An Ayurvedic Dosage Form “Gutika”: An Overview

Anjitha A.A,1, Dr. Shebina P Rasheed2,3, Dr. Prasanth S.S3, Sujith Unnikrishnan4, Anziya P.R5, Riya Babu6

1 Department of Pharmaceutical Analysis, Al Shifa College of Pharmacy, Perinthalmanna, Kerala, India.
2 Department of Pharmaceutical Analysis, Professor, Al Shifa College of Pharmacy, Perinthalmanna, Malappuram, Kerala, India.
3 Department of pharmaceutical Analysis, Head of the department, Al Shifa College of pharmacy, Perinthalmanna, Malappuram, Kerala, India.
4 Department of Pharmaceutical Analysis, Assistant Professor Al Shifa College of Pharmacy, Perinthalmanna, Kerala, India.
5 Department of Pharmaceutical Analysis, Al Shifa College of Pharmacy, Perinthalmanna, Kerala, India.
6 Department of Pharmaceutical Analysis, Al Shifa College of Pharmacy, Perinthalmanna, Kerala, India.

*Corresponding author’s E-mail: shebinprasheed@gmail.com; ORCID No: 0000-0001-7882-8412.

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ABSTRACT

The holistic medicinal approach is to restore health by understanding the underlying cause of the diseases. It makes an effort to address the underlying reasons while cleansing, bolstering body tissue, and harmonising physiological doshas to ensure full recovery. Medicines prepared in the form of tablet are known as vati and gutika. Gutika is an efficient ayurvedic formulation that maintain the balance of vata and Kapha doshas in the body. Gutika is standardize by various parameters like physiochemical parameters includes Ash value, Extractive value, LOD, physical parameters which include Hardness, Friability, Disintegration time, dissolution time and HPTLC fingerprinting, quantification of markers. In order to build a systematic strategy for the quality control parameters of gutika and to increase their public awareness, an effort is made to compile the physicochemical and biological assessment methodologies for gutika in this review.

Keywords: Gutika; HPTLC; LOD; Standardize; Physicochemical Parameter.

INTRODUCTION

Ayurveda is one of the oldest healing system of medicine. The principle of Ayurveda is based on that the diseases are causing because of Vata, Pitta and Kapha and can be treated by substances obtained from nature i.e. plant, minerals and metal, materials of marine origin etc. Drugs in Ayurveda are of two kinds’ use of single drug and use of combination of drugs (polyhedral formulation): Poly herbal formulation1 are the combinations of more than one herb to attain the desired therapeutic effects.

The alternate system of medicine, Ayurveda comprises of different types of formulations which includes Churnas2, Kashayam3, Taila4, Gutikas, and Bhasma5 etc. The major lacuna of Ayurveda is the lack of proper quality control for the safe use. Standardisation in Ayurvedic formulations deals with quality and purity of raw materials, quality contribute good quality finished product and storage product. The methods of manufacture and protocols for standardization of formulations mentioned in the classic texts of Ayurveda are quite premature, hence in the present era, changing trends have necessitated the establishment of standards for ayurvedic drugs and formulations using modern techniques of analysis is extremely important6. The equivalent words of gutikais portrayed by Achraya Sharangdhar are Gutika, Vati, Varti, Vataka, Panda or Pindi, Modaka7.

Gutika

An ancient and traditional ayurvedic dose form, gutika is a product of kalkakalpana, one of the five fundamental principles of ayurvedic sciences. They are very minute in size as compared to vati. According to Acharya Sharangdhar gutika is a synonym of vatikalpana which called as pills in modern dosage form. A key component of the ayurvedic pharmacy is gutika. Modern terminology refers to gutika as pills, and spheroïdes as agglomerates of fine powder or granules of bulk pharmaceuticals as well as excipients8.

Importance of Gutika

There are different advantages of this dosage form like:

![Figure 1: Different advantages of gutika](image)
Types of Gutika

There are two types of gutika

1. Agnisandhya vati

This gutika is prepared over a fire. Here, the sugar is heated to a high concentration and combined with additional powdered materials to resemble thick glue. The mixture is then moulded into a sphere.

2. Anagnisandhya vati

This sort of vati is made without the use of fire by pounding the other powdered components with sugar or guggul in the specified liquid medium until they are the right shape.

Preparation of Gutika

Methods can be divided into 2 categories:

With the use of fire

- The desired amount of base medication, such as jaggery, sugar, or guggul, is taken in a clean, suitable-sized wide-mouthed stainless steel container.
- The necessary amount of water is added, and the mixture is cooked on fire while being constantly stirred.
- When the syrup is ready, the fine medication powder is added in small amounts and well mixed until the required consistency is reached.
- The bulk is then formed into pills of the desired shape and size.
- The prepared pills are later dried in shade and stored in airtight containers.

Figure 2: Procedure for preparing gutika using fire

Without the aid of fire

- Guggul and jaggery, two common base medications, are thoroughly mashed in a mortar and pestle.
- Fine powder of drugs are then added.
- The medication mass is rolled into tablets of the specified size and shape once it has reached the necessary consistency.
- Then dried in shades and stored in airtight container.

Figure 3: Procedure for preparing gutika without fire

Mode of Action of Gutika

Before the medicine molecules in a tablet are absorbed into your bloodstream, the tablet will first breakdown in your stomach and intestines after you take it. It can travel throughout the body once it is in the blood to reach various organs and tissues.

Need for Standardization of Gutika

Evaluation of a drug means confirmation of its identity and determination of its quality and purity and detection of its nature of adulteration. Standardization is the process for the establishment of standard for a particular or drug.
Evaluation of Gutika

Organoleptic evaluation

Table 1. Parameters for organoleptic evaluation

<table>
<thead>
<tr>
<th>Characters</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>description</td>
<td>Provide a small description about the gutika</td>
</tr>
<tr>
<td>Colour</td>
<td>Identify the colour and matches the standard</td>
</tr>
<tr>
<td>Odour</td>
<td>Identify the odour and matches the standard</td>
</tr>
<tr>
<td>Taste</td>
<td>Check if the any odour</td>
</tr>
<tr>
<td>Size and shape</td>
<td>Check for the shape and size and matches the standard</td>
</tr>
<tr>
<td>Microscopic characters</td>
<td>If any vegetable part is used as ingredients</td>
</tr>
</tbody>
</table>

Physico-chemical analysis

1. Determination of foreign matter

Weigh the drug sample to be tested between 100 and 500 g, or the minimal amount recommended in the monograph, and then spread it out into a thin layer. The foreign object should be visible to the unassisted eye or through the use of a lens (6x). Calculate the percentage present after you separate, weigh, and weigh it.

2. Determination of Total Ash

About 2 to 3 g of the pulverised drug, precisely weighed, should be burned in a platinum or silica dish coated with tar until carbon-free, then cooled and weighed. If a carbon-free ash cannot be produced in this manner, burn the charred matter with hot water, collect the residue on ashless filter paper, add the filtrate, burn the residue and filter paper until dry, and ignite at a temperature no higher than 450°C. Determine the amount of ash in relation to the air-dried medication.

3. Determination of Acid Insoluble Ash

Using 25 ml of diluted hydrochloric acid, boil the ash for 5 minutes. Then, collect the insoluble material in a Gooch crucible or on ashless filter paper, wash with hot water, and ignite to a constant weight. Determine the amount of acid-insoluble ash in the drug's air-dried form.

4. Determination of Water Soluble Ash

In a Gooch crucible or on ashless filter paper, boil the ash for 5 minutes with 25 ml of water; collect the insoluble material; wash with hot water; and ignite for 15 minutes at a temperature no higher than 450°C. Calculate the water soluble ash by deducting the weight of the insoluble material from the weight of the ash. Determine the amount of water-soluble ash in relation to the air-dried medication.

5. Determination of Alcohol Soluble Extractive

In a closed flask, macerate 5 g of the air-dried medication in 100 ml of the necessary strength of alcohol for twenty-four hours, shaking frequently for the first six hours, and then letting stand for the last eighteen hours. Filter the filtrate quickly while taking steps to prevent solvent loss, evaporate 25 ml of the filtrate to dryness on a flat, shallow dish that has been covered with tar, and dry at 105°C to a constant weight and weigh. Determine the amount of extractive that is alcohol-soluble in relation to the air-dried substance.

6. Determination of Water-soluble Extractive

Follow the instructions for determining the alcohol-soluble extractive, but use chloroform water rather than ethanol.

7. Loss on drying

After precisely weighing the medication (to within 0.01 g), put about 10 g of it in a tar-coated evaporating plate (without first drying it). Drugs are weighed after 5 hours of drying at 105°C in a tarred evaporating plate. Continue drying and weighing every hour until the difference in weight between two subsequent measurements is no greater than 0.25 percent. When two subsequent weighs after drying for 30 minutes and cooling for 30 minutes in a desiccator show a variation of no more than 0.01 g, the weight is considered constant.

8. Determination of pH

The pH value of a liquid can be determined potentiometrically by means of the glass electrode, a reference electrode and a pH meter either of the digital or analogue type.

9. Weight variation test

Twenty pills were chosen at random and each one was weighed using a Shimadzu electronic analytical balance. The average weight was determined, and the following formula was used to determine the percentage of variance. Individual weights of two tablets should not deviate from the average weight by more than 5%, and none should deviate by more than 10%, per USP guidelines.

10. Hardness

Hardness is the measure of the mechanical integrity of the tablets. It is the force required to break the tablets in a specific plan. To endure the mechanical shaking of handling during manufacture, packaging, and shipping, tablets need to have a particular amount of strength or hardness and resistance. Pfizer’s tablet hardness tester was used to independently test the randomly chosen tablets. Between the hardness tester's jaws, the tablet was held vertically. By gradually applying more pressure to the tablet's edge while pressing the jaws with the aid of a hand, the tablet eventually broke. The reading was taken, and each group's average hardness was determined independently. The reading is given in Newton's or kg/cm² (N)
11. Disintegrating time

Disintegration is defined as that state in which no residue of the tablet remains on the screen of apparatus. This test determines whether the tablet disintegrates within a prescribed time when placed in a liquid medium under the prescribed experimental conditions. The tank of the disintegration apparatus was filled with distilled water up to the mark. 750 ml of distilled water in each of the 1000 ml beaker was taken. The timer of the instrument was set for 60 minutes. The temperature of water in beakers to 37°C and that of water in the main tank to 37°C was maintained. One tablet was introduced into each tube and added a disk to each tube. The assembly was suspended in the beaker containing water and the apparatus was operated. The time duration at which the tablet disintegrates was noted. As per set criteria by USP if 6 tablets are tested, all the 6 tablets should be disintegrated. 8

12. Friability

One of the often used tests to assess a tablet’s ability to withstand mechanical stresses at a high rate is to surface abrasion and chipping by spinning it in a rotating drum. The friability of the tablets is measured by the amount of weight loss following tumbling. The friability test is conducted in the Roche friability apparatus by taking 20 tablets. This consists of a plastic drum that revolves at 25rpm, dropping the tablets through six inches in the friabilitator to undergo shock, which is then operated for 100 revolutions. The tablets are reweighed. The tablet that lose less than 1.0% of the tablet weight are considered as acceptable. 8

13. Heavy metal determination

In this assessment, heavy metals like lead, chromium, copper, cadmium, nickel, zinc, cobalt, and bismuth are examined using standardised techniques, and the outcomes are compared to standardised values that are appropriate for health. 28

Table 2: List of heavy metal with permitted limit

<table>
<thead>
<tr>
<th>Test for heavy (permissible limit)</th>
<th>As per WHO/FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>10.0 ppm</td>
</tr>
<tr>
<td>Mercury</td>
<td>0.30 ppm</td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.30 ppm</td>
</tr>
<tr>
<td>Arsenic</td>
<td>10.0 ppm</td>
</tr>
</tbody>
</table>

14. Microbial contamination

The WHO’s most widely recognised method for counting all microorganisms in plant materials and herbal preparations is total viable count. The overall viable count ranges in every pharmacopoeia from 105 to 107 cfu/g. Spread plate technique is used to count all aerobic and anaerobic bacteria, which is followed by a 24-hour incubation period at 30-35°C. Spread plate technique is utilised in saboraud and dextrose agar is incubated at 30-35°C for 24 hours to count yeast and mould. The WHO has set a limit of 107 cfu/g for total aerobic microorganisms and 104 cfu/g for fungus and mould in plant materials. 33

15. Chromatographic Evaluation

HPTLC conditions Chromatographic separation was achieved on HPTLC plates precoated with silica gel 60 F254 (E. Merck) of 0.2 mm thickness with aluminum sheet support. Samples were spotted using CAMAG Linomat IV Automatic Sample Spotter (Camag Muttenz, Switzerland) equipped with syringe (Hamilton, 100 μL). Plates were developed in a glass twin trough chamber (CAMAG) pre-saturated with mobile phase. Scanning device was used CAMAG TLC Scanner II equipped with CATS 3 software. The experimental condition was maintained at 20 ± 2°C. Detection of piperine was possible after derivatizing the plates with anisaldehyde sulphuric acid reagent and photo documentation with CAMAG Reprostar 3 at 550 nm. 34

16. Test for pesticide residue

Table 3: List of pesticide residue with permitted limit

<table>
<thead>
<tr>
<th>Pesticide residue – organochlorine pesticide</th>
<th>Permissible limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>1.0mg/kg</td>
</tr>
<tr>
<td>HCH</td>
<td>0.3mg/kg</td>
</tr>
<tr>
<td>Endosulfan</td>
<td>3.0mg/kg</td>
</tr>
<tr>
<td>Alderin</td>
<td>0.05mg/kg</td>
</tr>
<tr>
<td>Organophosphorus</td>
<td>Permissible limit</td>
</tr>
<tr>
<td>Malathion</td>
<td>1.0mg/kg</td>
</tr>
<tr>
<td>Parathion</td>
<td>0.5mg/kg</td>
</tr>
</tbody>
</table>

17. Test for Aflatoxins

Table 4: List of Aflatoxins with permitted limit

<table>
<thead>
<tr>
<th>Test for Aflatoxins</th>
<th>Permissible limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>B2</td>
<td>0.1 ppm</td>
</tr>
<tr>
<td>G1</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>G2</td>
<td>0.1 ppm</td>
</tr>
</tbody>
</table>

Pharmacological Studies

Here, particular pharmacological activity of the samples is examined utilising animal models. GLP guidelines must be followed in the selection and care of the animals. Agents that induce specific disease states are used. This comprises research on a particular activity as well as toxicological and histological examinations of the gutika under investigation.

CONCLUSION

Gutika plays a significant role in the pharmaceutics of Ayurveda, despite the fact that many different formulation types are currently in use. This is because it has many benefits, including ease of administration, palatability, a convenient form for dispensing and transport, the ability to keep the medicine potent for a long time, and quick action.
Tables can be made in a variety of ways, and the effectiveness of the final product depends on the formulation's proper composition. Numerous gutika products became well-known in the pharmaceutical industry as a result of the availability of several formulation techniques, excellent patient compliance, and enormous potential. Additionally, it is emphasised that newer scientific and technological advancements must be made in order for a viable and adaptable dosage form with innovative performance and attributes to materialise.

REFERENCES


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