

A Review to Formulate and Evaluate Polyherbal Tablet for Antiurolithatic Activity by using Horse Gram

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Abstract: Today's generation has move away from traditional foods and it is high time to create awareness about the benefits And importance of lesser known pulses such as HORSE GRAM. Horse gram is a kind of bean commonly used In many south Indian states. This plant is native to the different parts of India. It is high in protein and iron which Make it a whole some food that should be added to our diet on a regular basis. Horse gram is known to have many Therapeutic effects but not scientifically proven though it has been recommended in Ayurveda medicine to treat Renal stone, gall stone, weight loss, menstrual problems, diabetes, piles, edema etc. Urolithiasis is when a solidpiece of material occurs in the urinary tract. Kidney stones typically form in the kidney And leave the body in the urine stream. A small stone may pass without causing symptoms. If a stone grows more Than 5mm, it can cause blockage of ureter resulting in severe pain in the lower back or abdomen. A stone may Also result in the blood in urine, vomiting, or painful urination. The presents study aims to formulate and evaluate Polyherbal tablet for antiurolithatic activity.

Keywords: Urolithiasis, Polyherbal, Antiurolithatic, Cystone, Calcium oxalate

I. INTRODUCTION

Kidney :-

The kidneys are two bean-shaped organs responsible filtering minerals from the blood, maintaining overall fluid balance, excreting waste products, and regulating blood volume to name a few.

The kidneys are very important organs in the body. About one-third of all blood leaving the heart passes into the kidneys for filtration before being pumped to the cells and tissues of the body. When the kidneys malfunction, or if they stop working (kidney failure), it may lead to various complications such as fluid retention that can lead to edema or swelling of the extremities, pulmonary edema or fluid in the lungs, hyperkalemia or increased potassium levels in the blood, anemia, heart disease, and pericarditis, among others.

Anatomy of Kidney Location

The kidneys are located on either side of the spine, in the retroperitoneal space. The left kidney is situated a little higher than the right one, because of the liver on the right side of the abdominal cavity, above the right kidney.

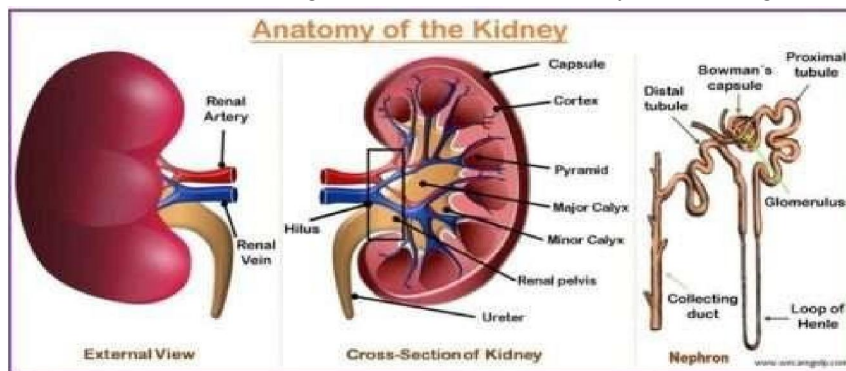


Fig. 1 Human kidney Anatomy

Structure

Each of the two bean-shaped organs weighs about 125 to 175 grams and 115 to 155 grams in males and females respectively. The kidney typically measures approximately 11 to 14 centimeters in length, 6 centimeters in width and is about 4 centimeters thick.

The kidneys are protected by fat, muscles, and ribs of the back. Perirenal fat, also called the renal fat pad, protects the kidneys from external force or damage. The kidneys have a medial dimple called the renal hilum, which is the entry and exit point for structures that supply or drain the kidneys such as the nerves, ureters, vessels, and lymphatics.

Function

Your kidneys have many important functions. They clean toxins and waste out of your blood. Common waste products include nitrogen waste (urea), muscle waste (creatinine) and acids. They help your body remove these substances. Your kidneys filter about half a cup of blood every minute.

- Blood flows into your kidneys through a large blood vessel called the renal artery.
- Tiny blood vessels in your kidney filter the blood.
- The filtered blood returns to your bloodstream through a large blood vessel called the renal vein.
- Pee travels through tubes of muscle called ureters (yer-it-ter) to your bladder.
- Your bladder stores pee until you release it through urination (peeing).
- Control the acid-base balance (pH balance) of your blood.
- Make sugar (glucose) if your blood doesn't have enough sugar.
- Make a protein called renin that increases blood pressure.
- Produce the hormones calcitriol and erythropoietin. Calcitriol is a form of vitamin D that helps your body absorb calcium. Erythropoietin helps your body make red blood cells. An adrenal gland sits on top of each kidney. It produces hormones, including cortisol, which helps your body respond to stress

KIDNEY STONES

Overview of kidney stones

Kidney stones are mainly lodged in the kidney(s). Mankind has been afflicted by urinary stones since centuries dating back to 4000 B.C. and it is the most common disease of the urinary tract. The prevention of renal stone recurrence remains to be a serious problem in human health.

The prevention of stone recurrence requires better understanding of the mechanisms involved in stone formation. Kidney stones have been associated with an increased risk of chronic kidney diseases, end-stage renal failure, cardiovascular diseases, diabetes, and hypertension. It has been suggested that kidney stone may be a systemic disorder linked to the metabolic syndrome. Nephrolithiasis is responsible for 2 to 3% of end-stage renal cases if it is associated with nephrocalcinosis.

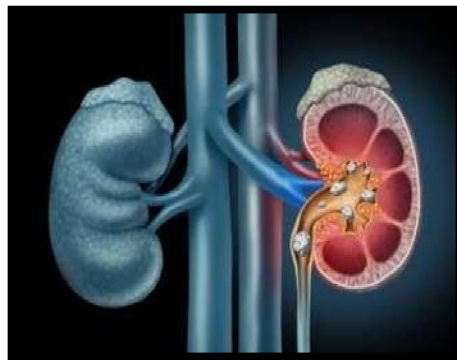


Fig. 2 Epidemiological of kidney stones

Epidemiology of kidney stones

Globally, kidney stone disease prevalence and recurrence rates are increasing , with limited options of effective drugs. Urolithiasis affects about 12% of the world population at some stage in their lifetime . It affects all ages, sexes, and races but occurs more frequently in men than in women within the age of 20–49 years. If patients do not apply metaphylaxis, the relapsing rate of secondary stone formations is estimated to be 10–23% per year, 50% in 5–10 years, and 75% in 20 years of the patient. However, lifetime recurrence rate is higher in males, although the incidence of nephrolithiasis is growing among females . Therefore, prophylactic management is of great importance to manage urolithiasis.

Recent studies have reported that the prevalence of urolithiasis has been increasing in the past decades in both developed and developing countries. This growing trend is believed to be associated with changes in lifestyle modifications such as lack of physical activity and dietary habits and global warming. In the United States, kidney stone affects 1 in 11 people , and it is estimated that 600,000 Americans suffer from urinary stones every year. In Indian population, about 12% of them are expected to have urinary stones and out of which 50% may end up with loss of kidney functions .

Types of kidney stones

The chemical composition of kidney stones depends on the abnormalities in urine composition of various chemicals. Stones differ in size, shape, and chemical compositions (mineralogy) . Based on variations in mineral composition and pathogenesis, kidney stones are commonly classified into five types as follows .

Calcium Stones:

Calcium Oxalate and Calcium Phosphate Calcium stones are predominant renal stones comprising about 80% of all urinary calculi . The proportion of calcium stones may account for pure calcium oxalate (CaOx) (50%), calcium phosphate (CaP, termed as apatite) (5%), and a mixture of both (45%) . The main constituent of calcium stones is brushite (calcium hydrogen phosphate) or hydroxyapatite. Calcium oxalate is found in the majority of kidney stones and exists in the form of CaOx monohydrate (COM, termed as mineral names: whewellite, CaC2O4·H2O), and CaOx dihydrate (COD, weddellite, CaC2O4·2H2O), or as a combination of both which accounts for greater than 60% . COM is the most thermodynamically stable form of stone. COM is more frequently observed than COD in clinical stones.

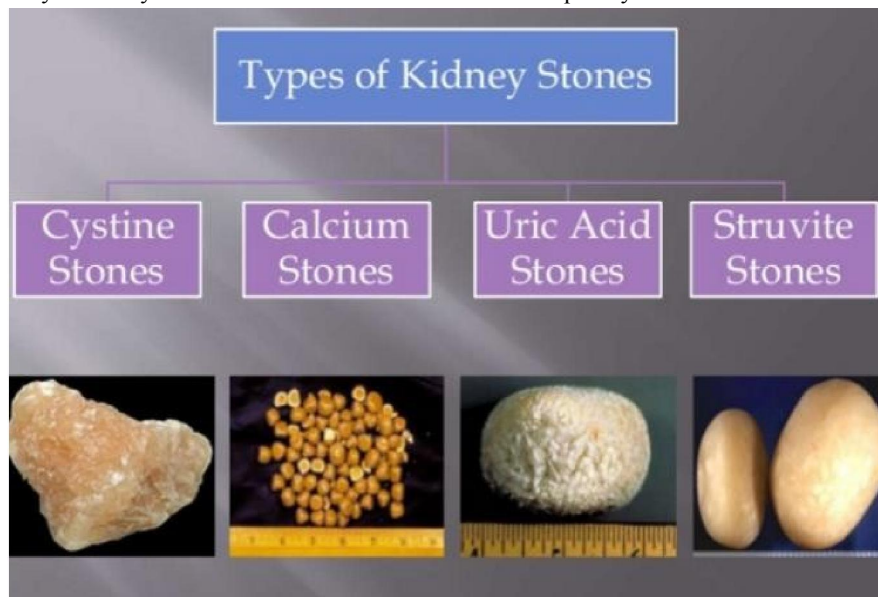


Fig. 3 Types of kidney stones

Struvite or Magnesium Ammonium Phosphate Stones

Struvite stones occur to the extent of 10–15% and have also been referred to as infection stones and triple phosphate stones. It occurs among patients with chronic urinary tract infections that produce urease, the most common being *Proteus mirabilis* and less common pathogens include *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Enterobacter*. Urease is necessary to split/cleave urea to ammonia and CO₂, making urine more alkaline which elevates pH (typically > 7). Phosphate is less soluble at alkaline versus acidic pH, so phosphate precipitates on to the insoluble ammonium products, yielding to a large staghorn stone formation

Uric Acid Stones or Urate

This accounts approximately for 3–10% of all stone types. Diets high in purines especially those containing animal protein diet such as meat and fish, results in hyperuricosuria, low urine volume, and low urinary pH (pH < 5.05) exacerbates uric acid stone formation. Peoples with gouty arthritis may form stones in the kidney(s). The most prevalent cause of uric acid nephrolithiasis is idiopathic [34], and uric acid stones are more common in men than in women.

Cystine Stones

These stones comprise less than 2% of all stone types. It is a genetic disorder of the transport of an amino acid and cystine. It results in an excess of cystinuria in urinary excretions, which is an autosomal recessive disorder caused by a defect in the rBAT gene on chromosome 2, resulting in impaired renal tubular absorption of cystine or leaking cystine into urine. It does not dissolve in urine and leads to cystine stone formation. People who are homozygous for cystinuria excrete more than 600 millimole insoluble cystine per day. The development of urinary cystine is the only clinical manifestation of this cystine stone disease .

Drug-Induced Stones

This accounts for about 1% of all stone types. Drugs such as guaifenesin, triamterene, atazanavir, and sulfa drugs induce these stones. For instance, people who take the protease inhibitor indinavir sulphate, a drug used to treat HIV infection, are at risk of developing kidney stones. Such lithogenic drugs or its metabolites may deposit to form a nidus or on renal calculi already present. On the other hand, these drugs may induce the formation of calculi through its metabolic action by interfering with calcium oxalate or purine metabolisms

Risk factors

Factors that increase your risk of developing kidney stones include:

Family or personal history :-

If someone in your family has had kidney stones, you're more likely to develop stones, too. If you've already had one or more kidney stones, you're at increased risk of developing another.

Dehydration:-

Not drinking enough water each day can increase your risk of kidney stones. People who live in warm, dry climates and those who sweat a lot may be at higher risk than others.

Certain diets:-

Eating a diet that's high in protein, sodium (salt) and sugar may increase your risk of some types of kidney stones. This is especially true with a high-sodium diet. Too much salt in your diet increases the amount of calcium your kidneys must filter and significantly increases your risk of kidney stones.

Obesity:-

High body mass index (BMI), large waist size and weight gain have been linked to an increased risk of kidney stones.

Digestive diseases and surgery:- Gastric bypass surgery, inflammatory bowel disease or chronic diarrhea can cause changes in the digestive process that affect your absorption of calcium and water, increasing the amounts of stone-forming substances in your urine.

Other medical conditions:-

Such as renal tubular acidosis, cystinuria, hyperparathyroidism and repeated urinary tract infections also can increase your risk of kidney stones.

II. LITERATURE REVIEW

Vaibhavkumar B. Patel (et.al) – say that, *Macrotyloma uniflorum* Linn. (Fabaceae) seeds are widely used for their diuretic and urolithiatic effects in India. The present study investigated the effect of aqueous extract of *Macrotyloma uniflorum* seeds (AEMU) on ethylene glycol induced urolithiasis in rats. To induce urolithiasis, 0.75% v/v ethylene glycol was administered orally for 14 days. The curative doses of 400 and 800 mg/kg were administered from 15th to 28th day. On the 28th day, 24 h urine, serum was collected and various biochemical parameters were estimated in urine, serum and kidney homogenate along with histology of kidney

Ishwar das (et.al) – say that, Edible plant the pulse *Macrotyloma uniflorum* (KPE) extracts were found to be effective in the inhibition of calcium oxalate crystallization. Various physicochemical techniques, viz. conductometric and nephelometric titrations, UV–vis and IR spectroscopy and potential measurements in the absence and presence of these extracts were employed. KPE both reduced the particle size considerably from 250 to 5–50 μm range as revealed by microphotographs. Considerable solubility in the presence of KPE was also observed by flame photometric studies. Dissolution was found to vary with time. Particle size distribution in CaC_2O_4 precipitate may be one of the reasons.

D. Anantha krishna Chaitanya (et.al) – say that, The effect of oral administration of aqueous and alcohol extracts of *Macrotyloma uniflorum* (Fabaceae) seeds on calcium oxalate urolithiasis has been studied in male albino wistar rats. Ethylene glycol feeding resulted in hyperoxaluria as well as increased renal excretion of calcium and phosphate.

Supplementation with aqueous and alcohol extract of *Macrotyloma uniflorum* seeds significantly reduced the elevated urinary oxalate showing a regulatory action on endogenous oxalate synthesis. The increased deposition of stone forming constituents in the kidneys of calculogenic rats was significantly lowered by curative and preventive treatment using aqueous and alcohol extracts. The results indicate that the seeds of *M. uniflorum* are endowed with significant antiurolithiatic activity and it also indicates that the alcoholic extract of *M. uniflorum* shows better anti urolithiatic activity than aqueous extract.

Unnati atodariya (et.al) - say that, Data from in-vitro, in- vivo and clinical trials reveal that phytotherapeutic agents could be useful as either alternative or an adjunct therapy in the management of Urolithiasis. Medicinal plants / natural products are more useful for body because they promote the repair mechanism in natural way. Various plant species of *Dolichos biflorus*, have been reported to possess antiurolithiatic property. In this study aqueous, chloroform, benzene extracts of *Dolichos biflorus* Linn and standard for dissolving kidney stones- calcium oxalate by an in-vitro model. Phenolic compound isolated from the benzene and aqueous, flavanoids and steroids from aqueous fraction of the seed. Aqueous fraction was more effective in dissolving calcium oxalate (48.5 \pm 0.022%). Reference standard-formulation Cystone was found to be more effective (53.5 \pm 0.02 %) when compared to phenolic and flavanoids fraction.

Sanyukta p. Nimje (et.al) – say that, Urolithiasis is a most common clinical condition observed in clinical practice, affecting more than 10% of population in industrialized countries. Renal calculi cause symptoms severe pain in the renal angle, pain that radiates to lower abdomen, pain on urination, cloudy or foul-smelling urine, nausea etc. Many treatment modalities have been introduced in medical sciences, but it is very costly and even the recurrence of production of stone cannot be prevented. *Kulatha* has property of *Dipana*, *Mutrala*, *Bhedan*, *Lekhan*, *Shothahar*. Renal calculi possess *Tridoshaja* mainly *Kaphavataj Samprapti* and the *Kulatha* has the property of *Vatakaphahara*, which breaks down the *Samprapti* of *Mutrashmari*. Conclusion: Our present findings suggest that *Kulatha Kwatha* markedly reduces pain, dysuria, and increased frequency of micturition, reduction of size and expulsion of calculus.

DRUG PROFILE

Horse gram (*Macrotyloma uniflorum*)



Fig. 5 Horse gram

Kulthi, commonly known as Horse gram, is a bean used in hilly regions of India. It is widely grown for human food as a pulse and fodder crop for livestock. It is very popular with the name of Ghahatin Uttarakhand Kumaon villages. It is also grown in states like Himachal, Tamilnadu, and MadhyaPradesh.

Kulthi is an excellent source of protein, carbohydrates, essential amino acids, iron, phosphorus, and vitamins such as carotene, thiamine, riboflavin, niacin, and vitamin C. It might not be great in taste as compared to other beans but it sure shows many health-benefiting properties. As per Ayurveda, Kulthi has a Vata-Kapha balancing property that helps to reduce the symptoms of cough and arthritis.

One of the most prominent uses of Kulthi is in kidney stone treatment. The water extracted after soaking or boiling Kulthi not only helps in dissolving kidney stones but stops them from developing again. This is due to its Mutral (diuretic) nature.

It may also be helpful in conditions like skin inflammation. It decreases the redness of the skin due to inflammation or skin rash when applied to the affected area. This is due to its Kashaya property. It is important to know that Kulthi contains a specific type of carbohydrate called raffinose oligosaccharides, which may cause gas and bloating, especially when eaten in large amounts.

Synonyms :- *Macrotyloma uniflorum*

Biological source :- The seed of horse gram plant.

Family :- Legumes

Chemical constituents:-

The seeds of *Macrotyloma uniflorum* contain much more bioactive substances such as alkaloid, phenolic acid, tannin, flavonoids, fiber, essential fatty acid etc., which have significant metabolic and physiological effects. Horse gram is a rich source of flavonoid and shows antioxidant activities.

Uses :- Kulthi dal is used in traditional medicine for having potential effect on amenorrhea, Urolithiasis, bile stones, conjunctivitis, rheumatism, piles, diabetes mellitus, dysuria, colic and Flatulence (with *Asafoetida*), oedema, and mumps, goitre, and phlegmatic diseases (with pepper). They also contain diuretic and astringent properties. These properties help in keeping the body warm during winters, along with other health issues

AIM

To Formulate And Evaluate Polyherbal Tablet For Antiurolithatic Activity by Using Horse Gram

OBJECTIVE

To develop a pharmaceutical-grade tablet containing horse gram (*Macrotyloma uniflorum*) extract intended for the prevention and management of kidney stones, leveraging the known medicinal properties of horse gram to promote the dissolution of stones and prevent their recurrence.

Utilize horse gram’s diuretic and anti-lithogenic properties to aid in the breakdown and elimination of kidney stones.

Evaluate the tablet’s effectiveness in reducing the size of existing stones and preventing the formation of new stones

EXPERIMENTAL WORK

Wet Granulation Method

Wet granulation is the most widely used process of granulation in the pharmaceutical Industry.

It involves addition of a liquid solution (with or without binder) to powders, to form a Wet mass or it forms granules by adding the powder together with an adhesive, Instead of by compaction

The wet mass is dried and then sized to obtained granules. The liquid added binds the Moist powder particles by a combination of capillary and viscous forces in the wet State.

More permanent bonds are formed during subsequent drying which leads to the Formation of agglomerates.

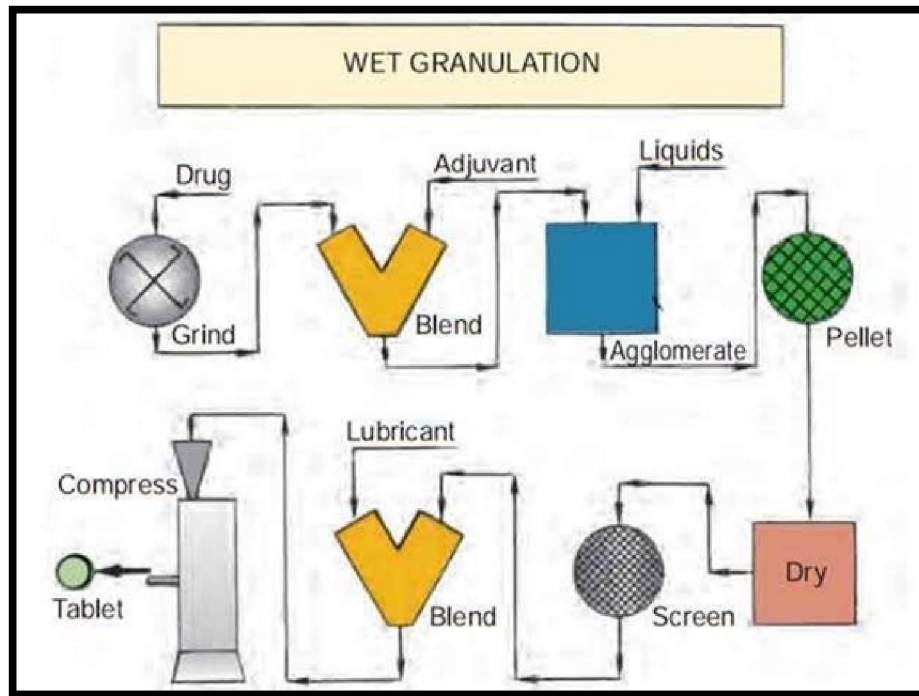


Fig. 6 Wet granulation

Step 1 : Weighing And Mixing Of Formulation Ingredients :

This step involves the weighing, sifting and introduction of specified quantities of drug Substance(s), bulking agent, filler or diluent, and disintegrant into a powder mixer. These Ingredients are mixed using either a planetary bowl mixer, ribbon/ trough mixers, rotating Drum mixer or high-speed mixer until a uniform powder mix is achieved. The mixing efficiency Can be enhanced by the use of powders that have similar average particle size, although this Is often not the case in many mixing operations. There are many diluents available in commerce but those used in wet granulation method Include lactose, microcrystalline cellulose, starch, powdered sucrose, mannitol, fructose, Sorbitol, calcium phosphate and calcium sulphate. Among these diluents, the most widely Used are lactose, because of its low cost, solubility and compatibility with most drug Substances and excipients and microcrystalline cellulose, because of its easy compaction, Compatibility with most formulation ingredients and consistent uniformity of supply.

Step 2 : Preparing the damp mass

Here, the binder solution is mixed with the powder mixture to form an adhesive mass which can be granulated. The amount of binding agent used as well as the quantity of fluid required to form a damp and coherent mass is part of the operator's skill; however, the resulting binder-powder mixture should compact when squeezed in the hand. The use of insufficient binder tends to poor adhesion, capping and soft tablets. Excessive binder solution yields hard tablets with slow disintegrating properties. Among granulating agents are solutions of Povidone, an aqueous preparation of corn starch, molasses, methylcellulose, Carboxymethyl cellulose, glucose solution and microcrystalline cellulose. Dry binder or non aqueous solution may be used for drug substances that are adversely affected by aqueous solution. Colorants or flavouring agents may be added to the binding agent to prepare a granulation with an added feature.

Step 3 : Wet screening / Screening the dampened powder into pellets or granules

The wet massed powder blend is screened using 6- to 12-mesh screen to prepare wet granules. This may be done by hand or with suitable equipment that prepares the granules by extrusion through perforations in the apparatus. The granules formed are spread evenly on trays and dried in an oven.

Step 4 : Drying of moist granules

The screened moist granules are dried in an oven at a controlled temperature not exceeding 55°C to a consistent weight or constant moisture content. The drying temperature and the duration of drying process depend on the nature of the active ingredient and the level of moisture required for the successful production of satisfactory tablets. Shelf or tray drier and fluidized-bed drier can be used for this purpose.

Step 5 : Sizing the granulation by dried

The dried granules are passed through a screen of smaller size than that used to prepare the moist granules. The size of final granules is dependent on the size of punches. Screen of 14- to 20-mesh size are generally used for this purpose.

Step 6 : Lubrication of granules

After dry screening the dried and screened granules are separated into coarse and fine granules by shaking them on a 250 mesh sieve. Appropriate quantity of lubricant is passed through a 200-mesh sieve. This is mixed with the fine granules before the coarse granules are incorporated. Examples of lubricants commonly used in wet granulation include Magnesium stearate, calcium stearate, stearic acid, talc, starch.



Fig. 7 Granules

Formulation of poly herbal anti-urolithiatic tablet :- Plant materials collection and extraction :-
The material *Macrotyloma uniflorum* used in the present study were collected from local market.

Excipient used to formulate tablet :-

In this formulation Lactose, Starch, croscrovidone, Ginger extract, Vitamine B6, Magnesium stearate, etc. Lactose and starch serve as diluents and binders to provide bulk and cohesion to the tablet mixture. The other ingredients remain the

same as before, with crospovidone aiding in tablet disintegration, ginger extract and vitamin B6 Providing digestive support, and the remaining excipients aiding in tablet formation, stability, and appearance.

Formulation of polyherbal anti urolithiasis tablet :-

In the present study dried extract of Macrotyloma uniflorum were used in tablet dosage form by wet granulation Method.

Table 1.composition of formulation ingredient for poly herbal anti-urolithiatic tablet

Sr. No.	Ingredients used	Quantity taken		Category
		Batch 1	Batch 2	
1.	Horse gram	400	200	API
2.	Lactose	100	110	Diluent
3.	Starch	150	140	Binder
4.	Crospovidone	20	20	Disintegrant
5.	Ginger extract	10	10	Digestive aid
6.	Vitamin B6	5	5	Neutraceutical
7.	Magnesium sterate	5	5	Lubricant

Method Of Preparation Of Tablet (Compression Method) :

This wet mass was passed through sieve no. 24 and dried to get uniform granules. The Prepared and evaluated granules were compressed into biconvex shaped tablets using a Rotary Tablet Compression machine with average weight of 550 mg.

A single-punch press possesses one die and one pair of punches. The granule is held in a Hopper which is connected to a hopper shoe located at the die table. The hopper shoe moves To and fro over the die, by either a rotational or a translational movement.

When the hopper shoe is located over the die, the powder is fed into the die by gravitational Powder flow. The amount of powder filled into the die is controlled by the position of the Lower punchy.

When the hopper shoe is located beside the die, the upper punch descends and the Powder is compressed. The lower punch is stationary during compression and the pressure Is thus applied by the upper punch and controlled by the upper punch displacement. After Ejection, the tablet is pushed away by the hopper shoe as it moves back to the die for next Tablet.

The tablets were evaluated for the average weight, hardness, thickness, friability and Disintegration test.



Fig. 8 Tablet

Evaluation parameters of tablets :-

Tablets were subjected to following evaluation parameters.

Organoleptic properties:-

Odour , shape, color, taste was determined.

Tablet Hardness:-

The hardness was being evaluated by using Monsanto hardness tester



Fig. 10 Monsanto Hardness tester

Weight Variation Test:

For variation 20 tablets average weight was determined. Individually each tablet weight was Examined. In Each case deviation from the average weight was calculated and expressed as Percentage. Not more than two of The tablets from the sample size deviate from the average Weightby a greater percentage and none of the tablets Deviate by more than double that Percentage.

Thickness :

Vernier caliper was use to evaluate tablet thichness :



Fig. 11 Vernier caliper

Friability test :-

Friability test is carried out, using Friability apparatus. The weighted tablets are being placed in the apparatus And which is been rotated at 25 rpm for 5 minutes. After an interval tablets are takenout from apparatus and Once again they are weight. The friability is calculated by given formula:

$$\text{Friability} = \frac{\text{Initial weight (Wi)} - \text{Final weight (Wf)}}{\text{Initial weight (Wi)}} \times 100$$



Fig. 12 Friability tester

Disintegration test :-

6 tablets were taken for the estimation of the disintegration time. The tablets were placed in the disintegration apparatus and then the time was observed uptill the tablet were totally disintegrated. The temperature for the apparatus was maintained at 37° C.



Fig. 13 Disintegration test apparatus

III. RESULT AND DISCUSSION

Formulation of herbal anti-urolithiatic tablet: formulation prepared by wet granulation method were tested for the preformulation studies for potential evaluation to tablet compression. All the evaluated preformulation parameters are shown in table 4. Based on the preformulation studies powder flow properties are good. Then the process is continued with compression of tablet by wet granulation method, after compression tablets were evaluated by post compression parameters observed were displayed on below table

Sr. No.	Parameters	Result
1.	Colour	Brown
2.	Odour	Swelling like nuts
3.	Taste	Bitter
4.	Hardness (kg/cm ²)	4.2
5.	% Wt variation	2.48
6.	Thickness	3.6
7.	% Friability	0.81
8.	Disintegration	15

IV. CONCLUSION

Herbs play a major role in the treatment than the allopathic medicines because of less side effects, low cost and easy availability. The research work done on that basis and the selected plants for the formulation was literally proved for the therapeutic use of antidiuretic purpose. From these studies it is concluded that tablet, which is more acceptable dosage form, able to solve the various complications which are associated with kidney stone. From the overall study and the physicochemical parameters, pre-formulation and evaluation we concluded that the prepared dosage form proved to be effective medication in the management of urolithiasis

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