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Formulation & Evaluation of herbal tablets for kidney stone

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Abstract: -

The present study focuses on the formulation and evaluation of a herbal tablet intended for the prevention and management of kidney stones, incorporating natural extracts of Citrus aurantium (sour orange fruit), Moringa oleifera, and blueberry (Vaccinium spp.). These botanicals were selected based on their traditionally reported antioxidant, anti-inflammatory, and diuretic properties, which are beneficial in managing nephrolithiasis. Standardized extracts were prepared and subjected to phytochemical screening to confirm the presence of bioactive compounds such as flavonoids, phenolics, and alkaloids. Tablets were formulated using direct compression techniques and evaluated for key pharmaceutical parameters including hardness, friability, disintegration time, weight variation, and drug content uniformity. In vitro anti-urolithiatic activity was assessed through calcium oxalate crystallization inhibition studies. Results demonstrated that the formulated tablets met standard quality control specifications and exhibited significant inhibition of calcium oxalate crystal formation, indicating potential efficacy in the prevention and management of kidney stones. The study supports the development of a safe, effective, and natural alternative for nephrolithiasis treatment.

Keywords: Herbal formulation, Kidney stones, Moringa oleifera, Citrus aurantium, Blueberry extract, Anti-urolithiatic activity, Nephrolithiasis, Calcium oxalate.

INTRODUCTION :-

A kidney stone is a piece of solid material that forms in the kidney when minerals in the urine become very concentrated. Small stones often pass through the body with little discomfort, but larger stones can be very painful and even block the urinary tract. Kidney stones are more common in adults but can also occur in children of any age.

Kidney stones (nephrolithiasis) are a prevalent urological disorder characterized by the formation of crystalline mineral deposits in the renal system. Factors such as dehydration, dietary habits, metabolic disorders, and genetic predisposition contribute significantly to the pathophysiology of kidney stone formation. Despite the availability of synthetic drugs and surgical interventions, their associated side effects, recurrence rates, and high costs have led to a growing interest in alternative herbal remedies.

Herbal medicine offers a promising approach for the management and prevention of kidney stones, leveraging the natural therapeutic properties of medicinal plants. Traditionally used for their diuretic, anti-inflammatory, and antioxidant activities, certain herbs have demonstrated potential in dissolving or inhibiting the formation of urinary calculi.

This research focuses on the formulation and evaluation of an herbal tablet composed of three key ingredients: Blueberry (Vaccinium spp.), Moringa oleifera leaves, and Sour Orange (Citrus aurantium) fruit. Blueberries are rich in antioxidants and phenolic compounds that may help reduce oxidative stress, a known contributor to stone formation. Moringa oleifera leaves possess diuretic and anti-inflammatory properties, and have been shown to modulate calcium oxalate levels in preclinical models. Sour orange fruit, traditionally used in various cultures for its detoxifying and digestive benefits, contains bioactive flavonoids and limonoids that may contribute to renal health.

The objective of this study Is to formulate a stable and effective herbal tablet incorporating these three plant materials and to evaluate its physicochemical properties, in vitro disintegration time, and potential antiurolithiatic activity. The research aims to provide a scientifically validated, cost-effective, and natural therapeutic option for individuals suffering from kidney stones.

The most common types include :-

1)Calcium oxalate stones (most prevalent)

2)Uric acid stones

3)Struvite stones (linked to infections)

4)Cystine stones (genetic disorder)

Calcium stones :- To help prevent calcium stones from forming, your Doctor may prescribe a thiazide diuretic or a phosphate-containing Preparation.

Uric acid stones :- Your doctor may prescribe allopurinol (Zyloprim, Aloprim,) to reduce uric acid levels in your blood and urine and a Medicine to keep your urine alkaline. In some cases, allopurinol and an Alkalizing agent may dissolve the uric acid stones.

Struvite stones :- To prevent struvite stones, your doctor may Recommend strategies to keep your urine free of bacteria that cause Infection, including drinking fluids to maintain good urine flow and Frequent voiding. In rare cases long-term use of antibiotics in small or Intermittent doses may help achieve this goal. For instance, your Doctor may recommend an antibiotic before and for a while after Surgery to treat your kidney stones.

Cystine stones :- Along with suggesting a diet lower in salt and Protein, your doctor may recommend that you drink more fluids so that You produce a lot more urine. If that alone doesn't help, your doctor May also prescribe a medication that increases the solubility of cystine In your urine

Risk Factors:

Genetics:

A family history of kidney stones increases the risk.

Diet:

High intake of oxalate-rich foods, sodium, and processed foods can contribute to stone formation.

Dehydration:

Low fluid intake leads to concentrated urine, increasing the risk of crystal formation.

Underlying Medical Conditions:

Certain conditions like diabetes, hypertension, and metabolic syndrome can increase the risk.

Lifestyle:

Smoking, alcohol consumption, and lack of physical activity can also play a role.

Symptoms:

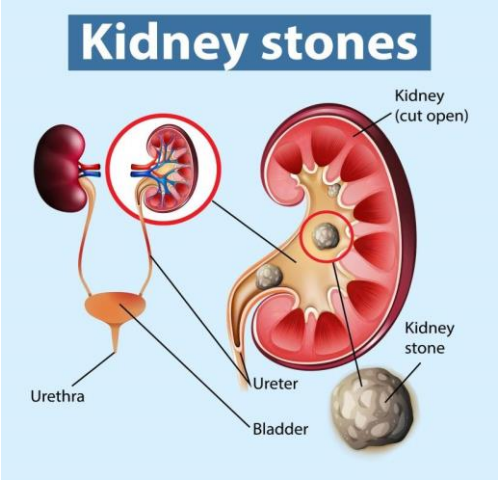
Flank pain: Intense, sudden pain in the side or back that can radiate to the groin.

Nausea and vomiting: Often associated with severe pain.

Blood in the urine: Can indicate damage to the urinary tract.

Frequent urination: The urge to urinate more often, even when the bladder is not full.

Fever and chills: May indicate an infection related to the stone.



Objective :-

1.To formulate and evaluate herbal tablets containing blueberry, Moringa oleifera leaves, and sour orange fruit as a natural remedy for the prevention and management of kidney stones, focusing on their antioxidant, anti-inflammatory, and diuretic properties.

2.Selection and Standardization of Herbal Ingredients

✓To identify and select herbal materials with documented or potential anti-urolithiatic activity.

✓To authenticate and standardize the selected plant materials based on macroscopic, microscopic, and phytochemical characteristics.

3.Formulation Development

✓To formulate herbal tablets using appropriate concentrations of blueberry, Moringa oleifera leaves, and sour orange fruit extract.

✓To incorporate suitable pharmaceutical excipients such as lactose (diluent), starch (binder/disintegrant), magnesium stearate (lubricant), and sodium benzoate (preservative) to achieve optimal tablet characteristics.

4.Pre-formulation Studies

✓To conduct compatibility studies between herbal extracts and excipients using techniques like FTIR or DSC.

✓To determine key pre-compression parameters such as flowability, bulk density, and compressibility of the powder blend.

5.Evaluation of Tablet Properties

✓To evaluate the formulated tablets for standard physical and mechanical parameters including weight variation, hardness, friability, disintegration time, and dissolution rate ✓To determine the uniformity of drug content across different batches.

6.Pharmacological Evaluation

✓To assess the in vitro anti-urolithiatic activity of the formulated tablets using standard experimental models (e.g., calcium oxalate crystal inhibition assay).

✓To compare the performance of the herbal formulation with standard anti-urolithiatic agents, if applicable.

7.Stability Studies (if applicable)

✓To perform accelerated stability studies on the optimized formulation in accordance with ICH guidelines to evaluate its shelf life and integrity over time.

Epidemiology of Kidney Stone.

The lifetime risk of kidney stones is about 10 to 15%.

Kidney stones are more prevalent in hot, arid, or dry climates such as mountains, deserts, or tropical areas.

The highest Incidence of kidney stones is in the summer months, from June through September.

The risk of kidney stone disease correlates with weight and body mass index.

About 65% of those with kidney stones are men

INGREDIENTS USED IN KIDNEY STONE

Active Herbal Ingredients :- 1)MORINGA OLEIFERA :

➤**Kingdom**: Plantae

➤**Order:** Brassicales

➤**Family**: Moringaceae

➤**Genus**: Moringa

➤**Species**: Moringa oleifera

➤**Botanical Name**:Moringa oleifera

➤**Synonyms**: Drumstick tree ,Horseradish tree ,Miracle tree ,Sajna /

Soanjhna (India/Pakistan) ,Malunggay (Philippines) ,Ben oil tree

➤**Medicinal Properties:-**

1.**Highly Nutritious :-** Rich in vitamins (A, C, E), minerals (calcium, Iron), protein, and fiber. Supports overall health.
2.Powerful Antioxidant :- Protects your body from harmful molecules (free radicals) that cause aging and disease.
3.Reduces Inflammation :-Helps relieve swelling, pain, and joint Problems like arthritis.
4.Lowers Blood Sugar :- Can help manage diabetes by reducing blood Sugar levels.
5.Lowers Cholesterol :-Supports heart health by lowering "bad" Cholesterol (LDL).
6 .Fights Infections :- Natural antibacterial and antifungal properties Protect against bacteria and fungi.
7 .Supports Brain Health :- May improve memory, reduce stress, and Protect against brain aging.
8.Immroves Digestion :- Helps with constipation and supports a healthy

Gut

9.Boosts Immunity :- Strengthens your body's defense system to fight Illness.
10.Good for Skin and Hair :- Promotes glowing skin, heals wounds, and Strengthens hair.

2)BLUBERRY :-

➤**Kingdom**: Plantae ➤**Order**: Ericales
➤**Family**: Ericaceae

➤**Genus**: Vaccinium

➤**Species**: There are several, but the most common are:

Vaccinium corymbosum (Highbush Blueberry)

Vaccinium angustifolium (Lowbush Blueberry)

➤**BOTANICAL NAME :-** Vaccinium corymbosum
Vaccinium angustifolium

➤SYNONYMS :-

Cyanococcus (sometimes used for a section of Vaccinium) Other local/common names include:
Bilberry (though it's technically different, often confused)

Wild blueberry (usually V. angustifolium)

Highbush/Lowbush blueberryMedicinal

➤ MEDICINAL PROPERTIES :-

Antioxidant-rich

Kidney protection

Anti-inflammatory

Cardioprotective

Cognitive support

Antidiabetic

Urinary tract health

Vision support

3) SOUR ORANGE FRUITS :-

➤**Kingdom**: Plantae

➤**Order**: Sapindales

➤**Family**: Rutaceae

➤**Genus**: Citrus

➤**Species**: Citrus aurantium

➤**Botanical Name:** Citrus aurantium

➤**Synonyms** : Bitter orange ,Seville orange ,Bigarade orange ,Marmalade

Orange

Khatta orange (in some South Asian regions)

EXCIPIENTS	**PURPOSE**
Lactose	Diluent (add bulk to the tablet)
Starch	Binder
Magnesium stearate	Lubricant (Prevent Sticking during compression)
Sodium starch glycolate	Super disintegrant (Helps tablet break up quickly in the stomach)
Sodium benzoate	Preservative (Extends Shelf life)

➤Medicinal Properties :-

1. Aids Digestive
2. Boosts Appetite
3. Supports Weight Loss
4. Relieves Cough and Cold Symptoms
5. Calms the Nerves
6. Improves Skin Health
7. Anti-inflammatory
8. Antimicrobial

HARMACEUTICAL EXCIPIENT:

COMPOSITION:

Sr.no	INGREDIENTS	FORMULA
1.	Moringa oleifera	2.6g
2.	Bluberry	2.6g
3.	Sour orange fruit	2g
4.	Lactose	0.8g
5.	Starch	1g
6.	Magnesium sterate	0.3g
7.	Sodium benzoate	0.2g
8.	Sodium starch glyconate	0.6g

Method of Extraction: - Extraction of crude drugs by Decoction **method.**
DECOCTION: DECOCTION IS A METHOD OF EXTRACTION BY
BOILING HERBAL OR PLANT MATERIAL (WHICH MAY INCLUDE LEAVES) TO DISSOLVE THE CHEMICALS OF THE MATERIAL.

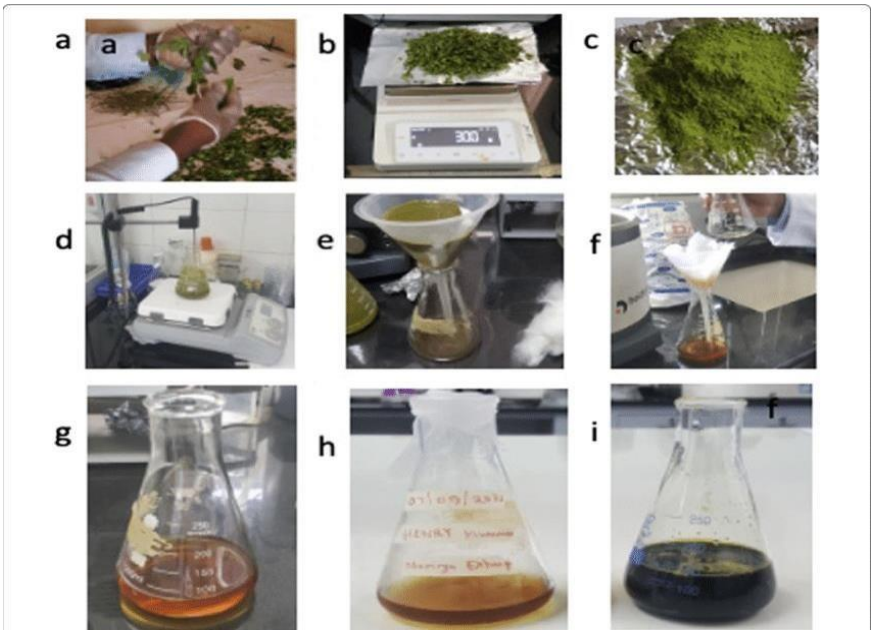
Method of Preparation:

Preparation of Herbal Extracts:

For each herb, prepare a decoction as follows:

***EXTRACTION OF MORINGA OLIFERA**

- Weigh the specified amount of dried herb.
- Add the herb to 26 mL of distilled water
- Heat the mixture to 60°C using a heating mantle.
- Maintain the temperature for 1 hourFilter the extract remove solid residues.



***Repeat this process for Bluberry**

PROCEDURE: -

Step 1: Powder Preparation:

All herbal extracts were dried (if needed) and sieved through mesh #60.

Excipients such as lactose, starch, sodium starch glycolate, and sodium

Benzoate were also sieved to ensure uniform particle size.

Step 2. Weighing Of Ingredients

Accurately weigh the required quantities of Herbal extract

Step 3: Blending of Ingredients

Active herbal powders were accurately weighed and mixed in a fixed ratio (e.g., 1:1:1 or based on optimization).

Excipients such as lactose, starch, sodium starch glycolate, and sodium Benzoate were added and mixed thoroughly.

Step 4: Granulation

Wet granulation was carried out using starch paste (prepared by heating starch In water).

The damp mass was passed through a sieve to form granules.

Step 5: Drying and Sieving

Granules were dried at 40–50°C in a tray dryer.Dried granules were again passed through a 20-mesh sieve to obtain uniform Size.

Step 6: Lubrication

Dried granules were mixed with magnesium stearate (as lubricant) just before Compression. **Step 7: Tablet Compression**
Granules were compressed into tablets using a tablet punching machine.

Each tablet was designed to contain a fixed amount of the herbal blend (e.g., 500 mg). **Step 8 : Packaging**

Tablet were stored in airtight containers and protected from light and moisture for evaluation .

EVALUATION PARAMETERS:

PRE-EVALUATION TEST: -

A. Bulk Density

Definition: The mass of powder divided by the bulk volume it occupies.

Formula:

Method: 10 g of granules were poured into a 100 mL graduated cylinder, and the volume was noted without tapping.
Purpose: Indicates how well granules can pack under gravity.

Principle: It is the mass of powder divided by the bulk volume it occupies.

Significance: Helps in determining the tablet size and weight.

B.Tapped Density

Definition: The mass of powder divided by the volume after tapping the Cylinder until the volume becomes constant.

Formula:

Method: The same sample was tapped 500 times using a tapping machine, And the final volume was recorded.

Purpose: To assess the powder's tendency to settle or pack upon tapping.

Method: Tapping a measuring cylinder filled with powder until no volume Change occurs.

Significance: Useful in calculating flow indices like Carr's Index and Hausner's Ratio.

C.Angle of Repose

Definition: The maximum angle formed between the surface of a powder pile And the horizontal plane.

Formula:

Where:

H = height of the powder cone

R = radius of the base

Method: The granules were allowed to flow through a funnel on a flat surface To form a cone, and the height and radius were measured.

Purpose: To measure the flowability of the granules.

Principle: It is the maximum angle formed between the surface of a pile of Powder and the horizontal plane.
Interpretation: An angle less than 30° usually indicates good flow, essential For uniform die filling during tablet compression.

D .Carr's Index (Compressibility Index)

Definition: Indicates the compressibility of a powder.

Formula: [(Tapped density – Bulk density) / Tapped density] × 100

Interpretation

5–15% = Excellent

16–20% = Good

21–25% = Fair

>25% = Poor

E Hausner's Ratio

Definition: A measure of flowability based on the relationship between Tapped and bulk density.

Formula: Tapped Density / Bulk Density **Interpretation**:
<1.25: Good flow

>1.5: Poor flow

Post Evaluation Test:-

➤**Colour** :-Whitish

➤**Size and shape :- a) Shape:-** Round
b) Size :- small-5-7mm In Diameter; medium-8-10mm in Diameter ;large-11-13mm in diameter

➤**Hardness test :**

Hardness testing is an important quality control step in tablet manufacturing, As it helps ensure that tablets will Remain intact and maintain their desired Dosage when handled and transported.Hardness testing is an Important tool for ensuring the quality and consistency Of tablet products, and helps manufacturers identify And correct any issues That could impact tablet performance or safety. By the Monsanto Hardness Tester the Hardness of the immediate release tablet is 3.5kg/cm2.

➤**Friability Test :**

Determine using Roche friabilater (<1% Weight Loss Acceptable)

Total weight of 6 tablets (Immediate release tablet) =3035mg

After Friability Test total weight of 6 tablets = 3027mg

Percentage of weight loss = 0.20%

➤ **Disintegration test :**

6 Tablets (Immediate release dosage form) to test the disintegration. The Average weight of the tablets is 500mg

Measured in distilled water at 37°C (should be <15 min).

➤**Dissolution Test :**

Performed using USP Apparatus II (paddle method).

Medium: 900 mL phosphate buffer (pH 6.8), 50 rpm, 37°C.

Samples withdrawn at 5, 10, 20, 30, 45, and 60 minutes.

Analyzed via UV-Vis spectrophotometry.

Result :-

Sr.no	Test	Result
1.	Colour	Whitish
2.	Shape	Round
3.	Size	10 mm in diameter
4.	Texture	Smooth surface with a slight roughness
5.	Odure	Slightly pungent
6.	Taste	Slightly astringent

CONCLUSION :-

The formulated herbal tablets containing Vaccinium corymbosum (blueberry), Moringa oleifera leaves, and Citrus aurantium (sour orange) demonstrated Acceptable pharmaceutical properties, including good hardness, low friability, Rapid disintegration, and efficient drug release. The combination of these Natural ingredients offers potential nephroprotective, antioxidant, and Alkalizing effects, making the formulation a promising candidate for kidney Stone prevention and management. Further in vivo and clinical studies are Recommended to validate its therapeutic efficacy and safety.

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