IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

FORMULATION AND EVALUATION OF GOKHRU GRANULES

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Abstract: Gokhru is a creeping annual (occasionally perennial) herb, and the entire plant, particularly the fruits, have traditionally been utilised for sexual health advantages. Since ancient times, Gokhru has been utilized as an aphrodisiac and diuretic as powder formulation. Recent research has revealed that it can help with musculoskeletal, cardiovascular, and other illnesses. Formulation of gokhru granules from the gokhru powder in order to impart the stability to the powder formulation has been demonstrated in the studies. The investigations are concerned with the formulation, evaluation of gokhru granules and the discussion of the results.

Index Terms **– Gokhru, Aphrodisiac, Diuretic, Wet Granulation.**

I. INTRODUCTION

Tribulus terrestris is an annual plant in the caltrop family widely distributed around the world. It is adapted to grow in dry climate locations in which few other plants can survive. It is native to warm temperate and tropical regions in southern Eurasia and Africa**.**
Tribulus terrestris (scientific name)
Zygophyllaceae family
Zygophyllales is an order of plants.
Kingdom: Plantae
It has long been used for puerperal disorders, digestive tonics, ulcers, fevers, wounds, and other ailments, as well as general debility.
Gokhru has aphrodisiac and diuretic properties, among other things.
Plants' powdered fruits are commonly used for the desired activity.

Figure 1: *Tribulus terrestris* plants

Chemical Constituent

Steroids, saponins, flavonoids, alkaloids, unsaturated fatty acids, vitamins, tannins, resins, nitrate potassium, aspartic acid, and glutamic acid are all found in *T. terrestris*.This plant contains steroidal saponins and diosgenin. It is high in calcium and proteins. Semi-drying oil, peroxides, diastase, traces of glucosides, resins, protein, and a substantial amount of inorganic materials are all found in dried fruits.An ethereal or alcoholic extract of the powdered fruits yields a crystalline residue in water that contains an alkaloid-like material precipitated from its solution by ammonia and linked with hydrochloric acid or alkaline chlorides.

Pharmacological action of Gokhru:

On sexual function:

Traditional Unani medication *Tribulus terrestris* (TT) is used to improve sexual performance. In the treated addicted group, *Tribulus terrestris* induced a significant increase ($P < 0.05$) in hormones, and oral consumption of TT may significantly counteract the loss of sex hormones and gonadotropins.

Diuretic effect:
The presence of potassium salts in high concentrations was credited with the diuretic effect, which was validated by the activity of *T. terrestris* in albino rats with little adverse effects.
Analgesic activity:
Analgesic activity shown by the extract of the whole dried plant when administered intraperitoneally to the mice

Need for the formulation of the Gokhru granules:
Mainly the powder formulation of gokharu is available in the market but the powder formulati0on has some marked drawbacks as follows:

- Bitter or unpleasant taste can't be masked in the powder formulation, hence there are patient compliance issue.
- Hygroscopic material can't be dispensed as powder
- Overdosing, and nonuniformity of content.

While the bitter and harsh taste of the powder can be disguised by employing flavouring ingredients like vanillin during the granulation. Granules has the better stability than that of the powder as less surface area is in contact with the atmosphere. The main advantage of granules over powder is that they are free-flowing, which promotes compressibility and content consistency. They can also be utilized to make tablets and capsules. As a result, gokhru granules must be formulated for greater patient compliance, stability, and content uniformity.

II. RESEARCH AND METHODOLOGY

- **Authentication of the Gokhru powder:**

Authentication of gokhru powder is done by determining the ash values i.e., total ash value and acid insoluble ash value and comparing the values with standard values as per the Indian pharmacopoeia.

a. **Determination of the total ash value:** First the weight of the empty crucible is taken. Then 2g of the raw material is weighed and taken in the crucible. The crucible is then placed in the muffle furnace at 500℃ to 600℃ till the material become white indicating total loss of carbon. Then the crucible containing the ash is placed in the desiccator for cooling and then weighed the total ash value is calculated by using the formula:

$$\textbf{Total ash value} = \frac{\text{weight of total ash}}{\text{weight of crude drug taken}} \times 100$$

b. **Determination of acid insoluble ash values:** 25 ml of the HCl is added to total ash and boiled gently for the 5 minutes**,** then 5 ml of hot water is added and the insoluble material is separated using the ashless filter paper. The ashless filter paper is then ignited and the acid insoluble matter is separated and acid insoluble ash value is measured using the following formula:

$$\textbf{Acid insoluble ash value} = \frac{\text{weight of acid insoluble ash}}{\text{Weight of crude drug taken}} \times 100$$

Fig 2: Determination of ash values

Observation:

	Observed value	Value according to the IP
Total ash value	**16**	**Not more than 15 percent**
Acid insoluble ash value	**1.7**	**Not more than 2 percent**

Table no: 1

- **Formulation of granules:**

Formulation of granules is done by wet granulation method at lab scale.
Ingredient used: gokhru powder (30 g), lactose (12g), Starch (4g), 5% w/v Acacia mucilage, Vanillin (0.2g)

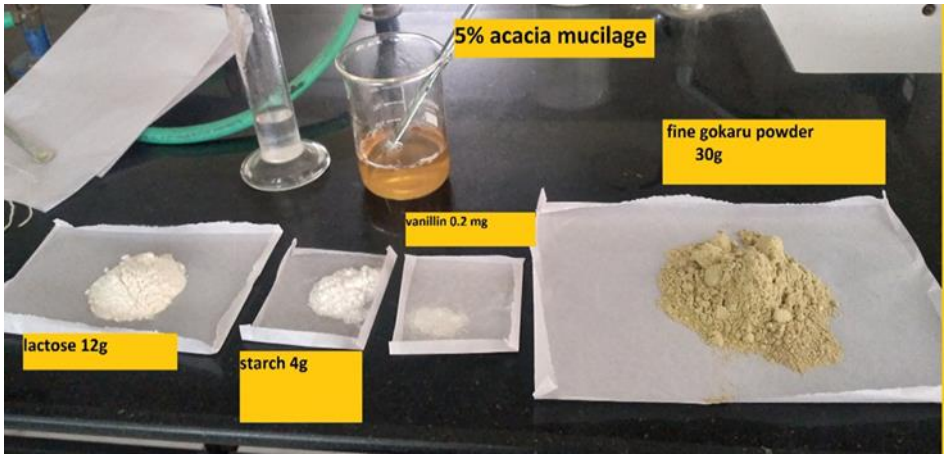

Fig 3: Ingredients used

Ingredients used	category
Gokhru powder	Active ingredient with the aphrodisiac and diuretic effect
starch	Disintegrant
Lactose	Diluent
Vanillin	Flavoring agent
5% acacia mucilage	Granulating liquid, binder.

Table no 2: Ingredient used

The formulation of granules done in the 3 major steps i.e.,

- Dry mixing
- Wet mixing
- Screening by using sieve no:12

i. **Dry mixing:** In this step all the ingredient are weighed separately and mixed using the mortar and pestle. The gokhru powder taken is first passed through the sieve no:100 to get fine powder.

Fig 4: Dry mixing

ii. **Wet mixing:** In this step the granulating liquid i.e., 5% w/v acacia mucilage is added to the above mixture. The granulating fluid is to be added till the formation of damp mass. The over wetting is to be avoided. For that the granulating liquid is added slowly with continuous mixing and checking whether the damp mass is formed or not. Over wetting leads to formation of fluidy mass and made hard to form granules.

iii. **Screening by using sieve no:12:** In this step the wet damp mass formed is screened through the sieve no: 12 in order to form uniform size granules. The granules are placed in the hot air oven for 1 hour at 60℃ for drying.

Fig 5: wet mixing

- **Quality control testing of granules:**
  Quality control testing of the granules is done by determining its flow properties, its moisture content and its size distribution (by sieving).

1. **Flow properties of granules:**

- **Bulk density**
  10g of granules was taken in a graduated measuring cylinder and tapped on a wooden surface. For the determination of bulk density, we use tap density volumetric flask in which we fell the 10g powder sample and calculate the bulk density by using following formula.

$$\textbf{Bulk density} = \frac{\textbf{Weight taken}}{\textbf{Bulk volume}}$$

- **Tapped density**
  Tap density of churna was determined after 50 tapping with the help of tap density apparatus. For the determination of tap density, we check the tap volume of churna and determine the ratio of weight taken and tap volume of churna sample. The following formula can be used for the determination of tap density:

$$\textbf{Tapped density} \quad \frac{\textbf{Weight taken}}{\textbf{Tapped volume}}$$

- **Angle of repose:**
  Angle of repose was determined by using funnel method. The powder was allowed to flow through a funnel fixed on a stand to form a heap. The height and the radius give the angle of repose.The angle of repose or critical angle of repose of granular material is the steepest angle of descent relative to a horizontal plane in which the powder is poured to create an angle from 0 degrees to 90 degrees.

  Angle of Repose (θ) = h/ r
  Where, h= height of the heap
  And r is the radius of the heap

Flow properties	Angle of repose values (degrees)
Excellent	25 – 30
Good	31 – 35
Fair	36 – 40
Passable	41 – 45
Poor	46 – 55
Very poor	>55

Table no 3: Angle of repose values

- **Compressibility / Carr's Index**
  The carr's index is done to detect the compressibility of the powder/granules It is name after the scientist Ralph J. Carr. This is calculated using the formula:

$$\textbf{Carr's Index} = \frac{\text{Bulk density (Tapped)} - \text{Bulk density (Untapped)}}{\text{Bulk density (Tapped)}} \times 100$$

- **Hausner's Ratio:**
  The formula used to determine Hausner's ratio we use bulk density and tap density ratio. For the determination of Hausner'ratio following formula: -

$$\textbf{Hausner's Ratio} = \frac{\text{Bulk density (Tapped)}}{\text{Bulk density (untapped}}$$

Carr's Index	Flow properties	Hausner's ratio
≤ 10	Excellent	1.00– 1.11
11 – 15	Good	1.12 – 1.18
16 – 20	Fair	1.19 – 1.25
21 – 25	Passable	1.26 – 1.34
26 – 31	Poor	1.35 – 1.45
32 – 37	Very poor	1.46 – 1.59
>38	Very very poor	>1.60

Table no 4: Flow properties according to the Carr's Index and Hausner's ratio

2. **Determination of size distribution of granules by sieving:**

1. Standard sieves set is selected (sieve no: 10, 22, 36, 44, 65, 80, 100,120) arrange them in such manner that the course remains at the top and finest at the bottom.
2. Weigh approximately 50g of sample, place the sample on the coarsest sieve no.10.
3. Fix the above sieves set on hand sieve shaker and shaken for 20 minutes. 4. Collect the Sample retained on each sieve into a paper, weigh all the ample.
5. Report the weights retained on each sieve in the table against corresponding sieve number. The percentage of the granules retained on any sieve is determined by following formula:

$$p_n = M_n/M * 100$$

where p_n is the percentage of granule retained on the n^{th} sieve and M_n is the granules retained on the sieve n.

Sieve no	Grade of powder
10	Coarse
20	Modular coarse
40	Moderately fine
80	Fine
120	Very fine

Table no 5: grades of powder according to British pharmacopeia

3. Determination of moisture content:

Moisture content is detected in order to determine the stability of the formulation. It is performed by placing the granules in the hot air oven at 60℃ for 60 min and the difference between the initial and final weight. Moisture content is calculated by using following formula:

$$MC = \frac{w-d}{w} \times 100$$

where w is the weight before drying and d is the weight after drying.

III. Result and Discussion

Parameters	Observation
Flow properties of granules	
Bulk density	0.4
Tapped density	0.5
Angle of repose	29.05°
Compressibility index	20
Hausner's ratio	1.25
Determination particle of size distribution	**56.25% of the weight of granules are retained on the sieve no: 14**
Determination of the moisture content	**Moisture content of the granules was found to be not more than 2%**

- The flow properties of granules are determined by determining the angle of repose, the value of the angle of repose for the gokhru granules was found to be in between 25 to 30 that indicates the granules have **good flow properties.** Hausners ratio also value was found to be 1.25 that indicates the good flow ability of the granules.
- Similarly, the compressibility index value for the gokhru granules was found to be 20 **indicating the fair compressibility of the granules.**
- Determination of the particle size distribution is done by sieving method using 40 g of gokhru granules **out of which 56.25%** granules retained on the sieve no:14 **so according to BP the powder grade of granules is coarse to moderately coarse.**
- The moisture content of the granules found to be not more than **2%.**
- The main problem was faced during the formulation was the over wetting of the powder mixture led to formation of the fluidly mass from which it was hard to get granules. Hence, wet mixing is the most important step in the wet granulation. Slow addition of the granulating liquid with the continuous mixing should be done.

IV. Acknowledgment: All the authors and co-authors would like to thank the principal of Allana College of Pharmacy, Pune and our guide Mrs. Sana Attar for guiding us during the project work. Also, would like to thank

all the laboratory staff for providing us all the requirement that are needed for the formulation and evaluation of the product.

V. Conclusion:

- The gokhru is commercially used as powder in the market. The studies done on the gokhru proves its diuretic and aphrodisiac activity.
- It was an attempt to formulate the gokhru granules in order to overcome the stability, content uniformity and patient compliance issue with powder formulation.
- Fine powder of gokhru passing through the sieve no 110 is bought from authentic sources and preformulation test have done for its authentication. The crude drug was found to be passing the limits.
- Formulation of granules done by the wet granulation method. After formulation the granules were stored. No effect on stability seen.
- The post formulation tests were done on the granules showing the formulation is the stable with good flow properties and better content uniformity.

REFERENCES:

1. Evaluation of standardization parameter of polyherbal digestive "churna" Abhishek Bhardwaj*, K.K.Jha, A. Panka, Anuj Agarwal, Bhuvnesh Singh, Neelanchal Trivedi Teerthankar Mahaveer College of Pharmacy, TMU, Moradabad, U.P. India.
2. https://chrominfo.blogspot.com/2020/12/advantage-of-granules-over-powders.html
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3609349/
4. REVIEW ON STANDARDIZATION OF HERBAL CHURNA Nitin V. Kokare1 *, Kiran A. Wadkar2, Manish S. Kondawar1 1Department of Quality Assurance, Appasaheb Birnale College of Pharmacy, Sangli, Maharashtra, India 2Department of Pharmacognosy and Phytochemistry, Appasaheb Birnale College of Pharmacy, Sangli, Maharashtra, India.
5. https://powderprocess.net/Powder_Flow/Moisture_Content.html
6. https://labmonk.com/particle-size-distribution-of-a-powder-sieving-method
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3609349/
8. https://en.wikipedia.org/wiki/Tribulus_terrestris
9. Indian Pharmacopoeia
10. British pharmacopoeia