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HERBAL IMMUNOMODULATORS: FORMULATION AND EVALUATION OF A TABLET CONTAINING INDIAN HERBS

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ABSTRACT: The quest for natural immunomodulators has led to the exploration of traditional Indian herbs, renowned for their immune-boosting properties. In this study the goal was to create and assess a polyherbal formulation that contained extracts of all herbs. A polyherbal tablet was formulated using a combination of Giloy (*Tinospora cordifolia*), Amla (*Emblica officinalis* Gaertn), and Tulsi (Ocimum sanctum) in a specific ratio. Giloy (*Tinospora cordifolia*) is a plant that contains antioxidants. It also has anti-inflammatory, antimicrobial, and antidiabetic properties. Tulsi (*Ocimum sanctum*) contains antioxidant, antimicrobial, anti-inflammatory, anti-diabetic, Immunomodulatory, anti-carcenogenic properties. Amla, also known as Indian gooseberry, has many properties, including antioxidant, anti-inflammatory, and hepatoprotective. The tablet's physicochemical properties, such as hardness, friability, and disintegration time, were evaluated. The formulated tablet exhibited satisfactory physicochemical properties. The polyherbal tablet containing Giloy, Amla, and Tulsi demonstrated potent immunomodulatory activity, validating the traditional use of these herbs in Ayurvedic medicine. This formulation offers a promising natural adjunct to conventional immunotherapies, warranting further clinical investigation. Polyherbal formulations have emerged as a promising strategy to modulate immune responses, exhibiting potent immunostimulatory and immunoprotective effects.

INTRODUCTION: Since the ancient times, around 80% of human population in the world relies on ayurveda or herbal for their essential medical requirements. Treatment of many diseases and disorders with phytomedicines is considered and observed as very safe with no or minimal side effects. Many medicinal plants and their preparations are practiced at home as remedies for treating and preventing various diseases and disorders.

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For example, medicinal plants and their crude parts such as Ashwagandha, Guduchi, Licorice and Pippali are used to cure or treat several common ailments. Herbs have been an integral part of society since the beginning of human civilization. They have been used both because of their culinary as well as features of medicinal value. Herbal medicine has provided numerous benefits to the pharmaceutical industry.

The occurrence of coronavirus disease (COVID-19) has been stated as a pandemic by the World Health Organization (WHO) on March 12, 2020 [3]. It is a viral disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) human get infected. COVID-19 induces an inflammatory immune response [2]. Based on the Ayurvedic and scientific literature, the Ministry of

AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy), India issued an advisory where it recommended the use of number of immune-boosting herbal medicinal drugs among that we have chosen most immune-boosting medicinal plants for our study to prepare polyherbal tablet formulation and for self-care which will develop immunity against severe infection caused by COVID-19. The current trends for surviving long and healthy life entirely dependent on the combination of various herbs (polyherbal) in a particular ratio will give a desirable therapeutic effect because the potent phytochemical constituents of individual plants are inadequate to achieve the beneficial effect.

The polyherbal formulation contains two or more herbs with different phytoconstituents possessing similar or dissimilar therapeutic potential have been collectively producing desirable effects during the management of human ailments. The popularity of polyherbal formulation is outstanding because of their wide therapeutic range i.e., effective at a low dose and safe at high dose, though produces fewer side effects whilst misused. The traditional medication systems in which Ayurveda is one of the most favorable systems because of it possess several natural elements to eliminate the critical causes of the disease by restoring the equilibrium and preventing further reoccurrence. WHO estimated that around 80% of the world's populations still trusting in traditional or Ayurvedic medicines for their healthy survival of life. The Indian philosophy behind Ayurveda is to prevent unnecessary suffering of survival when curing the human ailments and also well-known for the significant biodiversity centers through concerning 45,000 herbal plant species out of which about 15,000 medicinal plants have been recorded to curing different human ailments by using single or multiple herbs for the complete elimination of disease.

MATERIALS AND METHODS: *Tinospora cordifolia* or giloy (Menispermaceae), *Emblica officinalis Gaertn, Amla* (Phyllanthaceae) and Ocimum sanctum (OS) Holy Basil or Tulsi (Lamiaceae). The quantity of drugs used in the formulation was considered by their drug tolerance study and effective dose on the basis of toxicity studies report. The equal amount of extract powder, 25 mg has been used in this formulation for preparing polyherbal dispersible tablet as active constituents [14]. Traditional medicine is practiced all over the world. It is now the subject of intense activity of studies on various plant species and their therapeutic tenets. Because of their wide therapeutic range effective at low doses and safe at large doses, but with fewer negative effects when misused polyherbal formulations are quite popular.

The different plant parts seed, root, bark, stem, gum, leaves, flowers, fruit, *etc*. are utilized. The polyherbal tablet which we have made is to reduce cough, cold and soothe sore throat. We chose the majority of these medicinal plants for our study to prepare polyherbal tablet formulation [14]. The ingredients which have been used have effective results which not only cures but also boost up immunity.

We have used Tulsi this on lengthy racemes, the purple blooms are arranged in tight whorls. These are the aroma compounds found in Tulsi essential oil [15, 16]. Giloy contain the phytoconstituents, such as magnoflorine, tinocordioside, 11-hydroxymuskatone, cordifolioside A, N- methyl-2-pyrrolidone, and N-formylannonain, showed cytotoxic and immunomodulating activities. Isolated phytoconstituents enhanced the phagocytic property of macrophages, improving nitric oxide (NO) production by stimulation of splenocytes and the ability to yield reactive oxygen species (ROS) in neutrophil immune cells [6]. Amla Major components include vitamin C (2%), tannins including gallic acid and ellagic acid, embricol and phyllembic acid. Others include two alkaloids, phyllantidine and phyllantine. It also contains pectin and minerals. Asthma, bronchitis, diabetes, hyperacidity, peptic ulcer, eye diseases, inflammation, cardiac disorders, anemia, colic, flatulence, etc.

Chemicals All Herbal extracts were procured as a gift sample from Kisalaya Herbal Limited, Indore Moreover, croscarmellose sodium, microcrystalline cellulose, lactose monohydrate, Talcum powder and magnesium stearate were available at our institute.

Extraction of Plant Material [17]: The collected whole plant materials were cleaned dried under

shade, and coarsely powdered (40 mesh size) by a mechanical grinder. The coarsely powdered materials were macerated with ethanol and water (70:30v/v) for seven days with intermittent stirring and filtered after seven days and concentrated at an appropriate temperature (40 °C) on a rotary evaporator and dried.

Preformulation Studies: Carr's, Hausner ratio, and the angle of repose were used to calculate the formulation's flowability

Angle of Repose: The fixed funnel method was used to determine the angle of repose. The funnel's height was set such that the tip of the funnel barely touched the top of the mound of precisely weighted grains. Onto the surface, the granules were allowed to freely flow through the funnel. The powder cone's diameter was measured, and the angle of repose was computed using the formula below.

$$\text{Tan } \Theta = h/r$$

Loose Bulk Density: A graduated cylinder is used to measure the weight and volume of loose bulk density (LBD), which is calculated using a weighted quantity of granules.

LBD = Weight of powder / Volume of the packing.

Tapped Bulk Density: Tapped bulk density was determined by placing a graduated cylinder containing a known mass of granules in the furnace. The cylinder was allowed to fall under its own weight on a hard surface from a height of 10 cm. After drying, the granules were again screened through sieve no. 18 to remove larger granules and stored in desiccators.

Compressibility Index: The compressibility index of the blends was determined by the carrier's compressibility index.

Compressibility index (%) = (TBD-LBD) x 100/TBD

Development of Polyherbal Tablets [19, 21]: Direct compression was used as the preparation technique for the polyherbal tablets. All of the components for the formulations that are listed in **Table 1** were measured accurately and then blended using a mortar and a pestle. After that, the powder mixture was given a little opportunity to dry, after which it was thoroughly mixed once more and put *via* sieve no. 60. The mixture was compacted using a rotary machine with a circular concave shape and a break line on one side of the upper punch. The pressure used was 7-8 tonnes. Both official standards and unofficial tests were carried out on the tablets that had been compacted. Before the compaction took place, the medication and the polymers were subjected to a number of different assays.

TABLE 1: FORMULATION OF POLYHERBAL TABLET

Ingredients (Herbal extract powder)	HF1 (mg)	HF2 (mg)	HF3 (mg)	HF4 (mg)	HF5 (mg)
Giloy	100	100	100	100	100
Amla	100	100	100	100	100
Tulsi	100	100	100	100	100
Sod. Starch glycolate	10	25	------	-------	12.5
Croscarmellose sod.	------	------	10	25	12.5
Sorbitol	25	25	25	25	25
Microcrystalline cellulose	145	130	145	130	130
Magnesium stearate	10	10	10	10	10
Talc	10	10	10	10	10

Evaluation of Polyherbal Tablets [11, 13, 20-21]: For the evaluation of polyherbal tablets, the post compression parameters mentioned below were used

Thickness: A Vernier caliper was used to measure the thickness of each Tablet, from the given 5 batches each batch were sampled, and the average thickness of all of the tablets was computed.

Uniformity of Weight: Every single tablet that makes up a batch should have the same weight, and any deviation from that weight should fall within the acceptable range. A computerized balance was used to make measurements, and the results were accurate to within 1 mg.

Hardness and Friability: The Pfizer hardness tester and the Electro lab friabilator test apparatus

were used to evaluate each formulation's tablets in order to assess the tablets' levels of hardness and friability, respectively.

Disintegration Time: After inserting all six Tablet, a plastic disc was placed on top of the tablets and the tubes were sealed. The tablets are subjected to pressure as a result of the disc. In a water medium that was kept at 37 degrees Celsius, the test tubes were given the freedom to move up and down at a rate of 29-32 cycles per minute. The disintegration time of the pill was estimated to be the amount of time needed for all tablets to travel via the mesh [8-10].

RESULT AND DISCUSSION: The direct compression method was utilised in the preparation of all six separate polyherbal tablets. All of the different physical mixes of aqueous extract were analysed in order to establish their micromeritic characteristics. According to the results of the angle of repose, Carr's Index, and Hausner ratio, the powder combinations have good flow qualities and good packing ability **Table 2.**

TABLE 2: EVALUATION OF VARIOUS BLENDS

Parameters	HF1	HF2	HF3	HF4	HF5
Angle of repose	24° 18'± 0.12	23° 21'± 0.11	24° 61'± 0.16	25° 59'± 0.24	24° 43'± 0.05
Mean Apparent bulk density (g/cm^3)	0.51±0.32	0.48±0.18	0.47±0.23	0.63±0.28	0.53±0.43
Mean Tapped bulk density (g/cm^3)	0.61±0.48	0.55±0.62	0.58±0.31	0.71±0.56	0.59±0.19
Compressibility Index (%)	16.39	12.72	13.69	18.96	10.16
Hausner's Ratio	1.19± 0.02	1.14± 0.08	1.15± 0.04	1.23±0.07	1.11±0.05

Value shown in tables is mean of three determinations.

TABLE 3: DATA OF ASSESSMENT OF POLYHERBAL TABLETS

Parameters	HF1	HF2	HF3	HF4	HF5
Uniformity of weight (mg)	487.34±0.57	492.52±0.45	508.71±0.83	499.56±0.67	497.27±0.37
Thickness (mm)	4.35±0.17	4.98±0.24	5.12±0.12	4.24±0.68	4.71±0.46
Friability (%)	0.28±0.57	0.33±0.48	0.27±0.92	0.25±0.15	0.41±0.36
Tablet Hardness (Kp)	5.47±0.35	5.62±0.21	5.93±0.49	5.32±0.39	5.69±0.87
Disintegration time (min)	10.24±0.63	11.05±0.35	11.67±0.21	10.87±0.82	11.65±0.64

The physical properties of the Tablet, including its weight, hardness, drug content, and friability, were analysed, and the results were compared with those of other polyherbal tablets for uniformity. It was observed that the thickness of herbal tablet formulations varied between 4.24 and 5.12 millimetres across the board. All of the formulations' tablet weights were found to be within the limits specified by the USP, which ranged from 487 to 508 mg. The levels of hardness and friability of tablets produced by each batch of herbal tablets were within the permissible ranges. The herbal tablets have a poor friability, which suggests that they are compact and difficult. It was discovered that all of the formulations had a disintegration time that fell somewhere between 10.24- and 11.97-minutes **Table 3**. According to the findings of the drug release profile, the formulation achieves its maximal release of 90.8% after eight hours.

CONCLUSION: In Indian literatures the employment of medicinal plants and polyherbal mixtures for treatment of various ailments is recorded. As a stable solid dosage form, the formulated formulation of polyherbal tablets produced on a laboratory scale may be utilized. It is feasible to formulate medicinal plants into reasonably priced tablet forms to improve comsumer acceptance and compliance. The manufactured tablet had an appropriate rate of disintegration to a suitable degree of hardness. The researchers concluded that the selected herbs will have a significant impact as a consequence of them analysis. As was previously mentioned, there have been claims that plant extracts contain steroids, alkaloids, glycosides, and lactones as well as other active chemicals. These active ingredients all play various physiological and immunomodulatory roles, highlighting the plant's wide range of adaptability.

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