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Development and Physicochemical Evaluation of A Herb-Based Calcium Supplement Tablet: Asthiposhak Vati

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Abstract

Calcium is an essential element in various bodily mechanisms. Calcium supplementation becomes necessary when dietary intake falls short, particularly to combat or delay osteoporosis, or in cases of osteomalacia, hypocalcemic rickets, hypoparathyroidism, and hypocalcemia stemming from chronic kidney disease. The primary supplements employed are calcium carbonate and calcium citrate, with carbonate being more cost-effective but reliant on stomach acidity for absorption, while citrate boasts superior bioavailability. Though less common, calcium phosphate, lactate, and gluconate exist as oral alternatives, and intravenous calcium gluconate serves in acute hypocalcemia. Potential downsides of supplementation, especially in excess, encompass gastrointestinal disturbances, heightened risk of kidney stones, and controversially, the possible exacerbation of cardiovascular issues.

This research focuses on the development and physicochemical evaluation of a novel Ayurvedic proprietary calcium supplement tablet formulated with Kukkutand Twak Bhasma, Shigru, Arjun, Ashwagandha, Laksha, Haritaki, Dinka, Yawa, Guduchi, and Babbul Twak in equal proportions. Three batches were prepared and Physicochemical properties were analyzed according to the Ayurvedic Pharmacopoeia of India (API) to ensure quality and compliance with pharmacopeial standards. Results demonstrate that the developed tablets exhibit acceptable physical characteristics and comply with established limits for hardness, disintegration, friability, loss on drying, and ash values, suggesting potential as viable natural calcium supplement. The observations were consistent with minimal batch-to-batch variation, concluding that the Standard Operating Procedure (SOP) for the tablets has been successfully developed through the study.

Keywords: osteoporosis, Calcium supplementation, hypocalcemia, calcium carbonate, calcium citrate, SOP development.

1. INTRODUCTION:

Calcium is an essential mineral vital for bone health, nerve function, muscle contraction, and blood clotting [1]. While dietary intake is preferred, supplementation becomes necessary in cases of

insufficient consumption or specific health conditions such as osteoporosis, osteomalacia, and hypocalcemia [2]. The primary supplements employed are calcium carbonate and calcium citrate, with carbonate being more cost-effective but reliant on stomach acidity for absorption, while citrate boasts superior bioavailability. Though less common, calcium phosphate, lactate, and gluconate exist as oral alternatives, and intravenous calcium gluconate serves in acute hypocalcemia. Potential downsides of supplementation, especially in excess, encompass gastrointestinal disturbances, heightened risk of kidney stones, and controversially, the possible exacerbation of cardiovascular issues[3].

To combat this issue, a calcium supplement from organic source has been developed by using herbs and incinerated eggshells in the form of a tablet

Traditional Ayurvedic medicine offers a rich source of potential calcium supplements derived from natural sources. This study investigates the development and physicochemical characteristics of a novel calcium supplement tablet formulated with a blend of well-known Ayurvedic herbs and other ingredients, each contributing equally to the overall formulation. These ingredients were chosen based on their traditional use in promoting bone health and overall well-being:

1. **Kukkutand Twak Bhasma (incinerated hen eggshell ash):** Eggshell ash, a rich source of calcium carbonate [4].
2. **Shigru (Moringa oleifera Lam.):** Known for its nutrient density, including calcium and vitamins [5].
3. **Arjun (Terminalia arjuna Roxb.):** Traditionally used for cardiovascular health and may have bone-protective effects [6].
4. **Ashwagandha (Withania somnifera L.):** Adaptogenic herb with potential benefits for bone metabolism [7].
5. **Laksha (Laccifer lacca):** Resin with reported benefits for bone fracture healing [8].
6. **Haritaki (Terminalia chebula Retz.):** Part of the Triphala formulation, known for digestive and antioxidant properties, potentially aiding calcium absorption [9].
7. **Dinka (Acacia nilotica Linn.):** Natural gum used as a binding agent in tablet formulations [10].
8. **Yawa (Hordeum vulgare L.):** Barley, a source of minerals and fiber, potentially aiding in digestion [11].
9. **Guduchi (Tinospora cordifolia L.):** Immunomodulatory herb with potential anti-inflammatory effects [12].
10. **Babbul Twak (Acacia nilotica Lam.):** Bark with astringent properties, potentially aiding in tablet integrity [13].

The objective of this study was to formulate the tablet and develop the SOP for it preparation by performing a comprehensive physicochemical evaluation using established API methods to ensure its quality, safety, and suitability as a potential calcium supplement.

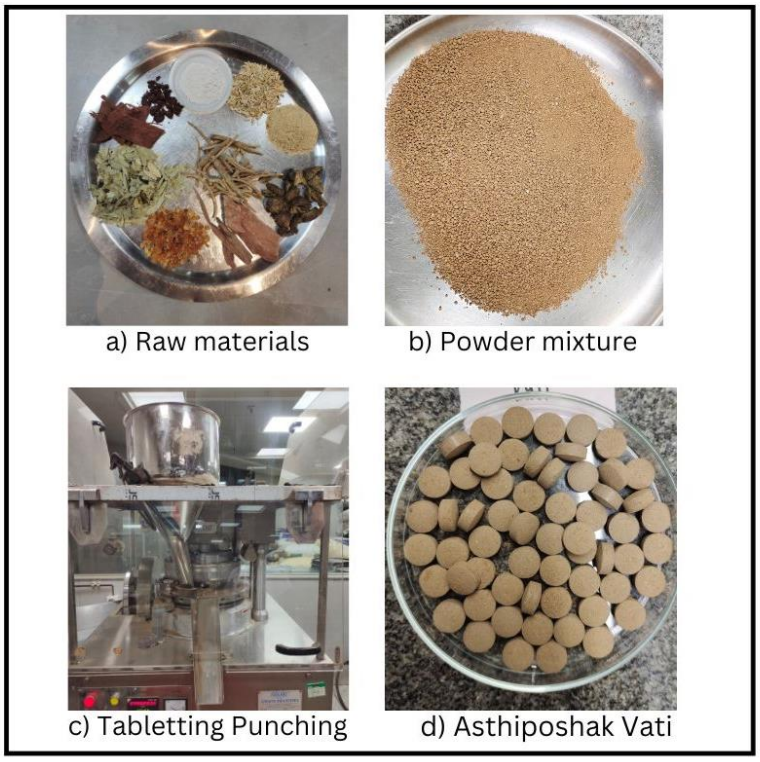
2. Materials and Methods:

2.1 Formulation of AP Tablets:

The ingredients (Kukkutand Twak Bhasma, Shigru, Arjun, Ashwagandha, Laksha, Haritaki, Dinka, Yawa, Guduchi, and Babbul Twak) were procured from certified suppliers and authenticated at authorized Institute according to Ayurvedic Pharmacopoeia of India (API) guidelines. The materials were then finely powdered through sieve mesh size 80 and mixed in equal proportions (100g of each ingredient for a total batch size of 1 kg) within a hexagonal mass mixer to ensure homogeneity.

Kukkutand Twak Bhasma was utilized directly as purchased from authorized pharmacy. 2% w/v solution of Gum Acacia (exudate of Acacia nilotica) was used as a binding agent and mixed with the homogenized powder mixture as required for granulation. Granules were formed using a rapid mixing granulator. Tablets with strength of 500mg each were punched using a single-punch tableting machine. Following the same process, two more batches were prepared. The observations of physicochemical analysis showed very minimal variation. Thus, the Standard Operating Procedure (SOP) for Asthiposhak Vati was developed.

Figure 1: Various stages of preparation of Asthiposhak Vati



2.2 Physicochemical Evaluation:

The raw materials formulated tablets were subjected to the following physicochemical tests, adhering to methods described in the Ayurvedic Pharmacopoeia of India (API) [14]:

- **Organoleptic Parameters:** Visual examination of color, odor, taste, and shape.
- **Thickness and Diameter:** Measured using a calibrated Vernier caliper.
- **Average Weight:** Determined by weighing 20 randomly selected tablets and calculating the average.
- **pH:** A 10% solution of the tablets was prepared, and the pH was measured using a calibrated digital pH meter (API).
- **Hardness Test:** Measured using a Monsanto hardness tester according to API guidelines.
- **Disintegration Test:** Determined using a disintegration apparatus according to API guidelines.
- **Friability Test:** Measured using a Roche friabilator according to API guidelines.
- **Loss on Drying (LOD):** Determined by heating a known weight of the powdered tablets in an oven until constant weight was achieved (API).
- **Total Ash:** Determined by igniting a known weight of the powdered tablets in a muffle furnace until complete ashing and weighing the residue (API).

- **Acid Insoluble Ash:** Determined by mixing the ash with hydrochloric acid and weighing the insoluble residue (API).
- **Water Soluble Extractive:** Determined by dissolving a known weight of the powdered tablets with water and weighing the residue after evaporation (API).
- **Alcohol Soluble Extractive:** Determined by dissolving a known weight of the powdered tablets with alcohol and weighing the residue after evaporation (API).

3. Observations & Results:

The physicochemical analysis of powdered ingredients was as follows (Table 1):

Table 1: Physicochemical Analysis of herbal ingredients.

Parameter	Sigru (Moringa oleifera)	Arjun (Terminalia arjuna)	Ashwagandha (Withania somnifera)	Laksha (Laccifer lacca)	Haritaki (Terminalia chebula)	Dinka (Acacia nilotica)	Yava (Hordeum vulgare)	Guduchi (Tinospora cordifolia)	Babbul Chhal (Acacia nilotica)
Part used	Whole plant	Stem bark	Root	Resin	Fruit	Exudate	Seed	Stem	Bark
Colour	Greenish brown	Brown	Buff white	Brownish red	Slightly yellow	Light brown	Off white (Creamy)	Yellowish brown	Reddish brown
Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Aromatic	Not distinct	Characteristic	Not distinct
Taste	Pungent	Astringent, Bitter	Bitter & acrid	Astringent, Bitter	Astringent, bitter	Bitter	Acrid	Bitter	Astringent
pH (10% Aqueous)	5.41	5.33	5.96	4.88	4.01	5.78	5.64	5.21	5.92
Foreign Matter (%)	0.40%	0.35%	0.10%	0.50%	0.05%	Nil	Nil	0.45%	0.45%
Loss on Drying (%)	7.10%	6.80%	7.20%	7.50%	5.78%	6.50 %	5.99%	6.20%	8.00%
Total Ash	3.50%	4.10%	4.00%	3.75%	4.51%	3.90 %	2.70%	4.25%	4.25%

(%)									
Acid Insoluble Ash (%)	1.10%	1.50%	0.05%	1.80%	2.43%	1.00 %	0.82%	1.20%	1.20%
Water Soluble Extractive (%)	11.80%	14.20%	3.21%	12.50%	68.37%	13.50 %	15.69 %	16.10%	10.00 %
Alcohol Soluble Extractive (%)	14.70%	16.50%	27.22%	18.75%	59.27%	19.30 %	7.66%	20.40%	17.00 %

The procured market sample of Kukkutanda Twak Bhasma was observed to be grayish white in color, tasteless, soft and fine to touch, odourless. The Loss on drying (LOD) observed was 1.29%, pH was 10, acid insoluble ash was 0.37%, Water soluble extractive was 7.38%, alscohol soluble extractive was 1.445%

The results of the physicochemical evaluation of the prepared batches of Asthiposhak Vati are summarized in Table 1.

Table 1: Physicochemical Evaluation of Ayurvedic Calcium Supplement Tablets

Parameter	**Batch-wise Observations**			**Mean Result**	**Limit**	**Compliance**
	Batch A	**Batch B**	**Batch C**			
Description	Light brown, Characteristic odor, Bitter taste, Round	Light brown, Characteristic odor, Bitter taste, Round	Light brown, Characteristic odor, Bitter taste, Round	Light brown, Characteristic odor, Bitter taste, Round	NA	NA
Thickness	0.81	0.83	0.82	0.82 mm	NA	NA
Diameter	0.57 mm	0.56 mm	0.57 mm	0.57 mm	NA	NA
Average Weight	530 mg ± 5%	532 mg ± 5%	529 mg ± 5%	531mg ± 5%	Complies API	Complies
pH (10% Solution)	8.24	8.28	8.26	8.26	NA	NA

Hardness Test (in kg/cm ²)	2.7	2.7	2.8	2.7 kg/cm ²	NMT 10 Kg/cm² (API)	Complies
Disintegration Test	5 min : 45 sec	5 min : 35 sec	5 min : 58 sec	5 min : 47 sec	NMT 15 Min. (API)	Complies
Friability Test	0.30%	0.40%	0.33%	0.33%	NMT 1% (API)	Complies
Loss on Drying	4.96%	4.88%	4.90%	4.93%	NMT 5% (API)	Complies
Total Ash	13.55%	13. 83%	13.68%	13.69%	NA	NA
Acid Insoluble Ash	1.96%	1.88%	1.89%	1.93%	NA	NA
Water Soluble Extractive	16.68%	16.54%	16.58%	16.64%	NA	NA
Alcohol Soluble Extractive	3.80%	3.86%	3.80%	3.82%	NA	NA

4. Discussion:

The physicochemical analysis revealed that the formulated Ayurvedic calcium supplement tablets meet the required standards for pharmaceutical quality as per the Ayurvedic Pharmacopoeia of India. The description matches the expected characteristics of the herbal ingredients. The tablet thickness and diameter were consistent. The average weight complied with API standards. The pH of the solution indicates that the tablets are slightly alkaline. The hardness test results are within the acceptable range, ensuring the tablets can withstand handling without breaking. The disintegration test results are well within the pharmacopeial limits, indicating that the tablets will dissolve within a reasonable time frame in the gastrointestinal tract for optimal absorption. The friability test results indicate good mechanical strength and resistance to abrasion. The loss on drying indicates acceptable moisture content, which is crucial for stability. The total ash, acid-insoluble ash, water-soluble extractive, and alcohol-soluble extractive values provide valuable information for future batch-to-batch consistency and quality control.
The pharmacological properties and actions of the contents coupled with the findings of the physicochemical analysis suggest that AP tablets have great potential as a pharmacological calcium supplement.

5. Conclusion:

The developed Ayurvedic herb-based calcium supplement tablets, formulated with ingredients in equal proportions and using a well-defined granulation and tableting process, exhibit satisfactory physicochemical properties as per API standards, indicating their potential as a viable natural calcium supplement. Further studies are warranted to evaluate their in vitro dissolution characteristics, in vivo bioavailability, safety, and efficacy in human subjects. This research provides a foundation for further investigation into the therapeutic potential of this novel Ayurvedic formulation for calcium supplementation

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