

**Product development and standardization of immune
enhancing tablets made from crude powder of *Emblica
officinalis*, *Tinospora cordifolia* and *Terminalia chebula***

(Jeewya)

By

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DECLARATION

The work described in this project was carried out by me at the Institute of Indigenous Medicine, University of Colombo, under the supervisions of Dr. P.K Perera, Head, Department of Ayurveda Pharmacology and Pharmaceutics, Institute of Indigenous Medicine, University of Colombo and Prof. K.K.D.S. Ranaweera, Department of Food Science and Technology University of Sri Jayewardenepura/Director at Bandaranaike Memorial Ayurveda Research Institute. This thesis has not been submitted to any University for another degree.

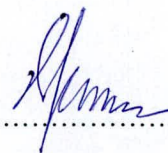
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ABSTRACT

Product development and standardization of immune enhancing tablets made from crude powder of *Emblica officinalis*, *Tinospora cordifolia* and *Terminalia chebula* (Jeewya)

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Combination of dried fruit powder of *Emblica officinalis* (Local name, *Nelli*), dried stem powder of *Tinospora cordifolia*, (Local name, *Rasakida*) and dried fruit powder of *Terminalia chebula* (Local name, *Aralu*) has been used in Sri Lankan Ayurveda for immune enhancing properties in many years form of decoction and ingredients of other formulations. The aim of this study was to formulate ready to use tablets by direct compression method using acacia as a binder. The tablets were evaluated using the necessary official tests *viz* moisture content, total ash, TLC finger print, weight variation, crushing strength, friability, thickness and disintegration time. Formulated tablet moisture content and total ash values were respectively 8.6% w/w and 5.0%w/w. TLC finger printing showed that similar pattern of Rf values and spots in tablet mixture compare with their raw materials. The formulated tablets complied with British Pharmacopoeia specification for weight uniformity, hardness (≥ 5 kgf) and tablet friability ($< 1\%$). For disintegration test, tablets formulated with acacia at concentrations of 1% w/w also complied with Pharmacopoeia specification. The average tablet weight was 450 ± 0.45 mg. Tablet had a crushing strength and friability of 4.5 kgf and 0.21%, respectively. From the results of disintegration, tablets formulated with acacia at concentrations 1% w/w complied with BP 2009 specification for normal release tablets. When considering all the quality parameters of Jeewya tablets, tablets are in standard quality for human consumption.

Key words: *Emblica officinalis*, *Tinospora cordifolia*, *Terminalia chebula*, tablets

CHAPTER I

INTRODUCTION

Ayurvedic medicine is one of the world's oldest medical systems. It originated in India more than 3,000 years ago and remains one of the country's traditional health care systems. Its concepts about health and disease promote the use of herbal compounds, special diets, and other unique health practices.

For the process of rejuvenation, Ayurveda has described a unique therapy viz. Rasayana therapy. Rasayana Stands as an answer to solve the problem of healthful longevity including mental development and resistance against disease. That is why; Rasayanatherapy has been included as one of the eight major divisions of Ashtanga Ayurveda. Rasayana Chikitsa or rejuvenation therapy helps to promote and preserve health and longevity in the healthy, and to cure disease in sick. Drugs described under Rasayana, act on Agni, Dhatu and Srotas level and help in formation of prashasta dhatus maintaining a perfect equilibrium of all the Doshas and Dhatus.

Amalaki (Sinhalese name, Nelli) (*Embllica officinalis*), Guduchi (Sinhalese name, Rasakida) (*Tinospora cordifolia*) and Haritaki (Sinhalese name, Aralu) (*Terminalia chebula*) are the best of plants for the Rasayana described by Charaka and Sushruta where Bala i.e Ojus is involved. Guduchi, Amalaki, and Haritaki are well known rasayana herbs were selected to evaluate their role in boosting the immunity.²¹In Ayurveda, Ojus is the essential substance of all dhatus and determines the capacity of the individual to combat the disease (Vyadhibala virodhitvam) and the power to resist the virulence of disease (Vyadhi utpadaka pratibandhakatvam) causing factors in future¹. Amalaki² and Guduchi² share common properties. Amalaki is best among Vayasthpaka (anti-ageing) herbs. Amalaki, is fortified with Vit-C which is a natural, abundantly available powerful antioxidant, anti inflammatory and free radical scavenger of the metabolism³. Guduchi include in almost among all Rasayana remedies in Ayurveda. They possess Tridosha hara, Sheeta Virya, Dahaprashamana, Chakshushya, Keshya, Vayasthapaka, Hridhya, Rasayana, Vrishya, Pramehaghna, Yakriduttejak properties. Guduchi a bitter active principle has anti-inflammatory and hepato-protective properties⁴. It acts on liver, the chief site of metabolism of food and

drugs, normalizing the elevated transaminases and repletes the hepatocyte glutathione sod dismutases responsible for scavenging of free radicals⁵.

T. cordifolia, is an herbaceous vine of the family Menispermaceae. It is indigenous to the tropical areas of India, Myanmar and Sri Lanka. The plant is a glabrous climbing shrub found throughout Sri Lanka, typically growing in deciduous and dry forests. The whole plant is used in traditional medicine for various ailments. *T. cordifolia* shows anti-inflammatory, analgesic, hepatoprotective and antipyretic actions. These activities have also been confirmed with animal studies. Ethanolic extract of the stem exhibits protective effect in carbon tetrachloride induced hepatotoxicity. Aqueous extract of stem and root of the plant has been used therapeutically because of immunomodulation property as well as antimalarial and antileprotic activities. The alcoholic extract of the plant is prescribed in Ayurveda and Allopathy as an immune promoter. The active principles of *T. cordifolia*, a traditional Indian medicinal plant were found to possess immune modulatory activities.

T. cordifolia is generally prescribed in general debility, diabetes, fever, jaundice, skin diseases, rheumatism, urinary diseases, dyspepsia, gout, gonorrhoea and leucorrhoea. The plant is used in Ayurvedic, "Rasayanas" to improve the immune system and the body resistance against infections. A decoction of the stems, leaves and roots is used to treat fever, cholera, diabetes, and snake-bites; an infusion of the stem is drunk as a vermifuge and also to treat sore eyes and syphilitic sores. The stem is registered in the Thailand Pharmacopoeia, and commonly use in hospital to treat diabetes. Traditionally an infusion is used to treat fever due to malaria and also in cases of jaundice and for use against intestinal worms. The leaves are given for the cure of gonorrhoea. It is also used externally as a cooling and soothing application in prurigo, eczema and impetigo.

Dried fruits of *E. officinalis* are found both in the wild and cultivated state all over Sri Lanka. *E. officinalis* fruits are very rich in Vitamin C. Studies indicate that it does not lose its Vitamin C content on storage. Vitamin C is highly important in the body mainly due its ability to remove free radicals which are harmful to body mainly due to its ability to remove free radicals. Emblica being a natural source of vitamin C serves great purpose. *E. officinalis* is effective in the treatment of Amlapitta (Gastritis) and in dyspepsia. The fruit exhibit hypolipidaemic and antiatherosclerotic effects in

experimental studies. The fruit extract has antimutagenic activity on certain directly acting mutagens in some strains of *Salmonella typhimurium*.

In *Ayurveda*, *Haritaki* (*Terminalia Chebula*) is praised as the best salutary drug which can be used in almost all stages and ages of human life. *T. chebula* (family-Combretaceae) is native to southern Asia. In traditional medicine, mostly the peel of the fruit is used. Researchers have isolated a number of glycosides from *Haritaki*, including Chebulic acid, Ellagic acid, Chebulinic acid, Gallic acid, Ethyl gallate, and Tannic acid²⁰.

Haritaki is one of the most versatile plants having a wide spectrum of pharmacological and medicinal activities. It shows rejuvenative, laxative (unripe), astringent (ripe), anthelmintic, expectorant, tonic, carminative, and appetite stimulant actions. It is used in people who have leprosy (including skin disorders), anaemia, narcosis, piles, chronic or intermittent fever, heart disease, diarrhoea, anorexia, cough and excessive secretion of mucus, and a range of other complaints and symptoms¹⁹.

These three plant combination widely used in Sri Lankan traditional medicine as form of decoction or herbal tea for various disease conditions. The difficulty of the administration as decoction is the bitter taste. Therefore our research aim was to develop a user friendly dosage forms viz. tablets form using this combination and standardization of this product for human consumption.

The main objective of the research was to develop a solid dosage form (Tablet) using the crude powder of *Embllica officinalis* (Gaertn.) *Tinospora cordifolia* (Thunb., Miers) and (*Terminalia chebula* Retz.) by direct compression method and standardized the product.

Specific objectives was,

1. Drug development and standardization
2. Developing a user friendly patent drug with market feasibility report.

In direct compression method of tablet production, dry ingredients are thoroughly mixed and then compressed into tablets. Direct compression is both efficient and economical, well suited to the production of high quality tablets, which exhibit

hardness, low friability and excellent dissolution rates. As an added benefit, direct compression can improve the physical and chemical stability of tablets as compared to wet granulation.

The presented novel tablet thought to be of better quality and will give answers to many of health problems related to human beings.