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FORMULATION AND EVALUATION OF POLYMER MODIFIED PUNARNAVA HERBAL TABLETS FOR KIDNEY STONE AND ANTI-AGING EFFECT

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ABSTRACT

Kidney stone disease (nephrolithiasis) remains a major global health problem, affecting millions and characterized by high recurrence rates and limited efficacy of conventional therapies. The increasing shift toward natural and safe alternatives has renewed interest in Ayurvedic herbs with proven nephroprotective and anti-aging potential. This review focuses on the formulation and evaluation of polymer-modified herbal tablets incorporating *Punarnava* (*Boerhavia diffusa*), *Tulsi* (*Ocimum sanctum*), and *Ashwagandha* (*Withania somnifera*). Each herb offers unique therapeutic properties: *Punarnava* acts as a potent diuretic and anti-inflammatory agent promoting renal detoxification; Tulsi provides antioxidant and antiurolithic effects; while *Ashwagandha* exhibits adaptogenic and anti-stress benefits contributing to cellular rejuvenation. The use of modified rice starch as a natural polymer matrix ensures sustained release and improved bioavailability of active phytoconstituents, while excipients like gum acacia and ispaghula husk enhance tablet stability and disintegration. This integration of traditional herbal knowledge with modern pharmaceutical technology presents a standardized, patient-compliant formulation for effective kidney stone management and age-related oxidative stress reduction. The review concludes that polymer-modified herbal tablets represent a

promising, safe, and economical alternative for nephrolithiasis prevention and therapy, warranting further pharmacological and clinical validation.

INTRODUCTION

Kidney stone disease, clinically termed nephrolithiasis or urolithiasis, has emerged as one of the most pressing global health concerns of the 21st century, affecting millions of individuals worldwide and exerting a substantial burden on healthcare systems.[1] The prevalence of kidney stones has shown a dramatic upward trajectory across the globe, with statistics revealing a rise from 8.7% in 2007–2008 to 10.1% in 2015–2016 in the United States, while countries in South Asia have witnessed an even more alarming increase, climbing from less than 40 per 100,000 inhabitants in the 1960s to 930 per 100,000 in India within a span of three decades.[1][2] This progressive surge encompasses all demographic groups irrespective of sex, race, or age, with the lifetime risk reaching as high as 10–15% in developed nations and escalating to 20–25% in the Middle East.[3] These crystalline mineral deposits, composed primarily of calcium oxalate and other stone-forming minerals, inflict unbearable, shooting pain and pose serious complications including urinary tract infections, haematuria, and chronic kidney damage, fundamentally compromising patients' quality of life.[4][5] While conventional pharmaceutical and surgical interventions remain the mainstay of clinical practice, their inherent limitations including high treatment costs, significant side effects, poor tolerability, and alarmingly high recurrence rates have catalysed a paradigm shift toward herbal and traditional medicine systems as promising complementary and alternative therapeutic modalities. For millennia, medicinal plants have been revered in traditional medicine systems such as Ayurveda for their multifaceted therapeutic properties, particularly their diuretic, anti-inflammatory, and antioxidant characteristics that address the pathophysiological mechanisms of stone formation. The scientific validation of these traditional approaches has revealed that herbal remedies function through multiple synergistic mechanisms: inhibiting calcium oxalate crystallization, regulating oxalate metabolism, preventing crystal aggregation and growth, and most importantly, promoting enhanced urinary flow to facilitate the natural elimination of stone-forming minerals.[4][5][6] Among the most extensively researched and clinically promising herbal interventions, three powerhouse botanicals Punarnava, Ashwagandha, and Tulsi have demonstrated remarkable potential in both preclinical investigations and traditional clinical applications. Punarnava (Boerhavia diffusa), whose Sanskrit name literally means "renewed again," stands as a cornerstone herb in Ayurvedic nephrolithiasis management, functioning as a potent diuretic that dramatically

increases urine output while simultaneously exerting powerful anti-inflammatory effects that quell tissue inflammation and facilitate the passage of smaller stones.[8][9] Ashwagandha (Withania somnifera), an adaptogenic medicinal plant with a rich phytochemical profile encompassing withanolides, alkaloids, and flavonoids, operates through a sophisticated multi-mechanistic approach by neutralizing free radicals to reduce oxidative stress, inhibiting pro-inflammatory cytokines to mitigate chronic inflammation, and promoting diuretic activity to enhance urinary clearance of stone-forming minerals collectively targeting the critical pathways implicated in kidney stone pathogenesis.[10][11] Holy Basil or Tulsi (Ocimum tenuiflorum L.), deeply revered in Indian traditional medicine, demonstrates remarkable inhibitory potential specifically against uric acid crystallization, the most troublesome contributor to certain kidney stone types, with research demonstrating a 19-fold increase in induction time and 3-fold decrease in crystal size at elevated extract concentrations.[12] The pharmaceutical formulation of these therapeutic herbs into a tablet delivery system incorporating modified starch excipients represents a significant advancement in herbal medicine technology, transforming traditional botanical remedies into standardized, patient-compliant pharmaceutical products. Modified starches, derived from sources such as maize and potato, function as multifunctional excipients possessing superior binding and disintegrant properties that enhance tablet structural integrity while ensuring rapid and complete drug release thereby optimizing bioavailability and therapeutic efficacy of the herbal actives. This innovative formulation approach combines the ancient wisdom of Ayurvedic herbalism with contemporary pharmaceutical science, creating a synergistic combination product that leverages the collective nephroprotective, lithotropic, and diuretic properties of three potent medicinal plants while ensuring optimal dissolution, absorption, and clinical effectiveness.[14] The current article systematically explores the scientific evidence, phytochemical composition, pharmacological mechanisms, and formulation technologies that underpin this integrated herbal therapeutic approach, providing practitioners and researchers with a comprehensive, evidence-based framework for understanding how nature's botanical arsenal can offer safe, effective, cost-economical, and side-effect-minimal alternatives for both preventing recurrence and managing existing kidney stone disease.

Polymer Modification

Polymer modifications refer to the process of changing the structure and properties of natural polymers like starch (which is made up of glucose units) to improve or add new functions. polymer modifications change the starch’s molecular structure physically or chemically to

make it more useful for various industrial applications. These modifications can improve qualities like strength, stability, resistance to heat or acid, water solubility, and durability. Starch (polysaccharide)-complex of carbohydrates molecule made up of long chain monosaccharides (simple sugar).

METHODS

1. Physical modification
2. Chemical modification
3. Enzymetic modification/Biological modification.

Justification of physical modification

Physical modification is chosen because it is a simple, safe, and low-cost method. It changes the physical properties of a polymer using heat, moisture, or pressure without changing its chemical structure. The polymer modification will be helpful to improve the properties of natural polymer like solubility, stability, and strength, and is safe for use in food and medicine since no harmful chemicals are used**.**

Etiology

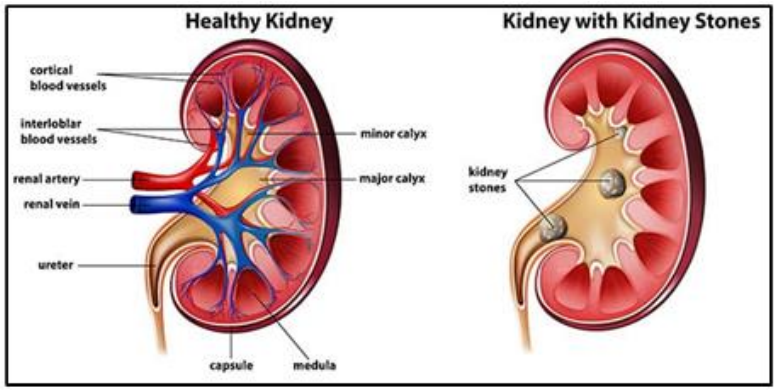

Fig. No. 1: Etiology of Kidney Stone.[16]

The etiology of kidney stones is multifactorial, involving a combination of dietary, lifestyle, genetic, metabolic, and medical factors that lead to the formation of solid crystals in the urine. Kidney stones develop when the urine contains a higher concentration of crystal-forming substances than can be diluted by the fluid in the urine. These substances include calcium oxalate, calcium phosphate, uric acid, cystine, and magnesium ammonium phosphate (struvite). The deficiency of substances that prevent crystal aggregation also contributes to stone formation.[16][17]

The main types of kidney stones and their causes include

- **Calcium stones:** (most common), usually calcium oxalate or calcium phosphate, linked to metabolic factors, high vitamin D doses, certain surgeries, or medications like topiramate.
- **Uric acid stones:** associated with dehydration, high-protein diets, metabolic syndrome, diabetes, and genetic predisposition.
- **Struvite stones:** formed in response to urinary tract infections by urease-producing bacteria.
- **Cystine stones:** resulting from a rare genetic disorder called cystinuria, causing excessive cystine in urine. Additional common causes or risk factors for kidney stones include low urine volume/dehydration, diets high in sodium, sugar, and animal protein, certain medical conditions (e.g., hyperparathyroidism, gout, inflammatory bowel disease, chronic urinary tract infections), obesity, and genetic factors affecting renal handling of calcium and other ions. The pathogenesis involves urinary supersaturation leading to nucleation, crystal growth, aggregation, and retention of crystals within the kidneys. Genetic defects may affect metabolism and renal epithelial cell function, altering the balance of promoters and inhibitors of crystallization.[17]

REVIEW OF INGREDIENTS

1] Punarnava (Boerhavia diffusa Linn.)

Fig. No. 2: Punarnava.[18]

Table No. 1: Scientific classification of Punarnava (Boerhavia diffusa Linn.)[19]

Rank	Name
Domain	Eukaryota
Kingdom	Plantae
Subkingdom	Viridiplantae
Phylum	Tracheophyta
Subphylum	Spermatophytina
Class	Magnoliopsida (Dicotyledons)
Subclass	Caryophyllidae
Superorder	Caryophyllanae
Order	Caryophyllales
Family	Nyctaginaceae
Genus	Boerhavia
Species	*Boerhavia diffusa*

Punarnava, scientifically known as *Boerhavia diffusa*, belongs to the Nyctaginaceae family. It is a well-known herb in Ayurvedic medicine, mainly used to treat kidney, liver, and urinary problems. The name "Punarnava" means "that which renews the body," showing its ability to restore health and strength.

The plant contains many useful natural chemicals such as punarnavine, boeravinones, flavonoids, alkaloids, tannins, and saponins. These compounds are responsible for its healing and protective effects. Punarnava is known to act as a natural diuretic, helping the body remove excess water and toxins, which is helpful in conditions like kidney stones and swelling (edema).

Studies have shown that Punarnava can protect the kidneys and liver, reduce inflammation, and act as an antioxidant, preventing damage caused by free radicals. It also helps in maintaining normal levels of urea and creatinine in the body, supporting overall kidney health.

Because of its many health benefits, Punarnava is often used as a main ingredient in herbal formulations for kidney stone treatment, liver tonics, and diuretic syrups. It is considered a safe and effective herb for improving general health and removing harmful waste from the body.[20]

2] Tulsi seed (Ocimum sanctum Linn.)

Fig. No. 3: Tulsi.[21]

Table No. 2: Scientific classification of Tulsi seed (Ocimum sanctum Linn.)[22]

Rank	Name
Domain	Eukaryota
Kingdom	Plantae
Subkingdom	Tracheobionta
Superdivision	Spermatophyta
Division	Magnoliophyta
Class	Magnoliopsida
Subclass	Asteridae
Order	Lamiales
Family	Lamiaceae
Genus	Ocimum
Species	*Ocimum sanctum Linn.*

Tulsi, also known as Holy Basil, belongs to the Lamiaceae family. It is a sacred and important herb in Ayurvedic medicine, known for promoting overall health and well-being. The plant has a pleasant aroma and contains many useful natural compounds such as eugenol, ursolic acid, rosmarinic acid, and flavonoids.

These compounds give Tulsi many medicinal properties, including antioxidant, antidiabetic, anti-inflammatory, and immune-boosting effects. Studies have shown that Tulsi helps to reduce blood sugar levels by improving insulin secretion and helping body cells use glucose more effectively. It also protects the pancreas and reduces oxidative stress, which are important for controlling diabetes.

Besides controlling blood sugar, Tulsi helps improve heart and liver health, supports the respiratory system, and helps the body cope with stress. Its natural antioxidants prevent cell damage and improve overall metabolism.

Because of these multiple benefits, Tulsi is often used in herbal formulations for diabetes, immunity, and stress management. It works well with other medicinal plants to support better health and balance in the body.[23]

3] Ashwagandha (Withania somnifera Dunal)

Fig. No. 4: Ashwagandha.[24]

Table No. 3: Scientific classification of Ashwagandha (Withania somnifera Dunal).[25]

Rank	Name
Domain	Eukaryota
Kingdom	Plantae
Subkingdom	Tracheobionta
Superdivision	Spermatophyta
Division	Magnoliophyta
Class	Magnoliopsida
Subclass	Asteridae
Order	Solanales
Family	Solanaceae
Genus	Withania
Species	*Withania somnifera* (L.) Dunal

Ashwagandha *(Withania somnifera Dunal)* belongs to the Solanaceae family and is a well-known rejuvenating herb in Ayurvedic medicine. It contains important bioactive compounds like withanolides, alkaloids, and steroidal lactones, which give it strong adaptogenic, antioxidant, and anti-inflammatory properties. Ashwagandha helps the body manage stress and fatigue, boosts energy and immunity, and supports nervous system balance.

Recent studies also show its antidiabetic effects, as it improves insulin sensitivity, enhances glucose uptake, and helps maintain normal blood sugar levels. Because of these combined benefits, Ashwagandha is often included in herbal formulations to promote strength, vitality, and metabolic health.[25]

Table No. 4: Herbal Agents with Anti-urolithic & Antiaging Properties.[19][22][25]

Plant Name (Scientific Name)	Family	Key Bioactive Compounds	Main Pharmacological Properties	Therapeutic/Health Benefits
Punarnava (*Boerhavia diffusa* Linn.)	Nyctaginaceae	Punarnavine, Boeravinones, Flavonoids, Alkaloids, Tannins, Saponins	Diuretic, Antioxidant, Anti-inflammatory, Hepatoprotective, Nephroprotective	Treats kidney and liver disorders, reduces swelling and toxins, supports urinary and metabolic health
Tulsi (*Ocimum sanctum* Linn.)	Lamiaceae	Eugenol, Ursolic acid, Rosmarinic acid, Flavonoids, Linalool	Antidiabetic, Antioxidant, Anti-inflammatory, Immunomodulatory	Lowers blood sugar, protects liver and heart, boosts immunity, relieves stress
Ashwagandha (*Withania somnifera*	Solanaceae	Withanolides, Alkaloids, Steroidal lactones	Adaptogenic, Antioxidant, Anti-inflammatory, Antidiabetic	Reduces stress and fatigue, boosts energy and immunity, improves insulin sensitivity and metabolic health

FORMULATION APPROACH AND SCIENTIFIC RATIONALE

The objective of this study was to develop a formulation of polymer modified Punarnava herbal tablet to ensure prolonged therapeutic activity and better patient compliance. The formulation combines punarnava (Boerhavia diffusa) as a main nephroprotective and anti-aging drug with supportive herbs Tulsi seed, ashwagandha and licorice root to achieve synergistic effect.[26] Tulsi contributes to diuretic and antioxidant activity, Ashwagandha acts as adaptogen promoting anti-aging and stress resistance, while licorice offers anti-inflammatory.[27] The formulation utilized modified rice starch as natural polymer for matrix modification, which played a key role in controlling the release of active phytoconstituents and improving tablet stability. Gum acacia was used as natural binder to impart adequate hardness and mechanical strength, whereas Ispaghula husk was added as disintegrant and natural fibre source to facilated proper tablet breakdown into gastrointestinal tract.[28] Talc and magnesium stearate were included as glidant and lubricant, ensuring uniform flow and

preventing sticking during compression. The scientific rationale behind this formulation lies in combining herbal actives with natural polymer to achieve sustained drug release, enhanced bioavailability, and prolonged therapeutic action. This polymer modification not only ensure controlled release but also minimizes dosing frequency, improve patient compliance and maintain the physiochemical stability of the herbal constituents. Overall, this approach provides a holistic, scientifically justified formulation that integrates traditional herbal wisdom with modern pharmaceutical principles for effective kidney stone management and anti-aging support.[29]

Table No. 5: Optimized Formulation Composition for kidney stone and anti-aging.

Sr. No.	Ingredients	Quantity (1 Tablet)	Quantity (for 300 tablet)	Percentage %	Role
1	Punarnava Powder	200	60.0	40.0	Nephroprotective, Anti-aging.
2	Tulsi seed Powder	50	15.0	10.0	Supportive Antiurothrolitic.
3	Ashwagandha Powder	50	15.0	10.0	Adaptogen, Anti-aging support.
4	Modified rice starch	55	46.5	31.0	Sustained release matrix, binder.
5	Gum Acacia	20	6.0	4.0	Natural binder, flow enhancer
6	Ispaghula Husk	10	3.0	2.0	Disintegrant, fibre support
7	Talc	5	1.5	1.0	Glidant
8	Magnesium stearate	5	1.5	1.0	Taste masking, patient acceptance
9	Licorice Root Powder	5	1.5	1.0	Additional sweet taste masking
	Total	500 mg	150.0 g	100%	

Table No. 6: Formulation Approach and Scientific Rationale.

Challenge	Description	Formulation Solution
Unpleasant Bitter Taste	Herbal extracts often have a strong, bitter flavour.	Incorporation of licorice extract as a natural sweetener to mask bitterness.
Low bioavailability of actives	Some phytochemicals have poor solubility or are subject to first-pass metabolism.	Improve solubility with solid dispersions, micronization, lipid-based carriers, or use permeability enhancers; consider fast-release vs controlled-release strategies or alternative routes.
Stability of Active Compounds	Bioactive ingredients can degrade during storage.	Optimization of pH, proper packaging, and storage conditions to maintain efficacy.

Content uniformity / dose accuracy	Low dose or uneven mixing of potent herbal extracts causes variability between tablets	Use potent drug layering, pre-blending with high-load excipients, validated mixing procedures, and in-process content assays; consider granulation to homogenize API distribution.
Poor patient compliance (swallowing difficulty, size)	Large or rough tablets reduce adherence, especially in elderly/children.	Reduce tablet size by increasing potency per mg (if safe), make scored tablets, use film coating for smoother surface, or offer alternate forms.

EVALUATION PARAMETERS

The rigorous evaluation of the developed anti-diabetic herbal syrup is essential to establish its quality, safety, and therapeutic efficacy. A series of standardized physicochemical, microbiological, and analytical tests were conducted in accordance with international pharmacopeial and regulatory guidelines to ensure the formulation's suitability for clinical application.

Table No. 7: Evaluation Parameters for polymer modified rice starch.

Sr. No.	Parameter	Objective	Method/Instrument	Acceptance Criteria
1.	Organoleptic Properties	To assess visual and sensory characteristics such as colour, texture and uniformity	Visual and tactile inspection	Smooth, Uniform, off-white fine powder.
2.	Solubility	To determine solubility and dispersion uniformity	Dispersion test in suitable solvent	Should disperse uniformly without forming lumps
3.	Swelling Index	To evaluate water absorption and swelling behaviour	Swelling index determination method	Good swelling ability
4.	Viscosity	To determine consistency and gel-forming ability	Brookfield viscometer	Moderate to high viscosity at gelatinization temperature
5.	pH	To ensure chemical stability and compatibility	Digital pH meter	pH 5.0-7.0
6.	Stability Study	To determine physical and chemical stability over time	Storage at room temperature and accelerated conditions	No lumping, color change, or microbial growth

Table No. 8: Evaluation Parameters and Corresponding Acceptance Criteria for Herbal Tablets Formulation.[30]

Sr. No.	Evaluation Parameters	Expected Result
1	Colour	Brownish-green
2	Odour	Characteristic
3	Taste	Slightly bitter
4	Texture	Smooth surface, non-crumbly
5	Shape	Round, uniform
6	Size	8 mm
7	Weight Variation Test	±5%
8	Hardness (Pfizer Tester)	4–6 kg/cm²
9	Friability Test	< 1.0%
10	Disintegration Test	15–30 minutes
11	Dissolution Test	45 minutes

CONCLUSION

Kidney stone disease continues to pose a major global health challenge, calling for effective and accessible treatment options. This research establishes a new herbal tablet formulation that combines Punarnava (Boerhavia diffusa), Tulsi (Ocimum sanctum), and Ashwagandha (Withania somnifera), each contributing distinct therapeutic effects to address multiple aspects of kidney stone pathology. Together, these plants provide diuretic, antioxidant, anti-inflammatory, adaptogenic, and metabolic support, targeting the underlying mechanisms of stone formation and kidney damage. The use of modified rice starch as a sustained-release matrix, complemented by natural excipients such as gum acacia and ispaghula husk, facilitates controlled release, improves bioavailability, and enhances patient adherence to treatment. This approach effectively merges traditional Ayurvedic botanical knowledge with modern pharmaceutical technology, offering a potentially safe, affordable, and standardized alternative for the prevention and management of nephrolithiasis and related oxidative stress conditions. This herbal formulation provides a scientifically grounded, comprehensive therapeutic option that may help reduce kidney stone recurrence rates and improve patient quality of life. Further rigorous preclinical and clinical research is recommended to confirm efficacy and safety, supporting wider clinical application.

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