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Formulation And Evaluation Of Ayurvedic Tablet For Git Regulation.

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ABSTRACT.

Herbal Medicine, an ancient practice dating back to the earliest civilizations, has beena mainstay in modern healthcare development. The current work concentrates on the preparation of Ayurvedic tablets from different Ayurvedic drugs by the direct compression technique. They have ingredients such as Triphala Churna, Jeera Churna, Liquorice Root Powder, Peppermint Leaves Powder, Black Salt, Sunthee Churna, and Ajwain. The tablets were tested for different pharmaceutical parameters like appearance, hardness, friability, disintegration, and dissolution. Findings showed that the tablets complied with the standards required for pharmaceutical quality. This study proves to be the viability of formulating tablet formulations using Ayurvedic ingredients as possible alternatives to conventional herbal medicine administration.

KEYWORD:

- Triphala Churna,
- Jeera Churna,
- Liquorice Root Powder,
- Peppermint Leaves Powder,
- Black Salt.

INTRODUCTION.

It is believed that the oldest known form of human healing is herbal medicine. Throughout history, all cultures have employed herbs. It served as the foundation for contemporary civilization. A few of the first men examined and relished the diverse range of plants available to them. Food, clothes, housing, and medicine were all made possible by plants. Trial and error and observation of wild animals appear to have taught many people how to employ medicinal plants. Over time, every group of people expanded their knowledge of therapeutic herbs from those that were native to their area.

Among themselves, they developed clear herbal pharmacopoeias and organized the methodical study of herbs. In fact, indigenous peoples' herbal knowledge served as the foundation for a significant portion of the scientific medical pharmacopoeia until the late 20th century. Some of these medications are, of course, entirely herbal in origin. Research indicates that there is at least one active ingredient made from plant material in about 25% of all prescription medications prescribed in the United States. Some are made from crude extracts that are acquired by extracting plant materials in a solvent, while others are chemically synthesized to create chemicals that are structurally same or comparable to natural plant products.

Herbal medications are made from one or more parts of plants and can come in a variety of forms, including extracts, powders, and essential oils. Since ancient times, herbal remedies have been used. The logic behind many of these customs can be explained by the fact that these practices have occasionally been supported by science.

According to WHO estimates, three-quarters of the world's population uses medications made from plants. For the diagnosis, prevention, and treatment of a variety of illnesses, several traditional herbal medicine techniques have been developed. To support the customs, some of these have been validated.

Indigestion can be caused by heartburn, upper abdominal pain, or incorrect food consumption. There are some elderly populations for whom indigestion is a daily problem. Herbal digestive tablets, which contain herbal medications, are used to treat indigestion issues. Due to their huge demand worldwide, herbal medications are a prominent form of traditional medicine.

AIM.

- To develop a tablet formulation using direct compression method for regulating gastrointestinal (GIT) functions.
- To evaluate the quality of the formulated tablets using various pre-compression and post-compression parameters.

OBJECTIVES:

- To formulate tablets containing Triphala Churna (a blend of Emblica officinalis, Terminalia bellerica, and Terminalia chebula), Jeera Churna, Liquorice Root Powder, Peppermint Leaves Powder, Black Salt, Sunthee Churna, and Ajwain Powder.
- To assess the pre-compression parameters of the powder blend, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio.
- To evaluate the post-compression characteristics of the tablets, including weight variation, hardness, friability, disintegration time, thickness, and organoleptic properties (appearance and taste).
- To determine the suitability of the direct compression method for formulating tablets with these Ayurvedic ingredients.

MATERIALS AND METHODS:

Materials:

Triphala Churna, Jeera Churna, Liquorice Root Powder, Peppermint (Mentha Piperita) Leaves Powder, Black Salt, Sunthee Churna and Ajwain were obtained from the Medical Store, local market and Shop. All excipients microcrystalline cellulose (MCC), dibasic calcium phosphate, Peg 4000, MethylParaben taken from College Practical Store House. All ingredients used were of analytical grade.

Preparation of tablets:

The direct compression process was used to create tablets that contained Triphala Churna, Jeera Churna, Liquorice Root Powder, Peppermint (Mentha piperita) Leaves Powder, Black Salt, Sunthee Churna, and Ajwain. Methyl paraben, Peg 4000, Dibasic calcium phosphate, and microcrystalline cellulose (MCC) are additional components. The excipient and API were weighed as indicated in Table 1 and then passed through sieve number 20. After that, all ingredients—aside from the lubricant—were completely combined using a geometric mixing technique for fifteen minutes. Using a single rotatory punching machine, the powder mixture was fully combined with Microcrystalline Cellulose (MCC), Dibasic Calcium Phosphate, Peg 4000, and Methyl Paraben before being compacted into a 650 mg tablet.

Direct compression method:

Since it offers the quickest, most efficient, and least complicated method of producing tablets, direct compression is the most widely used option. When a set of substances can be mixed, this method is typically employed. This works better with APIs that are sensitive to heat and moisture. The direct compression method is used to manufacture tablets of Triphala Churna, Jeera Churna, Liquorice Root Powder, Peppermint (Mentha Piperita) Leaves Powder, Black Salt, Sunthee Churna, and Ajwain, according to the composition.

Methods:

1. Sieving: The active ingredients was passed through the sieve #40. The other ingredients given in the formulation table was passed separately by the same sieve.

2. Dry mixing: All the materials (including the active ingredient) were weighed and taken in a vessel and mixed for 10 minutes.

3. Lubrication: The magnesium stearate was passed through the sieve # 60 and mixed together with the powder mixture in a polybag for 5 minutes to get a uniform blend

4. Compression: Finally, the powder mixture was compressed into tablets using single rotatory punching machine to prepare tablets each weighing 650mg.

5. Packing: The prepared tablets were packed in closed container.

Table 1. FORMULATION AND COMPOSITION OF TABLET:

Sr. No.	Name of Ingredient	Quantity Taken
1.	Triphala Churna	65 mg
2.	Jeera Churna	105 mg
3.	Liquorice Root Powder	130 mg
4.	Peppermint (Mentha Piperita) Leaves Powder	80 mg
5.	Black Salt	30 mg
6.	Sunthee Churna	70 mg
7.	Ajwain Powder	110 mg
8.	Microcrystalline cellulose (MCC)	30 mg
9.	Dibasic calcium phosphate	20 mg
10.	Peg 4000	10 mg
11.	Methyl Paraben	0.1 %

ROLE AND INFORMATION INGREDIENTS.

1. Triphala Churna:

Synonyms : Vara, Phaltrika, Phalatraya.

Biological Source :

Triphala consists of fruits of the plant species Emblica officinalis (Amalaki), Terminalia bellerica (Bibhitaki), and Terminalia chebula (Haritaki).

Family : Emblica officinalis = Euphorbiaceae, Terminalia bellerica = Combretaceae, andTerminalia

Chemical Constituents :

- Emblica officinalis : Vitamin C, Higher amount of polyphenols like gallic acid, ellagicacid, different tannins, minerals, vitamins, amino acids, fixed oils, and flavonoids like rutin and quercetin.
- Terminalia bellerica : Glucoside (bellericanin) , Gallo-tannic acid, resins and a greenish yellow oil [31]. Ellagic acid, gallic acid, lignans (termilignan and thannilignan), 7- hydroxy 3'4' (methylenedioxy) flavone and anolignanB [32]. Tannins, ellagic acid, ethyl gallate, galloyl glucose and chebulagic acid, phyllemblin, β-sitosterol, mannitol, glucose, fructose and rhamnose
- Terminalia chebula : 14 components of hydrolysable tannins (gallic acid, chebulic acid, punicalagin, chebulanin, corilagin, neochebulinic, ellagic acid, chebulegic acid, chebulinic acid

Uses:

- Free radical scavenging, antioxidant, anti- inflammatory, immunomodulating action.
- Appetite stimulation, gastric hyperacidity reduction.
- Analgesic, antibacterial, antimutagenic, wound healing, Hepatoprotective, effects·

2. Jeera Churna:

Synonyms : Safed Jeera, Jeera, Sada jeera, Sadarana jeera, Jire, Pandare jeere, Jeerakam,kammun, Avyaja, Jeearaka, jaran, dirghajirak, ajaji, kanavha, kanajirna, dipya, sitajaji, shuklajaji, dirghak.

Biological source: Seeds of annual herbaceous flowering plant Cuminum cyminum.

Family: Umbelliferae

Chemical Constituents: Cuminin, Apiin, P-cymene, Isoimperatorin, Isoimpinellin, Oxypeucedanin,Apigenin, Diacyl glycerol, Oxalic, Cuminaldihyde, Imperatorin.

Uses:

- Digestive Stimulant Action
- Gastroprotective Effect (Antiulcer)
- Anti-inflammatory.

3. Liquorice Root Powder:

Synonyms: Radix glycyrrhizae, Mulethi, Yashtimadhu, Licorice, Jethi Madh.

Biological Source: It consists of roots of Glycyrrhiza globra.

Family: Leguminosae.

Chemical Constituents:

- Saponin glycosides: Glycyrrhizin and glycyrrhetic acid.
- Flavonoids: Liquiritin, liquiritigenin, isoliquiritin and isoliquiritigenin.
- Coumarin derivatives: Herniarin, umbelliferone.

Uses:

- Hepatoprotective activity.
- Anti- inflammatory
- Anti-ulcerative
- Antimicrobial activity

4. Peppermint Leaves Powder (Mentha Piperita):

Synonyms: M. balsamea Wild.

Biological Source: Seed of annual herbaceous flowering plant Cuminum cyminum.

Family: Umbelliferae.

Chemical Constituents: Cuminin, Diacyl Glycerol, Imperation, Isoimperation, nIsompinellin, Oxypeucedanin, Apigenin, Apiin, Oxalic, Cuminaldihyde, P-cymene.

Uses:

- Antispasmodic
- Carminative
- Astringent

5. Black Salt:

Synonyms: Kala Namak, Lavana sal, Saindhava Lavana, Rock salt, Bay salt, Sorchal Salt.

Biological Source: The raw material for producing kala namak was originally obtained from natural halite from mines in Northern India in certain location of the Himalayas, salt harvested from the north Indian salt lakes of Sambhar or Didwana.

Chemical Constituents: Sodium Chloride and trace impurities of sodium sulfate, sodium bisulfate, sodium sulfide, iron sulfide and hydrogen sulfide, polyhalite

Uses:

- Antacid
- Anti-flatulent
- Anthelmintic
- Carminitive
- Digestive stimulant

6. Sunthee Churna:

Synonyms : Zinziber Soonth, Saunth

Biological source : Rhizomes of Zingiber officinale & dried in the sun.

Family : Zingiberaceae

Chemical Constituents :

1 to 2% volatile oil, 5 to 8% pungent principle, resinous Mass and starch. Volatile oil is responsible for the aromatic smell and consists of zingiberene, 6% sesquiterpenes hydrocarbon zingiberol, a sesquiterpenes alcohol And besaabolene. Ginigirol is a yellow pungent oily liquid and yield gingirone a ketone and aliphatic aldehyde. Shagaol is formed by loss of water form gingerol shagaol and gingirone are less pungent.

Uses:

- Stomachic
- Stimulant

7. Ajwain Powder:

Synonyms: caraway, bishop's weed.

Biological Source: Ajowan is the dried ripe seeds of Trachyspermum ammi.

Family: Apiaceae.

Chemical Constituents:

- Thymol(50-60%)
- γ-terpinene and *p*-cymene
- α- and β-pinenes
- α-thujen, myrcene,
- 1,8-cineole, and Ccarvacrol

Uses:

- Antiseptic
- Treats Colic Pain
- Assimilation of Food
- Treats intestinal

8. Microcrystalline cellulose (MCC):

Use as Disintegrant.

9. Dibasic calcium phosphate:

Use as Flowing Agent.

10. Peg 4000:

Use as Binder.

11. Methyl paraben:

Use as Preservative.

PRE-COMPRESSIONAL PARAMETERS STUDY

1. Angle of repose:
It is the wide angle that can be formed between the flat surface and the powder bulk's freestanding surface. The fixed funnel method was used to determine it.A predetermined quantity of powdered medication was added to the funnel while the funnel's opening was sealed up with a cap or thumb. Once the powder was evenly distributed across the funnel's surface, the angle of repose was measured.

$$\textbf{Angle of repose } (\theta) = \tan^{-1} h / r$$

2. Bulk Density:
It is the ratio of bulk mass of tablet formulation ingredient (herbal API) to the bulk volume. It is Denoted by homogenecity of the powder. Bulk density (ρb) = M / Vb. Where, M is the mass of the sample, Vb is bulk volume.

3. Tapped density:
It is the proportion of the powder's weight to the smallest volume that the measuring cylinder can hold. A graduated cylinder with a known weight of medication or a combination of the herbal API (active pharmaceutical ingredient) is placed on a mechanical tapper device to calculate the taped density.

4. Carr's index:

Based on the apparent bulk density of drug and the tapped density of the drug, the percentage compressibility of the powder mixture was determined by the following formula:

Carr's index = Tapped density - Bulk density × 100 / Tapped Density

5. Hausner's ratio:

Hausner's ratio is an indirect index of ease of measuring of powder flow. Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25).

Hausner's ratio = Tapped density / Bulk density

Pre- Compressional Studies of powder blend:

In development of new different dosage form per formulation study is the prior step in the ideal drug.

PRE-COMPRESSION PARAMETERS OF POWDER BLEND

Parameters	Result
Moisture content (%)	4.31
Angle of repose (θ)	26.565 ^{0}
Bulk density (g/ml)	0.8
Tapped density (g/ml)	1.14
Carr's index (%)	42.5
Hausner's ratio	1.425

- **POST-COMPRESSION STUDY:**

1. General appearance:
For tablets to be accepted by consumers, their overall elegance, visual identity, and general appeal are crucial. The tablets were examined for color consistency, pinholes, depressions, cracks, and chipped surfaces.

2. Uniformity of thickness and diameter
The tablets' diameter and thickness were measured using a Venire caliper. In every instance, the mean value of five determinations was noted.

3. Weight Variation test:

Twenty tablets were weighed individually and all together.Average weight was calculated from the total weight of the tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should between the permissible limits. The percent deviation was calculated using the following formula:

Percentage deviation = [(Individual weight – Average weight)/ Average weight]

4. Hardness test:

The force required to shatter a tablet in a certain plane is typically used to determine hardness. The chewing difficulty index can be derived from tablet hardness. The official Pfizer hardness tester was used to evaluate the hardness strength of six manufactured tablets that were chosen at random. Consequently, the average of the six conclusions was calculated. The characteristics were expressed in kilograms per centimetre.

5. Friability test:
The weight loss of a tablet in its container or package as a result of small particles being removed from its surface is known as friability. to guarantee that tablets are capable of withstanding shocks during handling, processing, shipping, and transportation. The allowed limit for friability is 1.0%. The friability of the tablets was assessed using the Roche friabilator. Five tablets were weighed all at once and put in the friabilator's chamber. The tablets in the friabilator were subjected to rolling, which caused them to fall freely inside the chamber. The speed at which it rotated was 25 rpm. Following 100 rotations (4 minutes), the pills were removed from the friabilator, and the total number of intact tablets was once more weighed. The percentage of tablets that were friable was determined by the equation.

The percent friability was determined using the following formula:

F = (1-W)/ W0 * 100

Where, W0 = weight of the tablet fefore test W= Weight of the tablets after test

6. Dissolution test:

The analytical methodology used to evaluate dissolution followed United States Pharmacopeia (2007) specifications, which describe the general methodology for capsule and tablet dissolution tests. Tests were carried out on a Vankel VK 7000 Total Solution Dissolution device using USP apparatus 2 (paddle), HCL. 0.1 M pH 1.2 medium, dissolution vessel volume of 900ml, 37.5 ± 0.5 ºC temperature, stirring speed of 75rpm, and sampling aliquots of 3ml withdrawn at 0, 5, 10, and 30 minutes.

- **Weight Variation:**

Standard IP/BP: Tablets should have a weight variation not exceeding ±5% of the average Weight.

Project Result: The weight variation for the prepared tablets ranged from +/-0.5% to +/-0.6%, which meets the stringent requirements of IP/BP standards.

- **Friability test:**

Standard IP/BP: Tablets should have a friability of not more than 1%.

Project Result: The friability of the tablets, calculated as a percentage, was found to be significantly below the maximum allowable limit of 1%, indicating minimal loss of weight and integrity during handling.

- **Disintegration Time:**

Standard IP/BP: Tablets should disintegrate completely within a specified time frame under standard test conditions.

Project Result: The disintegration time for the tablets was observed to be within the acceptable limit of 15 minutes, indicating prompt disintegration for drug release.

- **Appearance and Taste:**

Project Result: The tablets maintained a round, flat, plain shape on both sides, with a consistent thickness of 3 mm, meeting the standard requirements for shape and size.

Overall, the project results demonstrate compliance with standard pharmacopoeial requirements (IP/BP) for tablet quality attributes such as weight variation, hardness, friability, disintegration time, appearance, taste, shape, and thickness. These findings suggest that the formulated tablets possess suitable characteristics for pharmaceutical use, aligning with established quality standards.

RESULTS AND DISCUSSION:

The evolution of contemporary healthcare has been greatly aided by the use of herbal medicine, which dates back to ancient cultures. The direct compression method of creating Ayurvedic tablets with different Ayurvedic medications is the main topic of this study. Triphala Churna, Jeera Churna, Liquorice Root Powder, Peppermint Leaves Powder, Black Salt, Sunthee Churna, and Ajwain are among the substances included in these tablets. A number of pharmaceutical criteria, including appearance, hardness, friability, disintegration, and dissolution, were tested on the tablets. The tablets satisfied the necessary standards for pharmaceutical quality, according to the results. The viability of developing tablet formulations using Ayurvedic constituents is demonstrated by this study, providing viable substitutes for the conventional delivery of herbal medicines.

TABLE 1. Organoleptic Evaluation.

Sr.No	Parameter	Batch Code F1
1	Colour & Appearance	Brownish
2	Odour	Characteristic
3	Taste	Sour & Astringent
4	Shape	Oval flat plain both sides

TABLE 2. Evaluation test.

Sr.No	Parameter	Batch Code F1
1	Weight Variation(%)	+/-0.5%
2	Hardness (kg/cm2)	4.06
3	Friability (%)	0.384
4	Disintegration Time (min)	13 minutes 48 sec
5	Thickness (mm)	3

CONCLUSION:

Physicians recommend Triphala Churna, Jeera Churna, Liquorice Root Powder, Peppermint Leaves Powder, Black Salt, Sunthee Churna, and Ajwain as essential and highly effective Ayurvedic drugs for the regulation of the gastrointestinal tract. Lastly, the study showed that these drug powders can be appropriately tableted into tablets. The majority of the assessed parameters yielded excellent results from the generated tablets. The majority of the assessed parameters yielded excellent results from the generated tablets. The current study suggests that in order to satisfy customer preferences and requests as well as industrial applications, comparable data for various herbal medications or ayurvedic formulations must be generated. Consequently, it is determined that the created tablets might be a more effective substitute for the traditional applications of the plants. Moreover, this work may enlighten the field of herbal technology in future.

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