घेण्यापूर्वी या पत्रकात दिलेली सर्व माहिती तुम्ही वाचणे व समजून घेणे आवश्यक आहे. सहभागाबद्दल तुम्ही तुमच्या पालकांशी चर्चा करू शकता. टुमच्या पालकांनी माहितीपूर्ण संमतीपत्रकावर व तुम्ही बालकांच्या संमतीपत्रकावर स्वाक्षरी केल्यानंतरच तुम्हाला सहभागी करता येईल. या अभ्यासातील तुमचा सहभाग हा पूर्णपणे ऐच्छिक असून कुठल्याही क्षणी कुठलेही कारण न देता तुम्ही बाहेर पडू शकता.

स्वाक्षरी	
विद्यार्थ्याचे पूर्ण नाव	
दिनांक	
स्वाक्षरी	
अभ्यासकाचे पूर्ण नाव	
दिनांक	

#### **Assent Form – English**

**Title** - An Open Labeled, Randomized, Two Arm Study Of Effect Of Medhya Rasayana W.S.R. To Yashtimadhu Choorna Along With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study

**Objective** – To study the effect of medhya rasayana i.e. yashtimadhu choorna along with milk on health and cognitive parameters in healthy school going students.

Firstly the informed consent document will be issued to your parent and if they are willing for your participation, then only after your willingness, you can take part in the study. After signing the consent form by parent and assent form by you, thorough clinical examination will be done and if you are found eligible you will be included in the study, in anyone of the group. Grouping will be done randomly. Students in group A will be advised to take Yashtimadhu Choorna 1 gm with 50 ml of milk and students in group B will be advised to take 50 ml of milk two times in a day for 90 days. During randomization, every student will have equal opportunity to fall in either group. To evaluate the drug effect, you will be inquired and tests like Digit Letter Substitution Test (DLST) and Six Letter Cancellation Test (SLCT) will be done. Discussion with your teachers will be carried out to get information regarding your absenteeism due to illness, attentiveness in class; academic performance etc. conclusion will be drawn on the basis of these tests and discussions.

By participating you may be benefited by improvement in immunity status, health and intelligence. In case, if you come across any adverse effect, you will be withdrawn from the study if required and treated according to the investigator. Your all medical record will be kept confidential and identity will not be revealed in any publication.

Before taking decision of participation in study, you must read and understand the information given in this form. You may also discuss with your parents about your participation. Only after obtaining consent from your parent and expression of your willingness, inclusion will be done. Your participation in this study is voluntary and you may withdraw from the study at any time without giving any reason for the same.

Signature	
Name of Student	
Date	
Signature	
Name of Investigator	
Date	

#### **CASE RECORD FORM**

Name	2					
Addre	ess:-					
Gend	Gender: - Age: -					
Religi	on: -					
Date	of counselling/screening:	Date of inclusion	: <del>-</del>			
Stand	lard and division					
Conta	act Details of parents					
Conta	act Details of Class Teacher					
Conta	act Details of Class Teacher					
o						
Chief	complaints:-					
No.	Presenting symptoms		Duration & Details			
1.						
2.						
3.						
3.						
4.						
_						
5.						
Past I	l Medical History:-					
	,					
Kulvri	ittanta-:					
	a : Vegetarian / Mixed diet.					
	_					
N	on-vegetarian – Quantity & Frequency -					
Vihar	a:					
Prakr	uti :					
	n Open Labeled, Randomized, Two Arm Study Of Eff eters In Healthy Volunteers – A School Based Study	ect Of Yashtimadhu Choo	orna With Milk On Health And Cognitive			

#### Samanya Parikshana:-

	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day
Nadi				
Mutra				
Mala				
Jivha				
Kshudha				
Nakha				
Netra				
Agni				
Koshtha				
Nidra				
Height				
Weight				

#### SROTASA PARIKSHANAM

SR.NO	SROTASA	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day
1	Pranavaha				
2	Annavaha				
3	Udakvaha				
4	Rasavaha				
5	Raktavaha				
6	Mamsavaha				
7	Medovaha				
8	Asthivaha				
9	Majjavaha				
10	Shukravaha				
11	Purishavaha				
12	Mutravaha				
13	Swedavaha				
14	Artava vaha				

#### **OBJECTIVE CRITERIA**

#### 1. Digit Letter substitution Test (DLST) score

Timepoint	Baseline	90 <sup>th</sup> Day
DLST Score		

#### 2. Six Letter Cancellation Test (SLCT)

Timepoint	Baseline	90 <sup>th</sup> Day
SLCT Score		

#### 3. Academic Performance

Subjects	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day

#### 4. Accountability for Yashtimadhu Choorna

Description	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day
Dispensed				
Quantity				
Returned				
Quantity				

#### 5. Assessment of CGI -I Scale

Day	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day
CGI -I Scale				

#### **Teacher's Narrative**

Criteria	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day
Date				
No of absent days due				
to illness /Month				
Energy Level				
Physical fitness				
Attentiveness in class				
Academic improvement				
Social behavior				

#### Parent's Narrative

Criteria	Baseline	30 <sup>th</sup> Day	60 <sup>th</sup> Day	90 <sup>th</sup> Day
Date				
Episodes of illness				
Severity of illness				
Duration of illness				
Energy Level				
Physical fitness				
Academic improvement				
Social behavior				

### Scoring system for teacher's and Parent's narrative (CGI Scale)

Score	-3	-2	-1	0	1	2	3
Observation	Very dissatisfied	Somewhat dissatisfied		Neutral	A little satisfied	Somewhat satisfied	Very satisfied

### **ADVERSE EVENTS**

SR	AE TERM	ONSET	DURATION	SEVERITY	TREATMENT Taken	OUTCOME	CAUSALITY
1							
2							
3							
4							
5							
6							
7							

Signature of Investigator

Student's Name -

Class & Div.

Date -

Key

1 L	2 H		3 Y	4 N	5 R		6 E	7 D		8 T		9 J
L	11			11	10		L	D		1		<u>,                                     </u>
6	2	4	1	5	7	9	3	2	6		8	5
5	4	7	8	1	2	3	4	9	6		3	7
2	4	6	7	8	9	3	1	2	3		7	4
2	9	4	6	8	1	2	5	9	3		4	7
9	7	4	2	3	8	1	5	6	2		9	1
8	6	2	3	9	4	5	7	1	4		3	9
3	5	9	1	2	5	6	2	7	8		9	1
5	4	9	2	7	1	3	2	8	9		5	6

Total Attempted

Wrongly Attempted

Net Score

Student's Name Class & Division Date

Instructions 1. Search out the target letters given below and cancel them by "I" or "-" or "/"

- 2. Cancel the target letters as many as possible within 90 seconds
- 3. Follow the instructions regarding start and stop.

### Target letters – J, T, K, M, U, F

J	G	Y	L	S	Е	Т	В	L	U	V	G	K	Н	A	W	U	J	M	K	R	В
X	N	О	D	F	С	K	N	Е	Н	W	Z	L	J	S	D	Q	L	N	Н	U	О
U	K	W	A	I	M	P	G	Q	X	M	F	Y	В	I	R	X	G	F	P	J	K
Z	V	В	Н	J	S	Y	D	K	О	S	Q	T	M	P	О	Е	I	A	T	L	Е
T	L	Y	R	О	Z	L	F	A	U	I	N	Z	G	W	Т	J	K	D	R	Y	A
D	S	Q	С	Е	T	R	W	Z	J	A	Е	Н	L	U	Y	V	Z	S	О	N	X
Е	W	K	F	Н	M	N	С	P	X	R	О	K	I	С	R	F	G	P	I	K	S
G	U	A	P	S	V	I	О	В	D	С	S	F	X	Е	Н	W	Q	M	L	О	R
Н	T	Y	G	D	L	U	Q	G	Y	W	A	В	Z	D	Y	V	U	A	Е	Q	P
L	V	О	Е	J	Z	F	Т	L	Е	M	Н	Q	J	A	X	R	D	В	Z	N	J
S	W	N	Q	K	Н	С	A	Z	N	О	I	S	M	L	Е	J	S	Н	G	Т	F
A	P	F	X	О	R	I	J	В	D	P	K	W	I	J	K	О	R	I	В	Z	A
R	Т	Y	В	V	D	X	S	U	F	R	X	О	Q	В	Т	В	X	W	D	S	Z
M	I	G	U	W	K	О	С	Е	N	V	Т	Н	Z	M	N	С	U	Y	P	K	Е

Total Attempted -

Wrongly Attempted -

Net Score -



#### Clinical Trial Details (PDF Generation Date :- Wed, 18 Jul 2018 13:26:34 GMT)

CTRI Number Last Modified On Post Graduate Thesis

Yes

Type of Trial

Interventional

15/07/2018

Type of Study

Ayurveda

Study Design
Public Title of Study

Randomized, Parallel Group, Active Controlled Trial

To study the effectiveness of Yashtimadhu Choorna with milk on health and intelligence in healthy volunteers (school going children)

CTRI/2018/07/014909 [Registered on: 17/07/2018] - Trial Registered Prospectively

Scientific Title of Study

An Open Labeled, Randomized, Two Arm Study Of Effect Of Yashtimadhu Choorna With Milk On Health And Cognitive Parameters In Healthy Volunteers – A School Based Study

Secondary IDs if Any

Secondary ID Identifier

NIL NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator								
Name	Dr Vaishali Shailesh Deshpande							
DesignationPh. D. Scholar								
Affiliation Asst. Professor, Dept. of Kayachikitsa, SSAM Pune								
Address	Department of Ayurveda, Tilak Maharashtra Vidyapeeth, Gultekadi, Pune Sumatibhai Shah Ayurved College, Hadapsar, Pune Pune MAHARASHTRA 411 037 India							
Phone	9096082950							
Fax								
Email	dr.vaishalid@gmail.com							

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)			
Name	Dr Abhijit Joshi		
Designation	Guide		
Affiliation	Head of Department		
Address	Department of Ayurveda, Tilak Maharashtra Vidyapeeth, Gultekadi, Pune Pune MAHARASHTRA 411 037 India		
Phone	02024403080		
Fax			
Email	ayutmv@gmail.com		

Details Contact Person (Public Query)

ayatiiv @giriaii.com			
Details Contact Person (Public Query)			
Name	me Dr Vaishali Shailesh Deshpande		
Designation	Ph. D. Scholar		
Affiliation	Asst. Professor, Dept. Of Kayachikitsa, SSAM Pune		
Address	Department of Ayurveda, Tilak Maharashtra Vidyapeeth, Gultekadi, Pune Sumatibhai Shah Ayurved College, Malwadi, Hadapsar, Pune Pune MAHARASHTRA 411 037 India		



<b>Phone</b> 9096082950	
Fax	
Email	dr.vaishalid@gmail.com

#### Source of Monetary or Material Support

#### Source of Monetary or Material Support

 Dr. Vaishali Deshpande Sonai, Shri Adishakti coop. Hsg. So. No. 1, Sr. No. 28/8/5 &6, Chaitanya Nagar, Dhankawadi, Pune - 411043

#### **Primary Sponsor**

Primary Sponsor Details		
Name Dr Vaishali S Deshpande		
Address Tilak Maharashtr Vidyapeeth, Gultekadi, Pune		
Type of Sponsor Other [Ph. D. Scholar, ]		

#### **Details of Secondary Sponsor**

Name	Address
NIL	NIL

#### Countries of Recruitment

#### List of Countries India

#### Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Vaishali S Deshpande	Tilak Maharashtra Vidyapeeth	Department of Ayurved, First floor, Gultekadi,	9096082950
		Pune	dr.vaishalid@gmail.com
		Pune	
		MAHARASHTRA	

#### Details of Ethics Committee

Name of Committee	Approval Status	• •	Is Independent Ethics Committee?
Institutional Ethics Committee, The Late P. G. Nanal Department of Ayurved, Tilak Maharashtra Vidyapeeth, Gultekadi, Pune		26/06/2018	No

## Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

## Health Condition / Problems Studied

Health Type	Condition	
Healthy Human Volunteers	Health and Cognitive Parameters	

## Intervention / Comparator Agent

Туре	Name	Details
Intervention		2.5gm BD (in the morning on empty stomach and after dinner)with 50 ml of milk for 3 months
Comparator Agent		50 ml BD (in the morning on empty stomach and after dinner) for 3 months

#### **Inclusion Criteria**

Inclusion Criteria		
Age From 10.00 Year(s)		
Age To	14.00 Year(s)	
Gender	Both	
Details	1)Apparently healthy volunteers i.e. students of secondary school 2)No significant medical or surgical illness at the time of screening 3)Volunteers and their parents ready for the study and willing for treatment	



Exclusion Criteria  Method of Generating	Details 2	Exclusion  Exclusion  1)Presence of signiscreening requiring 2)Volunteers having infancy/childhood 3)K/C/O growth retains	rrespective of religion, gender, socioeconomic andard. o study related procedures  n Criteria ficant medical or surgical illness at the time of long term treatment. g history of delayed milestones in ardation, mentally retarded children.
Random Sequence Method of	An Open list of random number	rs	
Concealment			
Blinding/Masking	Not Applicable		
Primary Outcome	Outcome		Timepoints
	To evaluate the effect of consumption of Yashtimadhu Choorna along with milk on cognitive parameters in healthy volunteers in study group on the basis of 1.DLST (digit letter substitution test) 2.SLCT(six letter cancellation test) 3.Improvement in academic performance 2.To evaluate the cognitive parameters in healthy volunteers in control group on the basis of 1.DLST (digit letter substitution test) 2.SLCT(six letter cancellation test) 3.Improvement in academic performance		At the baseline (0 Day) and at the end of the study (90th Day)
Secondary Outcome	Outcome		Timepoints
			At the baseline (0 Day) and at the end of the study (90th Day)
	Assessment of health status on the basis of episodes, severity and duration of illnesses in both groups.		At the baseline (0 Day) and at the end of the study (90th Day)
	Assessment of difference in abschool due to illness in both gr	oups.	At the baseline (0 Day) and at the end of the study (90th Day)
	and stamina in both groups.		At the baseline (0 Day) and at the end of the study (90th Day)
	Assessment of growth parame and weight in both groups.	ters like height	At the baseline (0 Day) and at the end of the study (90th Day)
Target Sample Size	Total Sample Size=220 Sample Size from India=220		
Phase of Trial	Phase 2		
Date of First Enrollment (India)	23/07/2018		
Date of First	No Date Specified	<u></u>	

ICMR - National Institute of Medical Statistics

#### **PDF of Trial** CTRI Website URL - http://ctri.nic.in

**Enrollment (Global) Estimated Duration of** Trial

Years=1 Months=6 Days=0

**Recruitment Status of** Trial (Global)

Not Applicable

**Recruitment Status of** Trial (India)

Not Yet Recruiting

**Publication Details Brief Summary** 

None.

This is an Open label, Randomized, Multi center, Prospective, Two arm Clinical Study. After obtaining Ethics Committee approval registration at CTRI will be done. After obtaing CTRI registration number, the study will be started. The study will be conducted at Mahatma Phule Vidyaniketan Institution's Dnyanaprabodhini Madhyamik and Kanishtha Mahavidyalaya, Sasanenagar, Hadapsar Pune 28

Firstly the study design will be explained to the school officials including teachers. After obtaining their consent, parent meeting will be called. The study will be explained in detail to the parents. Each and every possible effort will be taken to answer study related queries. Parents' attendance will be taken. Also their willingness and correspondence details will be taken. The parents who are willing for participation will be called on next day with their ward for participation eligibility screening.

On screening day, the ascent from child and consent from parent will be taken and then only study related activities will be conducted. At baseline visit, according to randomization, the children will be included in respective groups. One follow up card and one accountability sheet will be issued to each participant. The participant will be instructed to tick on the accountability sheet after consumption of Yashtimadhu Choorna along with milk on daily basis.

Group A (Study Group): the students in this group will be advised to follow their regular routine which they are already following along with consumption of Yashtimadhu Choorna 2.5 gm along with 50 ml of milk, twice in a day for 3 months.

Group B (Control group): the students in this group will be advised to follow their regular routine which they are already following along with consumption of 50 ml of milk twice in a day for 3 months.

#### **Assessment Criteria**

- 1. Digit Letter Substitution Test (DLST) at baseline visit and at the end of the study.
- 2. Six Letter Cancellation Test (SLCT) at baseline and at the end of the study.
- 3. Improvement in academic performance at the baseline and at the end of the study.

#### **Methodology for Assessment parameters**

- 1. Digit Letter Substitution Test (DLST)
- a. The DLST worksheet consists of random digits, 1-9, in 8 rows and 12 columns.
- b.The coding sheet will have instructions about the test with example of substituting a specific letter for each digit 1-9, the same coding will be applied to an entire test group.
- c. Subjects will be instructed to make their own choice of letter substitution strategy, whether horizontally, vertically, or selecting a particular digit randomly in the array one at a time.
- d.They will be instructed to substitute as many target digits as possible in the specified time of 90 seconds
- 2. Six Letter Cancellation Test



- a.The six letter cancellation task worksheet consists of random alphabets, A-Z, in 14 rows and 22columns.
- b. Subjects will be instructed to seat with the worksheet turned over until the start of the test. All participants to be tested in one group will also be given instruction sheet indicating the six target letters to be cancelled.
- c.The instructions will be given regarding cancellation of as many target digits as possible in the specified time of 90 seconds.
- d. They will be given the choice of cancellation strategy to do it horizontally, vertically, or selecting a particular letter one at a time randomly in the array.
- e. Finally, after ensuring that they have understood the test by answering all their queries they will be instructed to turn over the worksheet and start the test as the bell rings.

#### 3. Academic improvement

- a. Discussion with school teacher as well as parents will be done.
- b For teacher the points under discussion will be absenteeism due to illness, attentiveness, energy level, physical fitness, social behavior in class.
- c.For parents the points under discussion will be episodes, severity and duration of illness, energy levels, physical fitness, stamina, social behavior at home.

**Accountability** - The volunteers in both group shall be inquired and confirmation will be obtained about history of regularity of consumption of Yashtimadhu Choorna with milk/milk with the help of accountability sheet.

**Data Analysis** - The data obtained through the study will be shared to qualified statistician for performing data analysis. Conclusion will be drawn on the basis of data analysis and study findings.



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महाराष्ट्र असोसिएशन फॉर द कल्टिव्हेशन ऑफ सायन्स

आघारकर अनुसंधान संस्थान

(विज्ञान और प्रौद्योगिकी विभाग, भारत सरकार के अधिन स्वायत्त संस्थान)

गो. ग. आगरकर पथ, पुणे – ४११ ००४.

Maharashtra Association for the Cultivation of Science AGHARKAR RESEARCH INSTITUTE

(An Autonomous Body under the Department of Science and Technology, Govt. of India)

G. G. Agarkar Road, Pune - 411 004.

July 25, 2018

#### **AUTHENTICATION CERTIFICATE**

Name of the party

: - Vd. Vaishali Deshpande

Address

: - Tilak Maharashtra Vidyapeeth, Vidyapeeth Bhavan,

Mukundnagar, Gultekadi, Pune 411 037

Reference

: - Ayu/18/72, dated: 9<sup>th</sup> July 2018

Name of the sample

: - Jeshtmadh

Sample size

- Dried sample (About 100 g)

Date of the receipt

: - 09/07/2018

#### Report: -

The sample has been critically studied with macroscopic, microscopic and organoleptic characters. We hereby authenticate that the given sample belongs to root of *Glycyrrhiza glabra* L. (Family-Leguminosae).

This certificate is issued at your request and is given only for the academic use.

R. K. Choudhar

Sr. Scientist,

Biodiversity and Palaeobiology (Plant)

Scientist

Plant Drug Authentication

Biodiversity and Palaeobiology Group

Auth.18- 165

Ref.: API (1989), ICMR (2011).