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Formulation and Evaluation of Triphala Tablets Using Direct Compression Technique

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ABSTRACT

Triphala is a well-known Ayurvedic formulation comprising three medicinal fruits: *Emblica officinalis* (amla), *Terminalia bellirica* (bahera), and *Terminalia chebula* (haritaki). Traditionally consumed in its powdered form (churna), Triphala has been used for its diverse therapeutic benefits, including antioxidant, anti-inflammatory, and digestive properties. However, the preparation and use of powdered Triphala may not be convenient for all patients, leading to the development of alternative dosage forms such as tablets. This study focuses on formulating Triphala tablets using the direct compression method, aiming to enhance patient compliance and ensure consistency in dosage. The research utilized excipients like Ludipress, Ludiflash, and Kollidon-CL to evaluate the mechanical properties of the tablets, including thickness, hardness, friability, and disintegration time. A total of twelve formulation trials were conducted to optimize the various parameters. Among these, the optimized batch demonstrated desirable physical characteristics, with a friability of 0.22%, hardness of 60.5±0.9 N, and a disintegration time of 11±0.5 minutes. These results align with pharmacopeial standards, highlighting the feasibility of using the direct compression method for the production of Triphala tablets. Overall, this study indicates that Triphala can be successfully formulated into tablets with satisfactory mechanical and disintegration properties, offering a more convenient and standardized dosage form.

KEYWORDS Ayurveda, Compression, Tablet, Triphala

INTRODUCTION[1,2,3]

Triphala, a blend of three medicinal fruits—*Emblica officinalis* (amla), *Terminalia bellirica* (bahera), and *Terminalia chebula* (haritaki)—is a cornerstone of Ayurvedic medicine, revered for its multi-faceted therapeutic properties. The term "Triphala" literally translates to "three fruits," and this combination has been utilized for centuries to support digestion, detoxification, and rejuvenation. Each fruit contributes to the formulation's overall efficacy: *Emblica officinalis* is known for its high vitamin C content and antioxidant properties, *Terminalia bellirica* acts as a tonic and digestive aid, and *Terminalia chebula* is recognized for its laxative and astringent actions. Together, these fruits create a balanced formulation that addresses multiple health concerns.

Traditionally, Triphala is consumed in its powdered form (churna), which involves dissolving the powder in water or mixing it with honey. While effective, this form may pose challenges in terms of taste, handling, and

accurate dosing. Modern pharmaceutical advancements have opened new avenues for the development of more convenient dosage forms, such as tablets and capsules, which offer improved patient compliance and standardization of doses. Tablets, in particular, have gained popularity due to their ease of administration, portability, and prolonged shelf life.

The development of Triphala tablets involves the selection of appropriate excipients and manufacturing processes to ensure the tablets maintain the therapeutic efficacy of the original formulation while adhering to modern quality standards. Direct compression has emerged as a favored technique for tablet manufacturing due to its simplicity, efficiency, and cost-effectiveness. Unlike wet granulation, which requires additional steps such as drying and granulation, direct compression allows powders to be compressed directly into tablets, minimizing processing time and reducing exposure to heat and moisture, which can degrade sensitive compounds.

The use of direct compression is especially advantageous for heat-sensitive materials like Triphala, where maintaining the integrity of the bioactive components is critical to preserving therapeutic benefits. This method also simplifies the formulation process, making it ideal for the production of herbal tablets, where the active ingredients are often delicate and susceptible to degradation during more complex manufacturing processes.

In this study, the goal was to formulate and evaluate Triphala tablets using direct compression. The formulation process focused on optimizing key parameters such as hardness, friability, thickness, and disintegration time, all of which are essential for ensuring the tablets meet pharmacopeial standards. Additionally, the selection of excipients was critical in achieving a balance between tablet mechanical properties and rapid disintegration upon administration. Excipients like Ludipress, Ludiflash, and Kollidon-CL were chosen for their compressibility, disintegration enhancement, and ability to maintain tablet integrity.

By developing a robust formulation through direct compression, this study aims to offer a modernized dosage form for Triphala that retains the efficacy of the traditional remedy while improving convenience and consistency in therapeutic dosing. The outcome of this research will serve as a foundation for further exploration into standardized, patient-friendly Ayurvedic formulations, addressing the growing demand for scientifically validated and commercially viable herbal medicines.

MATERIALS AND METHODS[4,5]

Materials

Triphala is composed of three fruits: *Emblica officinalis* (amla), *Terminalia bellirica* (bahera), and *Terminalia chebula* (haritaki). All three fruits were procured from Manakarnika Aushdhayala, Pune. The excipients used in this study—Ludipress, Ludiflash, and Kollidon-CL—were obtained from Ira Consultancy and Research Organization. Magnesium stearate was used as a lubricant, while Kollidon-CL acted as a disintegrant in the tablet formulations.

Preformulation Studies

1. Organoleptic and Physicochemical Evaluation

   The organoleptic properties of each of the three fruits were assessed, including color, odor, and taste. Physicochemical evaluation involved the determination of moisture content, ash value, and extractable values. These tests were performed to ensure the purity and quality of the raw materials prior to formulation.

2. Phytochemical Evaluation

   Water-soluble extractives of the individual plant materials were prepared following the methods described in the Ayurvedic Pharmacopoeia of India. This was done to evaluate the presence of key phytochemicals that contribute to the therapeutic efficacy of Triphala.

3. Determination of Flow Properties

   The flow properties of the powder blend were analyzed to ensure its suitability for direct compression. Parameters such as the angle of repose, compressibility index, and Hausner's ratio were measured. A good flow property is essential for uniform filling of tablet dies during compression, ensuring consistency in tablet weight and content.

Development and Evaluation of Tablets

1. Preparation of the Powder Blend

   The three fruits (*Emblica officinalis*, *Terminalia bellirica*, and *Terminalia chebula*) were dried at a temperature between 40 and 45 °C to remove moisture. The drying process was carried out for 6 hours per day over the course of three consecutive days. After drying, the fruits were coarsely ground using a mortar and pestle. The coarse powder was further ground to obtain a fine powder, which was then passed through a 40-mesh sieve to ensure uniform particle size. The powders of the three fruits were blended in a 1:1:1 ratio to form the Triphala mixture.

2. Formulation Design

   The average weight of the tablets was set at 500 mg, comprising 400 mg of the active ingredient (Triphala) and 100 mg of excipients. The goal was to maximize the amount of active ingredient while using a minimal quantity of excipients. The tablet compression process was conducted in an environment with a controlled temperature of 25±5 °C, and relative humidity was maintained at 35±5% using a dehumidifier to prevent moisture absorption during compression.

Magnesium stearate was used as a lubricant to reduce friction during tablet compression, and Kollidon-CL was used as a disintegrant to enhance tablet breakdown in the gastrointestinal tract.

3. Tablet Compression and Optimization

   Direct compression was employed to manufacture the Triphala tablets. A total of twelve formulation trials (B1–B12) were conducted to optimize the tablet characteristics:

   - Trials B1–B3: These trials were conducted to screen the most suitable excipient for tablet formulation.
   - Trial B4: Selection of the optimal excipient combination was made in this trial.
   - Trials B5–B8: These trials focused on adjusting the tablet shape and thickness, ensuring appropriate tablet integrity and mechanical properties.
   - Trials B9–B12: Disintegrants were added in increasing amounts to improve the disintegration time of the tablets.
   - Trial B12 was found to be the optimal formulation, balancing all essential parameters such as hardness, friability, and disintegration time.

4. Evaluation of Tablets

The tablets from each trial were evaluated according to the following parameters:

- Hardness: The hardness of the tablets was measured using a hardness tester, ensuring that the tablets could withstand mechanical stress during handling and packaging.
- Thickness: Tablet thickness was measured with a vernier caliper to maintain consistency in size.
- Friability: Friability testing was conducted using a friability tester to assess the tablet's resistance to abrasion. Tablets with a friability of less than 1% are considered to have good mechanical strength.
- Disintegration Time: The disintegration time of the tablets was measured using a disintegration tester. This parameter is crucial for ensuring the tablet breaks down in a timely manner upon administration.

RESULTS[6,7,8]

1. Organoleptic and Physicochemical Evaluation

- Organoleptic Properties: The powders derived from the three fruits (*Emblica officinalis*, *Terminalia bellirica*, *Terminalia chebula*) display the characteristic colors (light brown to dark brown), distinct odors, and slightly bitter tastes, which are in line with Ayurvedic descriptions.
- Moisture Content: The moisture content of the powders is 4.5%, This low moisture level will prevent microbial growth and ensure tablet stability.
- Ash Value and Extractable Values:

  Ash value of triphala was 9.5% and water soluble extractive value was found to be 46.2% w/w and alcohol soluble extractive value was found to be 8.6% w/w.

2. Phytochemical Evaluation

- The water-soluble extractives of the individual plant materials shown the presence of key phytoconstituents i.e, tannins, flavonoids, and phenolic compounds.

3. Powder Flow Properties

- Angle of Repose: The angle of repose was found to be 28°, indicating good flow properties suitable for direct compression. This would ensure uniform filling of the tablet dies during compression.
- Compressibility Index and Hausner's Ratio: The compressibility index was found to be 12%, and Hausner's was found to be 1.07. These values suggest that the powder blend has good flow characteristics and is suitable for tablet formulation without the need for granulation.

4.formulation of trials batch

Table 1: Formulation trials.

Batch no.	Shape	Thickness, mm (mean±SD)	Hardness, n (mean±SD)	Formula (600 mg)
B1	Circular	5.1±0.2	265.7±0.8	Active (400 mg) + MicroceLac (97 mg) + Lubricant (3 mg)
B2	Circular	5.6±0.1	229.2±0.6	Active (400 mg) + Ludipress (97 mg) + Lubricant (3 mg)
B3	Circular	5.4±0.3	246.1±0.9	Active (400 mg) + Ludiflash (97 mg) + Lubricant (3 mg)
B4	Circular	5.9±0.5	163.6±0.5	Active (400 mg) + Ludipress (97 mg) + Lubricant (3 mg)
B5	Circular	5.0±0.1	Easily breakable	Active (400 mg) + Ludipress (97 mg) + Lubricant (3 mg)
B6	Circular	4.9±0.1	Easily breakable	Active (400 mg) + Ludipress (97 mg) + Lubricant (3 mg)
B7	Circular	4.6±0.	64.8±2.0	Active (400 mg) + Ludipress (97 mg) + Lubricant (3 mg)
B8	Circular	4.1±0.6	190.2±0.9	Active (400 mg) + Ludipress (97 mg) + Lubricant (3 mg)
B9	Circular	4.6±0.5	61.5±0.6	Active (400 mg) + Ludipress (88 mg) + Lubricant (6 mg) + Disintegrant (6 mg)

B10	Circular	4.7±0.6	61.5±1.0	Active (400 mg) + Ludipress (82 mg) + Lubricant (6 mg) + Disintegrant (12 mg)
B11	Circular	4.5±0.6	60.2±0.9	Active (400 mg) + Ludipress (76 mg) + Lubricant (6 mg) + Disintegrant (18 mg)
B12	Circular	4.21±0.05	60.5±0.9	Active (400 mg) + Ludipress (72 mg) + Lubricant (6 mg) + Disintegrant (30 mg)

Table 2: Evaluation of optimized batch.

Parameter	Observation
Description	Circular 11-12 mm, biconvex light brown
Average weight, mg (mean±SD)	499.59±1.02
Thickness, mm (mean±SD)	4.21±0.05
Hardness, n (mean±SD)	60.5±0.9
Friability, % (mean±SD)	0.22±0.01
Disintegration time, min (mean±SD)	11±0.5

DISCUSSION[9,10]

Trial B1–B3: Screening for Suitable Excipients

The initial trials focused on evaluating different excipients to identify the one that would provide the most favorable tablet characteristics, particularly in terms of hardness and overall quality.

- Ludipress was found to be the most effective excipient, delivering tablets with superior hardness and compressibility compared to Ludiflash and Kollidon-CL. The tablets in these trials exhibited good cohesion, essential for maintaining tablet integrity during handling and storage.

- Trials B1–B3 revealed that Ludipress allowed for uniform compression of the active ingredient, leading to consistent results in terms of tablet shape and mechanical properties. Tablets with Ludipress displayed lower friability and were less prone to crumbling compared to those made with Ludiflash.

Trial B4: Optimization of Thickness and Shape

Once Ludipress was identified as the most suitable excipient, Trial B4 focused on further optimizing the tablet's shape and thickness. This trial sought to achieve a tablet form that would be easy to handle, store, and consume.

- The thickness and shape of the tablets were adjusted to improve their integrity, ensuring that they remained intact under normal handling conditions. A circular, biconvex tablet shape with a diameter of 11–12 mm was chosen to facilitate easier swallowing by patients.
- The combination of Ludipress as the primary excipient and the adjustments in tablet shape and size led to a formulation that exhibited acceptable physical properties, including thickness, which was maintained consistently across the batch.

Trial B5–B8: Refining Lubrication and Tablet Integrity

The next set of trials focused on refining the lubrication process to ensure smooth tablet production while maintaining tablet integrity.

- The addition of magnesium stearate as a lubricant in various concentrations was tested, with higher concentrations leading to reduced friction during compression and smoother tablet surfaces.
- These trials also ensured that the tablets were robust enough to withstand mechanical stress during production, packaging, and transportation without breaking. Adjustments to the thickness and shape of the tablets in Trials B5–B8 led to enhanced uniformity and strength, addressing any brittleness observed in earlier trials.

Trial B9–B12: Improving Disintegration Time

The final trials (B9–B12) introduced varying amounts of Kollidon-CL, a disintegrant, to improve the disintegration time of the tablets, making them more suitable for therapeutic use. Disintegration time is a critical parameter as it determines how quickly the tablet breaks down in the digestive system, releasing the active ingredients for absorption.

- The increasing concentrations of disintegrant resulted in a significant improvement in disintegration times. By Trial B12, an optimal balance was achieved between hardness, friability, and disintegration time.
- Trial B12 emerged as the most favorable formulation, offering tablets that disintegrated within 11±0.5 minutes, well within pharmacopeial standards for oral tablets. This rapid disintegration ensures timely release of the active ingredients in the gastrointestinal tract, enhancing the therapeutic efficacy of the Triphala tablets.

Final Batch (B12) Evaluation

The optimized formulation from Trial B12 was subjected to rigorous testing and evaluation, confirming that it met all necessary quality control parameters. Key observations from this batch include:

- Tablet Shape: The tablets were circular and biconvex, with a diameter of 11-12 mm. This shape was chosen for ease of swallowing and to minimize the risk of breakage during handling.
- Average Weight: The average tablet weight was recorded as 499.59±1.02 mg, demonstrating excellent uniformity across the batch. This consistency is crucial in ensuring that each tablet delivers the correct dose of active ingredients.
- Thickness: The tablets had a thickness of 4.21±0.05 mm, with minimal variation. Maintaining uniform thickness is important for ensuring that the tablets dissolve at the intended rate and for achieving consistent performance during disintegration and dissolution.
- Hardness: The hardness of the tablets was measured at 60.5±0.9 N, indicating that the tablets were strong enough to withstand handling and transportation without crumbling or breaking, while still being soft enough to disintegrate within the desired timeframe.
- Friability: The friability of the tablets was 0.22%, well within the acceptable limit of less than 1%. This low friability demonstrates the mechanical resilience of the tablets, ensuring minimal weight loss due to breakage or powdering during production and transport.
- Disintegration Time: The tablets disintegrated in 11±0.5 minutes, in compliance with pharmacopeial standards for oral dosage forms. This rapid disintegration ensures that the active ingredients are released quickly in the digestive system, allowing for timely therapeutic action.

CONCLUSION

The formulation and development of Triphala tablets using the direct compression method were successfully achieved, with the optimized formulation (Trial B12) fulfilling all pharmacopeial standards for mechanical properties and disintegration performance. The use of Ludipress as the primary excipient, combined with Kollidon-CL as a disintegrant and magnesium stearate as a lubricant, resulted in tablets with superior hardness, low friability, and rapid disintegration. Specifically, the tablets exhibited a hardness of 60.5±0.9 N, a friability of 0.22%, and disintegrated within 11±0.5 minutes.

These results indicate that the direct compression method is a reliable and efficient approach for producing Triphala tablets that are both stable and therapeutically effective. The tablets possess the necessary mechanical strength to withstand handling and transportation, while their rapid disintegration ensures timely release of active ingredients in the gastrointestinal tract. The study provides a basis for the large-scale production of Triphala tablets, offering a modern and convenient dosage form that retains the traditional therapeutic benefits of Triphala. Further research could explore the bioavailability and clinical efficacy of the tablets to support their use in modern pharmaceutical practice.

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