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Research Article

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 solid piece 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 present study aims to formulate and evaluate polyherbal tablet for antiurolithiatic activity. The tablets were tested for the physical properties: such as appearance, weight variation, friability, tablets thickness, tablets hardness, and disintegration time. The homogenous precipitation method was used for in vitro antiurolithiatic activity. Macrotyloma uniflorum shown an inhibitory effect on calcium oxalate precipitation thus may be beneficial in the treatment of urolithiasis. This effect may be due to the presence of phytochemicals like polyphenols, flavonoids, and saponins, etc.

INTRODUCTION

The two bean-shaped kidneys are around the size of a fist each. Each side of your spine has one of them, and they are situated right below the rib cage. About a half cup of blood is filtered by healthy kidneys each minute, eliminating waste and surplus water to produce urine. There are two little tubes of muscle on either side of your bladder called ureters that carry urine from your kidneys to the bladder. Urine accumulates in your bladder.

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The urinary tract includes your kidneys, ureters, and bladder [1]. The most prevalent disorder affecting the urinar system is nephrolithiasis, also known as kidney stones. It affects around 12% of the global population and affects 600,000 people in the United States each year. It is caused by a crystalline concretion that passes through the genitourinary system after leaving the kidney[2].Preventing the recurrence of kidney stones is still a major concern for human health. A comprehension deeper of the mechanics underlying stone formation is necessary for the avoidance of recurrence of stone[3]. Kidney stones are of two types i.e. primary and secondary stones[4].Primary stones include calcium, oxalate, uric acid, cystine and xanthine[4,5]. The secondary stones are formed by urea splitting organisms such as proteus, pseudomonas, klebsiella species and are named as struvite stones[6]. Calcium oxalate stones are more prevalent than calcium phosphate stones among calcium-derived stones. Hypercalciuria is a key risk factor for calcium nephrolithiasis pathogenesis. The second most prevalent type of urinary stones are called struvite stones, which are composed of phosphate, ammonium, and magnesium. These stones are also known as infection stones because of their potential connection to specific urinary tract conditions. The third most prevalent kind of urinary stones are uric acid stones, which can be brought on by either acidic urine pH or hyperuricosuria. Cysteine stones, which rarely occur, are composed of cysteine and are caused by hereditary kidney transport abnormalities. Furthermore, melaminerelated kidney stone disease has recently been discovered in youngsters[7]. The common epidemiological risk factors for kidney stone formation are age, sex, location, family history, and body size[8,9]. The words ureterolithiasis, urolithiasis, and nephrolithiasis denote the various organ systems where the stones originated the

kidney, urinary and tract. ureter. respectively[10,11]. In all over the world, approximately 4-15% of the human populations suffer from urinary stone. As per the survey of National Health and Nutrition Examination in 2012, 7.1% of women and 10.6% of men were affected by kidney stone disease in United States[12]. As per the epidemiological studies, men are more affected as compared to women and are more prevalent between 20-49 ages in both sexes[13]. The recurrence rate at every year is 10-23%, in that 50% occured in 5-10 years and 75% occurred in 20 years. Approximate 12% population of India is suffering with urolithiasis every year with the high incidence states denote as "Stone belt", i.e.Gujarat, Maharashtra, Rajasthan, Delhi, Punjab, Haryana[14]. An increased risk of end-stage renal failure,[15] cardiovascular disease[16,17], diabetes, hypertension[18], and chronic kidney disorders [19] has been caused by kidney stones.



Symptoms :-

- Severe pain in the lower back and abdomen.
- Blood in the urine
- Pain on urination
- Nausea and vomiting
- Pink, red or brown urine
- Fever and chills if the infection is present.[20]

Horse gram

Family :-Legumes Botanical name :- Macrotyloma uniflorum (horse gram, also known as horse gram, kulthi bean, hurali, or Madras gram).



Fig. No:- 2 Horse Gram Biological source :-The seeds of the horse gram plant.

Morphology:-

Horse gram (Macrotyloma uniflorum) is an annual legume that belongs to the Fabaceae family. It typically grows as a bushy plant with a height ranging from 30 to 60 cm. The leaves are trifoliate, with each leaflet being oval-shaped and about 2-3 cm long. The flowers are small, purple, and pealike, arranged in clusters of 1-3 flowers.

Organoleptic Character:

Horse gram seeds are small, oval-shaped, and reddish-brown in color. The seeds have a unique, nutty flavor and a slightly bitter taste. The aroma of horse gram seeds is earthy and slightly grassy.

Chemical Constituents :-

- Horse gram is a rich source of flavonoid and shows antioxcidant activities.
- Flavonoid concentration varies in different parts of seed.

Many people today who suffer from kidney stones look for natural remedies and medicinal herbs to help to remove kidney stones and to treat the related symptoms. As with kidney stones, it is evident for horse gram. According to data on the National Center for Biotechnology Information website, fennel [21]. It is widely known for having strong astringent and diuretic properties. Kidney stones can be dissolved by the diuretic properties of horse gram water. Diuretics promote the body's excretion of water. Thanks to the antioxidant and detoxifying properties of horse gram, kidney stones can be washed away. . Perhaps, for this reason, the treatment of kidney stones is considered both traditional and alternative medicine^[22].

MATERIALS AND METHOD :-

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, crospovidone, Ginger 4extract, Vitamine B6, Magnesium sterate, etc. lactose and starch serve as diluen 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.

Horse gram used in kidney stones :-

Table 1. Composition Of Formulation Ingredient For Poly Herbal Anti-Urolithiatic Tablet

Sr.no	Ingredient used	Category	Quantity taken
1.	Horse gram (extract)	API	200 mg



2.	lactose	Diluent	150 mg
3.	Starch	Binder	100 mg
4.	Crospovidone	Disintegrant	20 mg
5.	Ginger extract	Digestive aid	10 mg
6.	Vitamin B6	Nutraceutical	5 mg
7.	Magnesium stearate	Lubricant	5 mg

Preparation of granules with wet granulation :-Herbal tablet containing horse gram seed powder

prepared by wet granulation method. Other ingredients like starch as a diluents, crospovidone as a disintegrating agent, starch as a binder magnesium stearate as a lubricant. Firstly weigh the required amount of API and all excipients. Then diluent starch and half amount of disintegrating agent crospovidone are mixed with API. And then these mixture take and add binder solution in it. And then these damp mass is screened using sieve and forms granules. Now these wet granules are dried in hot air oven at 60 degree celcious. After drying these granules are screened through a sieve to get uniform size granules. Then these granules mixed with magnesium sterate and crospovidone and then punch the granules in punching machine to give proper size and shape to the tablet.



Fig. No. 3:- Preparation of tablet Evaluation of pre-compressional blend :-

It is essential to determine the basic physical and chemical characteristics of the drug molecule as well as additional derived qualities of the drug powders prior to the formulation of the primary dosage forms. Pre-formulation is the process of characterizing the physicochemical properties of a pharmacological ingredient using biopharmaceutical concepts in order to create the best possible drug delivery system. The preformulation scientist needs to take the following things into account before starting the preformulation programs :

- The quantity of medication that is accessible.
- The drugs physicochemical characteristics are well understood.
- The compounds expected dose and therapeutic category.
- The type of knowledge that a formulation needs to or desires to have.
- Determination of granules parameter :-
- Angle of Repose
- Bulk density
- Tapped bulk density
- Compressibility index.

Angle of Repose :-

Angle of repose is an important parameter to study the Flow property analysis of any powdered formulation with respect to their frictional forces. Using the funnel method, the position of repose was determined by placing a carefully weighed blend with in a funnel. The "head of blend" or "apex of the heap" was the point at which the funnel tip barely touches due to the arrangement of the funnel height. It was possible for "the drug excipient blend" to freely flow to the surface through the funnel. The link between Powder Flow and Angle of Repose is displayed in Table 2. The following formula was used to get the angle of repose and the diameter of the powder cone:

Tan $\Theta = h/r$,



$\Theta = \tan(h/r)$

r- radius in cm.

Where, Θ – the angle of repose,

h- the height in cm and

Table 2: Relationship between angle of repose (θ) and powder flow.

Angle of repose	Type of flow
25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk density:-

The bulk density is defined as the ratio of bulk mass of the granule to the bulk volume. And it is denoted by ρb . The Bulk density is used to find out homogenecity of the given sample to be found. (Nagaich U, 2014)

Bulk density $(\rho b) = M/Vb$

Where, M is given as the mass of the sample,

Vb as the bulk volume.

Tapped bulk density :-

The following formula was used to determine tapped density.

Tapped density (Dt) = mass of powder (M) / tapped volume (Vt)

Tapped density was determined by tapping the graduated 10ml. measuring cylinder 100 times from a height of about 1.5 inch.

Compressibility index :-

The Compressibility index of the blends was determined by Carr's compressibility index. Table 3 shows grading of powders for their flow properties.

i.e. Carr's index = Tapped density-Bulk density × 100/ Tapped Density.

Flow
Excellent
Good
Fair To Passable
Poor
Very Poor
Very-Very Poor

Table 3: Grading of powders for their flow properties.

Evaluation parameters of tablets :-

Tablets were subjected to following evaluation parameters.

Odour, shape, color, taste was determined.

Tablet Hardness:-

The hardness was being evaluated by using Monsanto hardness tester.



Fig. No. 4 :- Monsanto Hardness Tester

Weight Variation Test:

Organoleptic properties:-



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 Weight by a greater percentage and none of the tablets deviate by more than double that Percentage.

Thickness :

Vernier caliper was use to evaluate tablet .



Fig. No. 5 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 taken out from apparatus and Once again they are weight. The friability is calculated by given formula.

Friability = Initial weight (Wi) – Final weight (Wf)/Initial weight (Wi) × 100

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.

RESULT AND DISCUSSION

Formulation of herbal anti-urolithiatic tablet:

Formulation prepare 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 5.

Sr. No.	Parameter	Result	Interpretation
1.	Angle of Repose	28.79	Good
2.	Bulk Density	0.45	Fair
3.	Tapped Density	0.51	Fair
4.	Compressibility Index	17	Fair And Passable

 Table no. 4 :- Evaluation Of precompression tablet

Table No. 5 Evaluation parameters of a tablet



Sr. No.	Parameter	Result
1	Colour	Brown
2	Oduor	Smelling like nuts
3	Taste	Slightly bitter
4	Hardness (kg/cm2)	4.2
5	% Wt. variation	2.48
6	Thickness(mm2)	3.6
7	% Friability	0.81
8	Disintegration	15

CONCLUSION :-

Herbs plays 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 forms, able to solve the various complications which are associated with kidney From the overall study stone. and the physicochemical parameters, pre-formulation and evaluation we concluded that the prepared dosage form proved to be effective medicament in the management of urolithiasis.

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