



FORMULATION AND EVALUATION OF DISPERSIBLE POLYHERBAL IMMUNITY BOOSTER GREEN TEA TABLETS

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ABSTRACT

The concept of polyherbalism is highlighted in Ayurvedic literature, where multiple herbs within a particular ratio are utilized in the treatment of diseases. *Green tea* has many health benefits including antioxidant, immunomodulatory, antitumor properties, antihypertensive, antihyperlipidemic, antimicrobial and also prevents several diseases like Parkinson's disease, Alzheimer's disease and cancer. Therefore, people are taking green tea daily and is one of the most widely consumed beverages in the world. Green tea is used in the form of powder, tea bags, capsules, tablets and liquid extracts. *Ginger* and *Tulsi* are also reported for several medicinal properties and as an immunomodulatory agents. Tablets are the popular solid dosage form because of easy to manufacture, handle, transport, administration and also cost effective. Therefore, in present study, we have prepared dispersible polyherbal immunity booster tablets with *Green tea* extract, *Tulsi* leaves extract and *Ginger* extract which increases therapeutic efficacy and enhance health benefits along with improving patient compliance and patient convenience.

Keywords: Green tea extract, Ginger extract, Tulsi leaves extract, Green tea tablets, Polyherbal Dispersible Tablets, Immunity Booster

INTRODUCTION

Ayurveda is one of the ancient medicinal systems of India which is known as ‘mother of all healing’ [1, 3]. The word Ayurveda is a combination of two Sanskrit words “Ayur” means “life” and “Veda” means “the science of life” [1, 3]. Ayurveda is originated in India, thousand years ago and considered to be the knowledge for living the long healthy life and preventing unnecessary suffering [1, 3]. In Ayurveda root cause of the disease is eliminated by using natural elements and at the same time created a healthy life-style to prevent the recurrence of imbalance [1, 5]. WHO estimated that world’s eighty percent of inhabitants for their health care are still rely on traditional medicines [1, 5, 6]. The various parts of plants like seed, root, bark, stem, gum, leaves, flowers, fruit, etc are used in the Ayurvedic medicine [1, 3, 5]. Therapeutic effects of herbs are based on active constituents present in it. Therefore, single or multiple herbs are used in the treatment [1].

Concept of polyherbal medicines is highlighted in “Sarangdhar Samhit”, an Ayurvedic literature, to obtain increased therapeutic efficacy. When the active phytochemical constituents of individual plants are insufficient to provide the desirable therapeutic effects, polyherbal formulations are preferred to achieve desirable effects and reduce the toxicity [1, 3, 5].

The polyherbal formulations are combinations of two or more herbs with different

phytoconstituents having similar or different therapeutic potential in a particular ratio and collectively producing desirable effects during the management of human diseases [1, 3, 5, 6].

Green tea:

Green tea is one of the most widely consumed beverages in the world. Green tea, native to China and India, has been consumed and hailed for its health benefits, for centuries globally, but has only recently gained popular in the United States [7]. However, 78% of the Tea consumed worldwide is Black and only about 20% is Green. All type of Tea except herbal Tea is brewed from the dried leaves of the *Comellia sinensis* bush [7, 9]. The level of oxidation of the leaves determines the types of Tea. Green tea is made up from the unoxidized leaves and is one of the less processed types of tea. It is therefore containing the most antioxidants and beneficial polyphenols [14]. Green tea is considered one of the World’s healthiest drinks and contains one of the highest amounts of antioxidant of any tea [4, 7]. Natural chemicals called polyphenols in tea provides its anti-inflammatory and anti-carcinogenic effect. Green tea contains approximately 20-40% polyphenols by weight. Out of which 60-80% are Catechins such as EGCE [7, 8, 19]. It is reported that catechins in green tea has the ability as antioxidant, anticancer, antifungal, and antiviral. EGCG and EGC act as an immunomodulator by influencing the proliferation of lymphocyte T and cytokines

production. Green tea extract enhances lymphoblast to induce the production of lymphocytes, while EGCG stimulates the production of IL-1 α , IL-1 β , monocytes, and lymphocytes [8, 20].

Green tea was used in traditional Chinese and Indian medicine to control bleeding and heal wound, aid digestion, improve heart and mental health and regulate body temperature [4]. Recent studies have shown that green tea can potentially have positive effect on weight loss, liver disorder, type 2 diabetes and cancer prevention. Green tea is also used for the treatment of Alzheimer's disease, Parkinson's disease, Crohn's disease, chronic fatigue syndrome (CFS), dental cavities (caries), kidney stones, and skin damage [7, 9, 14, 19].

Ginger:

Ginger has several medicinal properties like used to treat nausea, as an anti-inflammatory, to reduce vomiting in patients treated with cytotoxic compounds, to promote digestion, to improve blood circulation, to lower blood glucose in the treatment of diabetes, to treat migraine head ache, help to promote salivation, a pain remedy, a warming remedy, also as a cholesterol lowering herb, anti-oxidant, and immunomodulatory. It contains major active components as Gingerol. The powdered Rhizomes contain 3-6% fatty oil 9% protein and 60-70% carbohydrates [10, 12, 21, 22].

Tulsi:

Tulsi herb has been known from as early as the Vedic period. Tulsi extract has numerous

pharmacological activities like hypoglycaemic, immunomodulatory, analgesic, antibacterial, antidepressant and antipyretic. The active constituents of the herb include volatile oil chiefly Eugenol, flavonoids and number of other components present in the fixed oils. Tulsi prepare the body to fight against various foreign elements like allergens, bacteria, viruses etc and acts as an immunity enhancing agent [11-14].

The present study designed to formulate and evaluate a novel polyherbal dispersible immunity booster tablets containing tulsi leaves extract, ginger extract along with green tea extract which were scientifically proven for antioxidant and immunity boosting properties by utilizing the method of direct compression.

MATERIALS AND METHODS:

Green tea extract, Ginger extract, Tulsi leaves extract were prepared at the laboratory and used further. All other chemicals used in the current study to formulate polyherbal immunity booster tablets were analytical grade.

METHOD OF PREPARATION:

Green tea extraction:

The green tea extract was prepared by taking 10 g of green tea powder and brewed in 75% Ethanol at 30⁰C for 10 min in a thermo-stated water bath (Solvent/tea = 60:1v/w) The infusion was then filtered. The filtrate was concentrated by a rotary evaporator under reduced pressure and finally dried by vacuum dryer [19].

Tulsi leaves extraction:

Tulsi leaves (*Ocimum sanctum*) were collected, washed with distilled water, dried in shades and then powdered in a mechanical grinder. Then this powder (50g) was placed in the thimble of Soxhlet apparatus and 500-700ml of ethanol used for extraction procedure. The extraction was continued till clear solvent was seen in the thimble. The extract was concentrated using rotary evaporator and then dried in a digital water bath till a dark green residue was obtained [13].

Ginger extraction:

The 20 gm of fresh ginger was washed by water and grinded. 100 ml of absolute ethanol was added to the flask with the grinded paste of ginger. Extraction was carried out at refluxing at 78.4⁰C for 12 hours with 5 to 6 heat cycles in a heating mental for 1 hour. Then extract was

filtered by Whatman filter paper No. 1 and the filtrate was centrifuged at 5,500 rpm for 10 min at 4°C. The supernatant was subsequently filtered through a 0.2 µm nylon membrane filter and dried by vacuum dryer [23, 24].

PREPARATION OF THE POLYHERBAL TABLETS BY DIRECT COMPRESSION TECHNIQUE: [2, 5]

The polyherbal immunity booster dispersible tablets were prepared by direct compression method. The plant extracts and the excipients are weighted in accordance to the formula shown in **Table 1**. The ingredients are mixed properly and then taken to the tablet press and the tablets were formed by direct compression technique. The prepared polyherbal tablets are depicted in **Figure 1**.

Table 1: Different formulas used in the formulation of dispersible polyherbal immunity booster tablets					
INGREDIENT	F-A	F - B	F - C	F - D	F - E
Green tea extract	250 mg	250 mg	200 mg	200 mg	200 mg
Ginger extract	75 mg				
Tulsi leaves extract	75 mg				
Microcrystalline cellulose	100 mg	-	75 mg	-	150 mg
Sodium starch glycolate	-	100 mg	75 mg	150 mg	-



Figure 1: Polyherbal Immunity Booster Green Tea tablets

EVALUATION OF TABLETS:**Weight variation:**

The weight variations in the tablet formulation studied by taking twenty tablets from each batch and weighed individually. The weight of each tablet was noted. The average weight of the tablets was calculated and then further substituted in the formula [3, 5, 16].

$$\% \text{Weight variation} = \frac{\text{average weight} - \text{individual weight}}{\text{average weight}} \times 100$$

Hardness

The hardness of the tablets was measured using the Monsanto hardness tester and the hardness of the tablets was recorded in kg/cm² unit. The tablet to be tested was placed between the spindle and anvil. The desired pressure needed to hold the tablet in position moved so that the indicator was fixed zero. The pressure was then applied till the tablet broken. The reading was noted, which indicate the pressure which was needed to break the tablet [2, 4, 15].

Friability

Roche friability tester was used for performing the friability studies of the tablets. 20 tablets from each batch were taken and weighed together and recorded as the initial weight of the tablets. Then the tablets were loaded in the apparatus and the apparatus is rotated for 4 min that is 100 rotations (25 rpm). Finally, the tablets were removed and de-dusted. The de-dusted tablets were weighed and recorded as final weight, and friability was calculated by the following formula [4, 16].

$$\text{Percentage of Friability} = \frac{(\text{Initial weight} - \text{final weight})}{\text{Initial weight}} \times 100$$

Dispersion time study:

In vitro dispersion time of polyherbal dispersible tablet was measured by dropping a tablet in a beaker containing 100 ml of water [3].

Accelerated stability testing:

The stability of the formulated polyherbal tablets was carried out for the period of 30 days at 25 °C ± 2 °C/RH 60 ± 5% (room temperature) and 40 °C ± 2 °C/RH 75 ± 5% (accelerated temperature); the evaluation was performed on the 7th, 15th, and 30th days [3, 17].

RESULT AND DISCUSSION:**Characterization of powder:**

The basic characterization of Green tea, Ginger and Tulsi extract powders used for formulation of polyherbal dispersible tablets mentioned in **Table 2**.

Formulation and characterization of tablets

All the dispersible polyherbal tablets were prepared by direct compression technique. After compression, tablets were evaluated for various physical parameters. Among all the formulas, F- E has shown the best results which are reported in the **Table 3 and 4**.

No tablets from F - E have shown manufacturing defects like capping, lamination, and chipping (**Figure 1**). The prepared polyherbal dispersible tablets were non-sticky and looked good quality.

Organoleptic properties of prepared polyherbal dispersible tablets showed the Brownish yellow

colour, round shape with characteristic odour and bitter taste.

The average weight of the tablets was in the range of 498-502 mg. Weight variation obtained was falls within the acceptable weight variation range, i.e., $\pm 5\%$, hence passing the weight variation test. The hardness of prepared tablets was in the range of 2.5 to 3.00 kg/cm², which falls within the limit of not < 3.0 kg/cm².

None of the tablets showed a friability value of more than 0.90% which is less than the ideal limit, i.e., 1%. The dispersion time of polyherbal dispersible tablets was observed by placing a tablet in 100 ml of water in a beaker and it was observed 2.81min (**Table 4**). which falls within the limit i.e. less than 3 min. Stability study showed that the tablets are stable (**Table 5**).

Name of extract	Green tea leaves extract	Ginger extract	Tulsi leaves extract
Colour	Greenish Brown	Yellowish	Greenish Brown
Odour	Characteristic	Characteristic	Characteristic
Taste	Characteristic	Pungent	Bitter
Texture	Free flowing	Amorphous	Amorphous

Colour	Brownish yellow
Odour	Characteristic
Taste	Bitter
Texture	Smooth

Sr. No.	Evaluation Parameters	Result
1.	Weight variation (mg)	498-502
2	Hardness of the tablets (kg/cm ²)	2.5-3.00
3.	Friability test (%)	0.90
4	Dispersion time (min)	2.81

Parameter	Initial	Room Temperature			Accelerated Temperature		
		25°C \pm 2°C/RH 60 \pm 5%			40°C \pm 2°C/RH 75 \pm 5%		
		7 th Day	15 th Day	30 th Day	7 th Day	15 th Day	30 th Day
Hardness of the tablets (kg/cm ²)	2.5	2.5	2.5	2.5	2.62	2.75	
Friability (%)	0.90	0.90	0.90	0.90	0.90	0.72	
Dispersion time (min)	2.81	2.81	2.81	2.81	2.92	2.98	

CONCLUSION:

The present study demonstrated successful formation of the polyherbal immunity booster tablets containing green tea extract, ginger

extract and tulsi leaves extract by direct compression method. All the extracts and ingredients were found to be compatible with each other and passed all the evaluation tests.

These polyherbal tablets were prepared by using different formulas and formula F- E found to be the best formula depending on the results of evaluation tests. These tablets can be carried away to any place and the immunity booster green tea can be enjoy anywhere by just dropping the single tablet into the cup of boiled water.

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