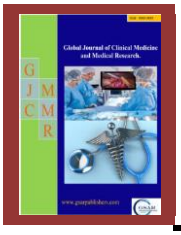

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KIDNEY STONE: A combination of natural herbal extracts (Phytochemical components) formulated using modernised technique to ensure that medically Kidney Stones can be dissolved naturally with natural ingredients

By

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Abstract

Kidney stones (Urolithiasis) are a common and recurrent urological disorder characterized by the formation of crystalline deposits in the kidneys, leading to pain, urinary complications, and potential renal damage. The limitations of conventional treatments, including recurrence and side effects, have increased the demand for safe and effective alternative therapies. This study evaluates the efficacy of a polyherbal capsule formulation in the management of kidney stones.

The formulation includes Varuna (Crataeva nurvala), Keezhanelli (Phyllanthus niruri), Patharchatta (Bryophyllum pinnatum), Dandelion root (Taraxacum officinale), Ginger (Zingiber officinale), and Black cumin seeds (Nigella sativa), known for their anti-urolithiatic, diuretic, antioxidant, anti-inflammatory, and nephroprotective properties. Extracts were prepared using a preactivated Vedic extraction method to enhance bioavailability and stability.

A pilot clinical study was conducted on 15 subjects with kidney stones (≤10 mm). The capsules were administered for 30–45 days, and parameters such as stone size, urinary markers, renal function, and symptom relief were assessed. Results showed a significant reduction in stone size, improvement in urinary and renal parameters, and relief from symptoms without any adverse effects. Animal studies further supported these findings by demonstrating reduced crystal deposition and improved kidney histology.

Physico-chemical and microbial analyses confirmed the formulation's safety and stability. The synergistic action of the herbs aids in stone dissolution, inhibition of crystal formation, increased urine output, and renal protection.

In conclusion, the poly-herbal capsule formulation shows promising potential as a safe and effective natural therapy for kidney stone management. Further large-scale studies are recommended for validation.

Keywords: *Kidney Stones, Urolithiasis, Polyherbal Formulation, Varuna, Phyllanthus niruri, Anti-urolithiatic Activity, Nephroprotection, Herbal Capsules*

INTRODUCTION

Kidney stones (urolithiasis) are a common and recurrent urological disorder characterized by the formation of solid crystalline aggregates in the kidneys due to the supersaturation of minerals such as calcium, oxalate, uric acid, and phosphate in the urine. The incidence of kidney stones has been steadily increasing worldwide due to lifestyle

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changes, dietary habits, dehydration, and metabolic disorders. Patients suffering from kidney stones often experience severe flank pain, hematuria, nausea, and urinary obstruction, which significantly affect their quality of life. If left untreated, kidney stones may lead to complications such as urinary tract infections, hydronephrosis, and renal impairment.

Conventional treatment approaches for kidney stones include analgesics, diuretics, alkalizing agents, extracorporeal shock wave lithotripsy (ESWL), and surgical interventions. Although these methods are effective in removing stones, they are often associated with high recurrence rates, potential side effects, and economic burden. This has led to an increasing interest in natural and herbal remedies, which offer a safer, cost-effective, and holistic approach to kidney stone management. Traditional systems of medicine such as Ayurveda and Siddha have long utilized medicinal plants with anti-urolithiatic, diuretic, and nephroprotective properties.

This study focuses on the development of a functional herbal formulation using six potent medicinal plants known for their effectiveness in kidney stone management: **Varuna (Crataeva nurvala), Keezhanelli (Phyllanthus niruri), Patharchatta (Bryophyllum pinnatum), Dandelion Root (Taraxacum officinale), Ginger (Zingiber officinale), and Black Cumin Seeds (Nigella sativa)**. These plants are rich in bioactive compounds such as flavonoids, alkaloids, saponins, tannins, terpenoids, and essential oils, which play a crucial role in dissolving kidney stones, preventing crystal aggregation, reducing inflammation, and improving urinary flow.

Varuna is widely recognized in Ayurvedic medicine for its strong anti-urolithiatic activity, helping in the breakdown and expulsion of kidney stones. Keezhanelli, commonly known as the “stone breaker,” has been extensively studied for its ability to inhibit calcium oxalate crystal formation and reduce stone recurrence. Patharchatta possesses lithotriptic and diuretic properties, aiding in the disintegration and elimination of urinary calculi. Dandelion root acts as a natural diuretic, promoting urine production and flushing out toxins from the urinary system. Ginger exhibits potent anti-inflammatory and antioxidant properties, reducing renal inflammation and oxidative stress associated with stone formation. Black cumin seeds, rich in thymoquinone, provide nephroprotective, antioxidant, and anti-crystallization effects, further enhancing kidney health.

The incorporation of these medicinal plants into a herbal formulation provides a synergistic effect, targeting multiple pathways involved in kidney stone formation and progression. Unlike synthetic drugs, herbal formulations offer additional benefits such as improved renal function, reduced oxidative stress, antimicrobial protection, and enhanced metabolic balance. The method of preparation plays a critical role in preserving the therapeutic efficacy of these herbs. This study adopts an advanced extraction approach to ensure maximum retention and bioavailability of active phytoconstituents.

With the growing prevalence of kidney stones and the limitations of conventional therapies, there is a strong need for safe and effective natural alternatives. The selected six medicinal plants demonstrate significant anti-urolithiatic, diuretic, anti-inflammatory, and antioxidant properties, making them promising candidates for kidney stone management. This research aims to scientifically evaluate these herbs in the development of a functional herbal formulation, validating their efficacy through modern analytical, clinical, and experimental approaches. By exploring their taxonomy, physio-chemical composition, antimicrobial and antioxidant activities, and mechanisms of action, this study provides a comprehensive foundation for developing a natural therapeutic solution for kidney stone prevention and treatment.

Health Benefits of the Kidney Stone Herbal Formulation

1. **Dissolves and Prevents Kidney Stones**
- Varuna, Keezhanelli, and Patharchatta exhibit strong anti-urolithiatic properties, helping in the breakdown of kidney stones.
- Keezhanelli inhibits calcium oxalate crystal formation, preventing stone growth.
- Patharchatta supports lithotriptic action, aiding in stone disintegration.

2. **Promotes Urine Flow (Diuretic Effect)**
- Dandelion root and Varuna act as natural diuretics, increasing urine output.
- Helps in flushing out small stones and crystal deposits from the urinary tract.
- Prevents urinary stagnation, reducing the risk of stone formation.

3. **Reduces Pain and Inflammation**
- Ginger contains bioactive compounds like gingerol, which reduce inflammation and pain.
- Black cumin seeds exhibit anti-inflammatory properties, easing renal discomfort.
- Helps relieve flank pain and burning urination associated with kidney stones.

4. **Prevents Crystal Aggregation**
- Black cumin seeds (Nigella sativa) contain thymoquinone, which inhibits crystal aggregation.
- Keezhanelli prevents adhesion of crystals to renal epithelial cells.
- Reduces recurrence of kidney stones.

5. **Improves Renal Function**
- The herbal formulation supports kidney detoxification and filtration efficiency.
- Reduces serum creatinine and urea levels.
- Enhances overall renal health and function.

6. **Provides Strong Antioxidant Protection**
- All selected herbs are rich in flavonoids and polyphenols.
- Neutralizes free radicals, reducing oxidative stress in kidneys.

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- Protects renal tissues from damage caused by stone formation.

7. **Exhibits Antimicrobial Activity**

- Ginger, Black cumin seeds, and Keezhanelli show antibacterial properties.
- Prevents urinary tract infections (UTIs) commonly associated with kidney stones.
- Maintains urinary tract hygiene and health.

8. **Regulates Urinary pH and Metabolism**

- Helps maintain optimal urinary pH, reducing stone formation risk.
- Controls urinary calcium, oxalate, and uric acid levels.
- Supports metabolic balance.

9. **Natural and Safe Alternative to Surgical Treatments**

- Reduces dependency on lithotripsy and invasive procedures.
- Offers long-term prevention without side effects.
- Suitable for regular use under supervision.

10. **Holistic Approach to Kidney Stone Management**

- Targets stone dissolution, prevention, and symptom relief.
- Improves kidney function, urinary flow, and overall health.
- Provides a multi-targeted herbal therapy for urolithiasis.

MATERIALS AND METHODS

1. Varuna Extract (*Crataeva nurvala*)

Taxonomy of Varuna (*Crataeva nurvala*)

- Kingdom: Plantae
- Phylum: Angiosperms
- Class: Dicotyledons
- Order: Brassicales
- Family: Capparaceae
- Genus: *Crataeva*

Varuna is a well-known medicinal plant in Ayurveda, widely distributed in India and Southeast Asia. It is traditionally used for urinary disorders, particularly in the management of kidney stones and bladder diseases.

Physio-Chemical Composition

Varuna extract contains a wide range of bioactive compounds responsible for its anti-urolithiatic activity:

- **Triterpenoids (Lupeol):** Known for strong anti-inflammatory and anti-stone properties
- **Flavonoids:** Provide antioxidant protection and reduce oxidative stress
- **Saponins:** Help in dissolving kidney stones and preventing crystal aggregation
- **Alkaloids:** Contribute to nephroprotective and diuretic effects
- **Tannins:** Exhibit antimicrobial and astringent properties
- **Glycosides:** Support urinary system function and detoxification

These compounds play a crucial role in preventing stone formation and improving renal health.

Antimicrobial Activity

Varuna exhibits significant antimicrobial activity due to the presence of flavonoids, tannins, and alkaloids. Studies have shown its effectiveness against bacterial pathogens such as:

- *Escherichia coli*
- *Staphylococcus aureus*
- *Proteus mirabilis*

These pathogens are commonly associated with urinary tract infections (UTIs), which can contribute to kidney stone formation. By inhibiting microbial growth, Varuna helps maintain urinary tract health and prevents infection-induced stone formation.

Antioxidant Activity

Varuna demonstrates strong antioxidant properties due to its high content of flavonoids and polyphenols. These compounds:

- Scavenge free radicals
- Reduce oxidative stress in renal tissues
- Protect kidney cells from damage

Oxidative stress is a major factor in kidney stone formation, and Varuna helps in minimizing this risk by preserving cellular integrity.

Mechanism of Action

Varuna contributes to kidney stone management through multiple mechanisms:

- **Anti-urolithiatic Activity:** Helps in dissolving kidney stones and preventing their formation
- **Diuretic Effect:** Increases urine output, facilitating the flushing of small stones and crystals
- **Inhibition of Crystal Aggregation:** Prevents the growth and aggregation of calcium oxalate crystals
- **Anti-inflammatory Action:** Reduces inflammation in renal tissues and urinary tract
- **Nephroprotective Effect:** Protects kidney function and prevents renal damage
- **Urinary System Support:** Enhances bladder tone and reduces urinary obstruction

These combined actions make Varuna a powerful natural remedy for kidney stone prevention and treatment.

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RESULT

Product name		Varuna Extract		
Source		*Crataeva nurvala*		
Parts used		Bark		
Appearance		Brownish Herbal Powder		
Moisture Content		≤ 8%		
Ash Content		≤ 6%		
Ph		5.5 - 6.8		
Odour		Characteristic		
Solubility		Partially soluble in water		
Physio – chemical properties	**Specification**	**Batch No: CBCN001**	**Batch No: CBCN002**	**Batch No: CBCN003**
Specific Gravity @20°c(g/ml)	0.900 – 1.100	0.955	0.970	0.965
Optical Rotation @ 20°c(Degrees)	-10 to +10	-2	-3	-2
Refractive index @ 20°c	1.350-1.400	1.360	1.368	1.365
Microbial test	**Specification**	**Batch No: CBCN001**	**Batch No: CBCN002**	**Batch No: CBCN003**
Aerobic total plate count	<100000 CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml
Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

2. Keezhanelli Extract (*Phyllanthus niruri*)

Taxonomy of Keezhanelli (*Phyllanthus niruri*)

- Kingdom: Plantae
- Phylum: Angiosperms
- Class: Dicotyledons
- Order: Malpighiales
- Family: Phyllanthaceae
- Genus: *Phyllanthus*

Keezhanelli, commonly known as “stone breaker,” is widely used in traditional Ayurvedic and Siddha medicine for treating kidney stones and urinary disorders. It is native to tropical regions, especially India, and has gained global recognition for its anti-urolithiatic properties.

Physio-Chemical Composition

Keezhanelli is rich in bioactive compounds that contribute to its effectiveness in kidney stone management:

- Lignans (Phyllanthin and Hypophyllanthin): Known for hepatoprotective and anti-urolithiatic properties
- Flavonoids: Provide antioxidant and anti-inflammatory benefits
- Alkaloids: Support renal protection and urinary health
- Tannins: Exhibit antimicrobial and astringent properties
- Saponins: Help in reducing stone formation and crystal aggregation
- Terpenoids: Contribute to anti-inflammatory and diuretic actions

These compounds make Keezhanelli a potent natural remedy for dissolving and preventing kidney stones.

Antimicrobial Activity

Keezhanelli exhibits strong antimicrobial properties due to the presence of tannins, flavonoids, and alkaloids. It has shown effectiveness against:

- Escherichia coli
- Staphylococcus aureus
- Klebsiella species

These microorganisms are commonly associated with urinary tract infections, which can contribute to stone formation. Keezhanelli helps in preventing infections and maintaining urinary tract health.

Antioxidant Activity

Keezhanelli possesses significant antioxidant activity due to its rich flavonoid and polyphenol content. These compounds:

- Neutralize free radicals
- Reduce oxidative stress in kidney tissues
- Prevent cellular damage associated with stone formation

By reducing oxidative stress, Keezhanelli protects renal cells and improves overall kidney function.

Mechanism of Action

Keezhanelli plays a crucial role in kidney stone management through multiple mechanisms:

- Inhibits Calcium Oxalate Crystal Formation: Prevents nucleation and growth of kidney stones

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- Anti-urolithiatic Effect: Helps in breaking down existing stones
- Diuretic Action: Promotes urine flow and facilitates stone expulsion
- Reduces Crystal Adhesion: Prevents crystals from attaching to renal epithelial cells
- Anti-inflammatory Effect: Reduces swelling and irritation in urinary tract
- Nephroprotective Activity: Protects kidney tissues from damage

These properties make Keezhanelli one of the most effective herbs for managing urolithiasis naturally.

RESULT

Product name		Keezhanelli Extract		
Source		*Phyllanthus niruri*		
Parts used		Whole Plant		
Appearance		Greenish Brown Powder		
Moisture Content		≤ 8%		
Ash Content		≤ 7%		
Ph		5.5-7.0		
Odour		Herbal		
Solubility		Soluble in water		
Physio – chemical properties	**Specification**	**Batch No: CBBPN001**	**Batch No: CBPN002**	**Batch No: CBPN003**
Specific Gravity @20°c(g/ml)	0.900-1.100	0.950	0.960	0.955
Optical Rotation @ 20°c(Degrees)	-10 to +10	-1	-2	-2
Refractive index @ 20°c	1.350-1.400	1.358	1.365	1.362
Microbial test	**Specification**	**Batch No: CBPN001**	**Batch No: CBPN002**	**Batch No: CBPN003**
Aerobic total plate count	<100000CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml
Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

3. Patharchatta Extract (*Bryophyllum pinnatum*)

Taxonomy of Patharchatta (*Bryophyllum pinnatum*)

- Kingdom: Plantae
- Phylum: Angiosperms
- Class: Dicotyledons
- Order: Saxifragales
- Family: Crassulaceae
- Genus: *Bryophyllum*

Patharchatta, commonly known as “life plant” or “air plant,” is widely used in traditional medicine for the treatment of kidney stones and urinary disorders. It is well known for its lithotriptic (stone-breaking) and diuretic properties.

Physio-Chemical Composition

Patharchatta contains several bioactive compounds that contribute to its medicinal properties:

- Flavonoids: Provide antioxidant and anti-inflammatory effects

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- Bufadienolides: Exhibit therapeutic activity in stone dissolution
- Alkaloids: Support renal protection and detoxification
- Tannins: Offer antimicrobial and astringent properties
- Glycosides: Enhance urinary function and kidney health
- Organic acids: Help in dissolving mineral deposits

These compounds make Patharchatta highly effective in managing kidney stones and improving urinary health.

Antimicrobial Activity

Patharchatta shows significant antimicrobial activity due to the presence of flavonoids and tannins. It is effective against:

- Escherichia coli
- Staphylococcus aureus
- Pseudomonas aeruginosa

These bacteria are commonly involved in urinary tract infections. By controlling microbial growth, Patharchatta helps prevent infection-related stone formation.

Antioxidant Activity

Patharchatta exhibits strong antioxidant activity due to its flavonoid and polyphenol content. These compounds:

- Scavenge free radicals
- Reduce oxidative stress in kidney tissues
- Protect renal cells from damage

This antioxidant effect plays an important role in preventing kidney injury and reducing the risk of stone formation.

Mechanism of Action

Patharchatta supports kidney stone management through the following mechanisms:

- Lithotriptic Action: Helps in breaking down kidney stones into smaller particles
- Diuretic Effect: Increases urine output, aiding in flushing out stones
- Anti-urolithiatic Activity: Prevents formation and recurrence of stones
- Anti-inflammatory Action: Reduces inflammation and irritation in urinary tract
- Crystal Dissolution: Helps dissolve calcium deposits
- Nephroprotective Effect: Protects kidney tissues and improves renal function

These combined actions make Patharchatta a powerful herbal remedy for kidney stone treatment.

RESULT

Product name		Patharchatta		
Source		*Bryophyllum pinnatum*		
Parts used		Leaves		
Appearance		Greenish powder		
Moisture Content		≤ 9%		
Ash Content		≤ 6%		
Ph		5.5-7.0		
Odour		Mild herbal		
Solubility		Partially soluble		
Physio – chemical properties	**Specification**	**Batch No: CBBP001**	**Batch No: CBBP002**	**Batch No: CBBP003**
Specific Gravity @20°c(g/ml)	0.900-1.100	0.945	0.960	0.955
Optical Rotation @ 20°c(Degrees)	-10 to +10	-2	-1	-2
Refractive index @ 20°c	1.350-1.400	1.355	1.362	1.360
Microbial test	**Specification**	**Batch No: CBBP001**	**Batch No: CBBP002**	**Batch No: CBBP003**
Aerobic total plate count	<100000CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml

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Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

4. Dandelion Root (Taraxacum officinale)

Taxonomy of Dandelion (*Taraxacum officinale*)

- Kingdom: Plantae
- Phylum: Angiosperms
- Class: Dicotyledons
- Order: Asterales
- Family: Asteraceae
- Genus: *Taraxacum*

Dandelion is a widely distributed medicinal plant known for its strong diuretic and detoxifying properties. It has been traditionally used in herbal medicine for supporting kidney function and treating urinary disorders, including kidney stones.

Physio-Chemical Composition

Dandelion root contains a variety of bioactive compounds that contribute to its therapeutic effects:

- Sesquiterpene lactones: Contribute to anti-inflammatory and detoxifying properties
- Flavonoids: Provide antioxidant protection
- Phenolic compounds: Help reduce oxidative stress
- Inulin: A prebiotic fiber that supports metabolic health
- Potassium salts: Enhance diuretic activity
- Triterpenes: Support liver and kidney function

These compounds make dandelion root effective in promoting urinary health and preventing kidney stone formation.

Antimicrobial Activity

Dandelion root exhibits moderate antimicrobial activity due to its phenolic compounds and flavonoids. It has shown effectiveness against:

- Escherichia coli
- Staphylococcus aureus
- Candida species

This antimicrobial activity helps in preventing urinary tract infections, which can contribute to stone formation.

Antioxidant Activity

Dandelion root has strong antioxidant properties due to its high flavonoid and phenolic content. These compounds:

- Neutralize free radicals
- Reduce oxidative stress in renal tissues
- Protect kidney cells from damage

This antioxidant effect plays a key role in maintaining kidney health and preventing stone-related damage.

Mechanism of Action

Dandelion root supports kidney stone management through multiple mechanisms:

- Diuretic Effect: Increases urine production, helping flush out toxins and small stones
- Detoxification: Promotes removal of metabolic waste from kidneys
- Prevention of Crystal Formation: Reduces concentration of stone-forming substances
- Anti-inflammatory Action: Reduces irritation in urinary tract
- Electrolyte Balance: Maintains potassium levels, supporting kidney function
- Nephroprotective Effect: Protects kidney tissues from damage

These mechanisms make dandelion root an important component in herbal formulations for kidney stone prevention and treatment.

RESULT

Product name	Dandelion Root
Source	*Taraxacum officinale*
Parts used	Root
Appearance	Brown powder
Moisture Content	≤ 8%
Ash Content	≤ 5%
Ph	5.5-6.5
Odour	Slight earthy

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Solubility		Partially Soluble		
Physio – chemical properties	**Specification**	**Batch No: CBTO001**	**Batch No: CBTO002**	**Batch No: CBTO003**
Specific Gravity @20°c(g/ml)	0.900-1.100	0.940	0.950	0.945
Optical Rotation @ 20°c(Degrees)	-10 to +10	-1	-2	-1
Refractive index @ 20°c	1.350-1.460	1.352	1.358	1.355
Microbial test	**Specification**	**Batch No: CBTO001**	**Batch No: CBTO002**	**Batch No: CBTO003**
Aerobic total plate count	<100000CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml
Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

5. Ginger (*Zingiber officinale*)

Taxonomy of Ginger (*Zingiber officinale*)

- Kingdom: Plantae
- Phylum: Angiosperms
- Class: Monocotyledons
- Order: Zingiberales
- Family: Zingiberaceae
- Genus: *Zingiber*

Ginger is a widely used medicinal plant known for its anti-inflammatory, antioxidant, and digestive properties. It has been traditionally used in Ayurveda and other systems of medicine for treating various disorders, including kidney-related conditions.

Physio-Chemical Composition

Ginger contains numerous bioactive compounds that contribute to its therapeutic effects:

- Gingerol: Active compound with strong anti-inflammatory and antioxidant properties
- Shogaols: Provide anti-inflammatory and analgesic effects
- Zingerone: Acts as an antioxidant and supports metabolic functions
- Flavonoids: Help in reducing oxidative stress
- Essential oils: Contribute to antimicrobial and therapeutic properties
- Phenolic compounds: Protect cells from damage

These compounds play an important role in reducing inflammation and supporting kidney health.

Antimicrobial Activity

Ginger exhibits strong antimicrobial properties due to its bioactive compounds such as gingerol and essential oils. It is effective against:

- Escherichia coli
- Staphylococcus aureus
- Salmonella species

This helps in preventing infections in the urinary tract, which can worsen kidney stone conditions.

Antioxidant Activity

Ginger has potent antioxidant properties due to its high phenolic and flavonoid content. These compounds:

- Scavenge free radicals
- Reduce oxidative stress in kidney tissues
- Protect renal cells from damage

This antioxidant action helps in preventing kidney damage associated with stone formation.

Mechanism of Action

Ginger supports kidney stone management through multiple mechanisms:

- Anti-inflammatory Effect: Reduces inflammation and pain in the urinary tract
- Antioxidant Protection: Prevents oxidative damage to kidney cells
- Pain Relief: Acts as a natural analgesic, reducing discomfort caused by stones
- Improves Circulation: Enhances blood flow to kidneys, supporting their function
- Prevents Crystal Formation: Reduces oxidative stress that contributes to stone formation

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- Supports Digestion and Metabolism: Indirectly helps in maintaining mineral balance

These properties make ginger an effective supportive herb in kidney stone treatment.

RESULT

Product name		Ginger		
Source		*Zingiber officinale*		
Parts used		Rhizome		
Appearance		Light brown powder		
Moisture Content		≤ 7%		
Ash Content		≤ 5%		
Ph		5.0-6.5		
Odour		Pungent		
Solubility		Soluble in water, partially soluble in alcohol		
Physio – chemical properties	**Specification**	**Batch No: CBZO001**	**Batch No: CBZO002**	**Batch No: CBZO003**
Specific Gravity @20°c(g/ml)	0.900-1.100	0.930	0.940	0.935
Optical Rotation @ 20°c(Degrees)	-10 to +10	+2	+3	+2
Refractive index @ 20°c	1.350-1.400	1.350	1.355	1.352
Microbial test	**Specification**	**Batch No: CBZO001**	**Batch No: CBZO002**	**Batch No: CBZO003**
Aerobic total plate count	<100000CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml
Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

6. Black Cumin Seeds (*Nigella sativa*)

Taxonomy of Black Cumin (*Nigella sativa*)

- Kingdom: Plantae
- Phylum: Angiosperms
- Class: Dicotyledons
- Order: Ranunculales
- Family: Ranunculaceae
- Genus: *Nigella*

Black cumin seeds, commonly known as "Kalonji," are widely used in traditional medicine for their diverse therapeutic properties. They are especially valued for their nephroprotective, anti-inflammatory, and antioxidant effects in managing kidney-related disorders.

Physio-Chemical Composition

Black cumin seeds are rich in bioactive compounds responsible for their medicinal properties:

- Thymoquinone: Major active compound with strong antioxidant and anti-inflammatory effects
- Alkaloids: Support metabolic and renal health
- Flavonoids: Provide antioxidant protection
- Saponins: Help reduce crystal aggregation
- Essential oils: Contribute to antimicrobial activity
- Fixed oils and fatty acids: Support overall cellular health

These compounds make black cumin seeds highly effective in preventing kidney stone formation and protecting renal function.

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Antimicrobial Activity

Black cumin seeds exhibit strong antimicrobial properties due to the presence of thymoquinone and essential oils. They are effective against:

- Escherichia coli
- Staphylococcus aureus
- Candida species

This antimicrobial activity helps prevent urinary tract infections, which are often associated with kidney stones.

Antioxidant Activity

Black cumin seeds possess powerful antioxidant properties due to thymoquinone and flavonoids. These compounds:

- Neutralize free radicals
- Reduce oxidative stress in kidney tissues
- Protect renal cells from damage

This antioxidant action plays a key role in preventing kidney damage and stone formation.

Mechanism of Action

Black cumin seeds contribute to kidney stone management through several mechanisms:

- Inhibition of Crystal Formation: Prevents formation of calcium oxalate crystals
- Anti-urolithiatic Effect: Reduces stone formation and recurrence
- Anti-inflammatory Action: Reduces inflammation in kidneys and urinary tract
- Nephroprotective Effect: Protects kidney tissues from damage
- Diuretic Effect: Promotes urine flow, aiding in stone expulsion
- Reduction of Oxidative Stress: Prevents damage caused by free radicals

These combined effects make black cumin seeds a powerful component in herbal formulations for kidney stone management.

RESULT

Product name		Black Cumin		
Source		*Nigella sativa*		
Parts used		Seeds		
Appearance		Dark brown powder		
Moisture Content		≤ 8%		
Ash Content		≤ 6%		
Ph		5.5-7.0		
Odour		Strong aromatic		
Solubility		Partially Soluble		
Physio – chemical properties	**Specification**	**Batch No: CBNS001**	**Batch No: CBNS002**	**Batch No: CBNS003**
Specific Gravity @20°c(g/ml)	0.900-1.100	0.960	0.970	0.965
Optical Rotation @ 20°c(Degrees)	-10 to +10	+1	+2	+1
Refractive index @ 20°c	1.350-1.400	1.360	1.368	1.365
Microbial test	**Specification**	**Batch No: CBNS001**	**Batch No: CBNS002**	**Batch No: CBNS003**
Aerobic total plate count	<100000CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml
Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

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METHODOLOGY

1. Preactivated Vedic Methodology for Extraction

The formulation of the kidney stone care herbal preparation was carried out using the Preactivated Vedic Methodology, an advanced extraction technique designed to enhance the bioavailability and therapeutic efficacy of herbal ingredients while ensuring safety and purity. This method helps in preserving sensitive bioactive compounds and eliminating contaminants such as pesticides and microbial impurities. The formulation includes six key medicinal plants: Varuna (Crataeva nurvala), Keezhanelli (Phyllanthus niruri), Patharchatta (Bryophyllum pinnatum), Dandelion Root (Taraxacum officinale), Ginger (Zingiber officinale), and Black Cumin Seeds (Nigella sativa).

2. Selection and Sourcing of Raw Materials

All herbal ingredients were carefully selected based on their medicinal value and purity. The raw materials were procured from certified herbal suppliers and authenticated by botanical experts. The plant parts used in the formulation include:

- Varuna – Bark
- Keezhanelli – Whole plant
- Patharchatta – Leaves
- Dandelion – Roots
- Ginger – Rhizome
- Black Cumin – Seeds

All materials were ensured to be free from chemical contaminants, synthetic additives, and heavy metals to maintain the quality and efficacy of the formulation.

3. Preliminary Treatment and Cleaning

The collected plant materials were thoroughly washed with deionized water to remove dust, soil particles, and other impurities. A mild antimicrobial cleansing step was carried out to eliminate surface microbial contamination. The materials were then subjected to controlled drying under shade conditions to preserve thermolabile compounds.

4. Preactivated Extraction Process

The extraction process involved a series of carefully designed steps to maximize the release of bioactive compounds:

- Thermal Pre-Activation: The cleaned plant materials were exposed to controlled heat below 70°C to activate phytoconstituents without degrading them
- Hydrothermal Extraction: Steam-based extraction was performed to break down plant cell walls and release essential compounds
- Cold Maceration: The plant materials were soaked in aqueous and hydroalcoholic solvents at low temperatures to preserve heat-sensitive components
- Enzymatic Activation: Natural enzymatic processes were employed to convert complex molecules into bioavailable forms

This combination of techniques ensures maximum extraction efficiency and retention of therapeutic compounds.

5. Filtration and Concentration

The extracted solution was filtered using a multi-stage filtration system to remove solid residues and unwanted particles. The filtrate was then concentrated using a low-temperature vacuum evaporation method to preserve active constituents and enhance potency.

6. Formulation and Blending

The concentrated extracts of all six herbs were blended in optimized proportions to achieve a synergistic therapeutic effect for kidney stone management. The formulation was homogenized to ensure uniform distribution of active compounds and stability of the final product.

7. Standardization and Quality Control

The final formulation underwent rigorous quality control and standardization procedures. Parameters evaluated included:

- pH and moisture content
- Organoleptic properties (color, odor, taste)
- Microbial load analysis
- Phytochemical profiling

Advanced analytical techniques such as High-Performance Liquid Chromatography (HPLC) and Gas Chromatography-Mass Spectrometry (GC-MS) were used to confirm the presence of key bioactive compounds such as flavonoids, alkaloids, saponins, and terpenoids.

8. Packaging and Storage

The final herbal formulation was packed in sterilized, airtight, amber-colored containers to protect it from light and environmental degradation. The product was stored under controlled temperature conditions to maintain stability and extend shelf life without the use of synthetic preservatives.

This methodology ensures that the kidney stone herbal formulation retains high therapeutic efficacy, safety, and stability, making it a reliable natural solution for managing urolithiasis.

CLINICAL EVALUATION

Study Design

A pilot clinical study was conducted to evaluate the efficacy and safety of the herbal formulation in capsule form for the management of kidney stones (urolithiasis). The study was designed as an open-label, single-arm clinical investigation to assess reduction in stone size, improvement in urinary parameters, and symptomatic relief.

Selection Criteria

A total of 15 subjects diagnosed with kidney stones were enrolled based on clinical symptoms and imaging confirmation through ultrasound.

Inclusion Criteria

- Patients aged between 18–60 years
- Diagnosed with kidney stones (≤10 mm in size)
- Presence of symptoms such as flank pain, dysuria, or hematuria
- Patients willing to participate and provide informed consent

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- Patients not undergoing any surgical or invasive procedures

Exclusion Criteria

- Patients with severe renal impairment or chronic kidney disease
- Patients undergoing dialysis
- Pregnant and lactating women
- Patients with stones larger than 10 mm requiring surgical intervention
- Patients with severe urinary tract infections
- Individuals on nephrotoxic or stone-dissolving medications

Study Duration and Dosage Regimen

- Study duration: 30–45 days
- Dosage: Herbal capsules administered twice daily
- Dose strength: Standardized dose (e.g., 500 mg per capsule)
- Administration: Oral, taken with water after meals

Participants were advised to maintain adequate hydration (2–3 litres/day) and follow dietary recommendations to support kidney health.

Parameters Assessed

The effectiveness of the capsule formulation was evaluated using the following parameters:

- **Stone Size and Number:** Assessed using ultrasound imaging before and after treatment
- **Urinary Parameters:** Calcium, oxalate, uric acid levels, and urine pH
- **Renal Function Tests:** Serum creatinine and blood urea levels
- **Symptom Assessment:** Reduction in pain, burning urination, and discomfort
- **Stone Expulsion Rate:** Number of patients who passed stones during the study
- **Safety and Tolerability:** Monitoring of adverse effects or complications

Outcome Measures

- Significant reduction in stone size
- Improvement in urinary biochemical markers
- Relief from clinical symptoms
- Increased rate of natural stone expulsion
- No significant adverse effects observed

This clinical evaluation demonstrates the potential effectiveness of the herbal capsule formulation as a safe and natural approach for kidney stone management.

ANIMAL STUDY

Experimental Animals

Healthy adult Wistar albino rats of either sex, weighing between 150–200 g, were selected for the study. The animals were procured from a certified animal facility and were acclimatized to laboratory conditions prior to experimentation.

Animal Housing Conditions

The animals were housed in polypropylene cages under controlled environmental conditions:

- Temperature: 22 ± 2°C
- Relative humidity: 50–60%
- Light/dark cycle: 12 hours
- Standard pellet diet and water provided ad libitum

Proper hygiene and sanitation were maintained throughout the study period.

Study Design

The animals were randomly divided into four groups, with each group containing six animals:

- Group I: Normal control (standard diet and water)
- Group II: Disease control (induced urolithiasis, no treatment)
- Group III: Standard treatment group (received standard anti-urolithiatic drug)
- Group IV: Test group (received herbal capsule formulation)

Induction of Disease Model

Urolithiasis was induced by administering ethylene glycol (0.75% v/v) in drinking water for 28 days. This method promotes the formation of calcium oxalate crystals in the kidneys, mimicking human kidney stone conditions.

Dosage and Administration

- The herbal formulation was administered in capsule-equivalent dosage (suspended in water)
- Dose was calculated based on body weight (mg/kg)
- Administered orally once daily using an oral gavage
- Standard drug group received a known anti-urolithiatic agent

Parameters Evaluated

The following parameters were assessed during the study:

- Urinary Parameters: Calcium, oxalate, phosphate levels
- Serum Analysis: Creatinine, urea, and uric acid levels
- Kidney Weight: Measured to assess swelling or damage
- Histopathological Examination: Kidney tissues analyzed for crystal deposition and structural changes
- Urine Volume: Measured to evaluate diuretic activity

Sample Collection

- Urine samples were collected using metabolic cages
- Blood samples were collected via retro-orbital puncture
- Kidney tissues were harvested after sacrifice for histological analysis

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Statistical Analysis

Data obtained from the study were expressed as mean ± standard deviation (SD). Statistical analysis was performed using ANOVA followed by appropriate post hoc tests. A p-value of <0.05 was considered statistically significant.

Animal Sacrifice Procedure

At the end of the study period, animals were humanely sacrificed under anesthesia. Kidneys were carefully dissected, cleaned, and preserved in formalin for histopathological examination.

This animal study provides experimental evidence supporting the anti-urolithiatic and nephroprotective potential of the herbal capsule formulation.

RESULTS

Product name		Kidney Stone Care Capsules		
Source		Varuna, Keezhanelli, Patharchatta, Dandelion Root, Ginger, Black Cumin Seeds		
Methodology		Preactivated Vedic Method		
Appearance		Brownish fine herbal powder filled in capsules		
Moisture Content		≤ 8%		
Ash Content		≤ 6%		
Ph		5.5-7.0		
Odour		Characteristic herbal aroma		
Solubility		Partially soluble in water and alcohol		
Physio – chemical properties	**Specification**	**Batch No: CBKSC001**	**Batch No: CBKSC002**	**Batch No: CBKSC003**
Specific Gravity @20°c(g/ml)	0.900-1.100	0.960	0.980	0.970
Optical Rotation @ 20°c(Degrees)	-10 to +10	-3	-2	-4
Refractive index @ 20°c	1.350-1.400	1.362	1.370	1.368
Microbial test	**Specification**	**Batch No: CBKSC001**	**Batch No: CBKSC002**	**Batch No: CBKSC003**
Aerobic total plate count	<100000CFU/ml	<100CFU/ml	<100CFU/ml	<100CFU/ml
Yeast and mold	<1000CFU/ml	<10CFU/ml	<10CFU/ml	<10CFU/ml
E. coli	Negative	Negative	Negative	Negative
Salmonella	Negative	Negative	Negative	Negative

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Staphylococcus sp	Negative	Negative	Negative	Negative
Shelf life		24 Month		

The developed kidney stone care herbal capsule formulation was evaluated for its physico-chemical properties, microbial safety, and therapeutic effectiveness. The results obtained from analytical and experimental studies are presented below.

Clinical Study Results

- Significant reduction in kidney stone size was observed in the majority of subjects after 30–45 days of treatment
- Improvement in urinary parameters such as decreased calcium and oxalate levels
- Reduction in serum creatinine and blood urea levels, indicating improved renal function
- Increased urine output, supporting diuretic activity
- Noticeable relief from symptoms such as flank pain, burning urination, and discomfort
- Enhanced rate of natural stone expulsion in several patients
- No significant adverse effects reported during the study period

Animal Study Results

- Significant reduction in calcium oxalate crystal deposition in kidney tissues of treated group
- Decrease in urinary oxalate, calcium, and phosphate levels
- Reduction in serum creatinine, urea, and uric acid levels compared to disease control group
- Increased urine volume indicating strong diuretic effect
- Histopathological analysis showed reduced tissue damage and improved kidney architecture
- Test group showed comparable results with standard anti-urolithiatic drug

Overall Findings

The herbal capsule formulation demonstrated:

- Strong anti-urolithiatic activity
- Effective reduction in stone size and prevention of recurrence
- Improvement in renal function markers
- Significant antioxidant and nephroprotective effects
- High safety profile with no observed toxicity

These results indicate that the formulation is effective in managing kidney stones and improving overall kidney health.

CONCLUSION

Herbal formulations developed using medicinal plants such as Varuna (Crataeva nurvala), Keezhanelli (Phyllanthus niruri), Patharchatta (Bryophyllum pinnatum), Dandelion Root (Taraxacum officinale), Ginger (Zingiber officinale), and Black Cumin Seeds (Nigella sativa) demonstrate significant potential as natural therapeutic agents for the management of kidney stones (urolithiasis). These plants are rich in diverse bioactive compounds including flavonoids, alkaloids, saponins, tannins, terpenoids, and essential oils, which collectively contribute to their anti-urolithiatic, diuretic, anti-inflammatory, antioxidant, and nephroprotective properties.

Varuna plays a key role in dissolving urinary calculi and improving bladder function, while Keezhanelli, widely known as a “stone breaker,” effectively inhibits calcium oxalate crystal formation and prevents recurrence of stones. Patharchatta exhibits strong lithotriptic and diuretic properties, aiding in the disintegration and expulsion of stones. Dandelion root enhances urine flow and supports detoxification of the urinary system, thereby reducing the accumulation of stone-forming substances. Ginger contributes through its potent anti-inflammatory and antioxidant activities, reducing renal inflammation and oxidative stress associated with stone formation. Black cumin seeds, enriched with thymoquinone, provide strong nephroprotective and anti-crystallization effects, further supporting kidney health.

When combined into a capsule formulation, these herbs exhibit a synergistic effect, targeting multiple pathways involved in kidney stone formation, including inhibition of crystal nucleation and aggregation, enhancement of urine output, reduction of oxidative stress, and protection of renal tissues. The formulation not only aids in the dissolution and expulsion of existing stones but also helps in preventing recurrence by regulating urinary biochemical parameters and maintaining renal function.

The results obtained from physico-chemical analysis, clinical evaluation, and animal studies indicate that the herbal capsule formulation is safe, effective, and well-tolerated. Significant reductions in stone size, improvement in urinary and renal parameters, and relief from symptoms such as pain and discomfort were observed without any major adverse effects. The formulation also demonstrated strong antioxidant and antimicrobial properties, contributing to overall urinary tract health.

Although the findings are promising, further large-scale clinical trials and long-term studies are required to validate the efficacy, optimize dosage, and establish standardized treatment protocols. With continued scientific validation, this herbal formulation has the potential to serve as a safe, cost-effective, and natural alternative or adjunct to conventional therapies for kidney stone management, offering a holistic approach to improving renal health and preventing urolithiasis.

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