Review Article



An Ayurvedic Dosage Form "Gutika": An Overview

Anjitha A.A¹, Dr. Shebina P Rasheed^{2*}, 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: shebinaprasheed@gmail.com; ORCID No: 0000-0001-7882-8412.

Received: 05-02-2023; Revised: 24-03-2023; Accepted: 30-03-2023; Published on: 15-04-2023.

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.

QUICK RESPONSE CODE →

DOI:



10.47583/ijpsrr.2023.v79i02.008

DOI link: http://dx.doi.org/10.47583/ijpsrr.2023.v79i02.008

INTRODUCTION

yurveda is one of the oldest healing system of medicine. The principle of Ayurveda is based on that the diseases are causing because of Vata, Pita 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 Poly herbal formulation¹ formulation): 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 portraved by Achrava 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 Sharangdhargutika 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 spheroids 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

International Journal of Pharmaceutical Sciences Review and Research

Available online at www.globalresearchonline.net ©Copyright protected. Unauthorised republication, reproduction, distribution, dissemination and copying of this document in whole or in part is strictly prohibited.

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.

With the use of fire

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:





Figure 3: Procedure for preparing gutika without fire

Mode of Acton 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 adulteration⁹. Standardization is the process for the establishment of standard for a particular or drug.



Available online at www.globalresearchonline.net

Evaluation of Gutika

Organoleptic evaluation 10

Table 1. Parameters for organoleptic evaluation

Characters	Characteristics
description	Provide a small description about the gutika
Colour	Identify the colour and matches the standard
Odour	Identify the odour and matches the standard
Taste	Check if the any odour
Size and shape	Check for the shape and size and matches the standard
Microscopic characters	If any vegetable part is used as ingredients

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 monograph¹¹, and then spread it out into a thin layer. The foreign object ¹² 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 ^{13, 14}.

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^{13, 15}.

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 ^{13, 16}.

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^{13, 17}.

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 ^{13, 18}.

6. Determination of Water-soluble Extractive

Follow the instructions for determining the alcohol-soluble extractive, but use chloroform water rather than $ethanol^{13}$, ¹⁹.

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 ¹³.

8. Determination of pH

The pH value of a liquid can be determined potentiometrically by means of the glass electrode²⁰, a reference electrode and a pH meter²¹ either of the digital or analogue type²².

9. Weight variation test

Twenty pills were chosen at random and each one was weighed using a Shimadzu electronic analytical balance²³. 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 guidelines²⁴.

10. Hardness

Hardness²⁴ 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 tester²⁵ 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)⁶



Available online at www.globalresearchonline.net

11. Disintegrating time

Disintegration²⁶ is defined as that state in which no residue of the tablet remains on the screen of apparatus. This test determines whether the tablet disintegrate within a prescribed time when placed in a liquid medium under the prescribed experimental conditions. The tank of the disintegration apparatus ²⁷was 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 ⁶.

12. Friability

One of the often used tests to assess a tablet's ability to withstand mechanical stresses evaluates how resistant it 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 apparatus²⁸ by taking 20 tablets. This consists of a plastic drum that revolves at 25rpm, dropping the tablets through six inches in the friabilator 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 ⁶

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 ²⁹.

Table 2: List of heavy metal with permitted limit

Test for heavy (permissible limit)	As per WHO/FDA
Lead	10.0 ppm
Mercury	0.30 ppm
Cadmium	0.30 ppm
Arsenic	10.0 ppm

14. Microbial contamination

The WHO's most widely recognised method for counting all microorganisms in plant materials and herbal preparations is total viable count³⁰. The overall viable count ranges in every pharmacopoeia from 105 to 107 cfu/g. Spread plate technique ³¹ 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 agar³² is incubated at 30-35°C for 24 hours to count yeast and mould. The WHO has set a limit of 107 cfu/g



©Copyright protected. Unauthorised republication, reproduction, distribution, dissemination and copying of this document in whole or in part is strictly prohibited.

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 μ L). Plates were developed in a glass twin trough chamber (CAMAG) presaturated with mobile phase. Scanning device used was 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 nm³⁴.

16. Test for pesticide residue³⁵

Table 3: List of pesticide residue with permitted limit

Pesticide residue – organochlorine pesticide	Permissible limit
DDT	1.0mg/kg
НСН	0.3mg/kg
Endosulfan	3.0mg/kg
Alderin	0.05mg/kg
Organophosphorus	Permissible limit
Malathion	1.0mg/kg
Parathion	0.5mg/kg

17. Test for Aflatoxins ³⁶

Table 4: List of Aflatoxins with permitted limit

Test for Aflatoxins	Permissible limit
B1	0.5 ppm
B2	0.1 ppm
G1	0.5 ppm
G2	0.1 ppm

Pharmacological Studies

Here, particular pharmacological activity of the samples is examined utilising animal models. GLP guidelines ³⁷must 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. Tablets 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

- Parasuraman S, Thing GS, Dhanaraj SA. Polyherbal formulation: Concept of ayurveda. Pharmacogn Rev. 2014 Jul;8(16):73-80. doi: 10.4103/0973-7847.134229. PMID: 25125878; PMCID: PMC4127824.
- Singh B, Gupta V, Bansal P, Kumar D, Krishna CM. Pharmacological potential of polyherbal formulation, sudarshan churna–a review. International Journal of Ayurvedic Medicine. 2011;2(2):52-61.
- Renganathan S, Srivastava A, Pillai RG. Dhanwantaram kashayam, an ayurvedic polyherbal formulation, reduces oxidative radicals and reverts lipids profile towards normal in diabetic rats. Biochemistry and biophysics Reports. 2020 Jul 1;22:100755.
- 4. Bhende SV, Parwe S. Role of Ashwagandha taila matrabasti in the management of katigraha. International Journal of Ayurvedic Medicine. 2020;11(2):310-
- Pal D, Sahu CK, Haldar A. Bhasma: the ancient Indian nanomedicine. Journal of advanced pharmaceutical technology & research. 2014 Jan;5(1):4.
- Namboodiri KS, Puranik P, J N. Formulation and Standardization of Trivrutadi Gutika - An Ayurvedic Formulation. IJAM [Internet]. 2020 Mar. 24 [cited 2022 Sep. 25]; 11(1):50-4.
- Purnendu Panda Et Al: Tablet & Tableting In Ayurveda (Vati Kalpana)-A Review. International Ayurvedic medical Journal {online} 2016 {cited 2016 July}
- Anand N, Singh S, Kaur S, Sabharwal S, Singh D. AN ANCIENT DOSAGE FORM "GUTIKA": A REVIEW. Plant Archives. 2021;21(1):1777-83
- Cordella C, Moussa I, Martel AC, Sbirrazzuoli N, Lizzani-Cuvelier L. Recent developments in food characterization and adulteration detection: Technique-oriented perspectives. Journal of agricultural and food chemistry. 2002 Mar 27;50(7):1751-64.
- 10. Patil SC, Baghel AS, Kamble SB, Rudrappa HC, Shukla VJ, Mehta MD. Pharmacognostical and physicochemical profile of Abhayadi Gutika: An polyherbal formulation. Journal of Indian System of Medicine. 2022 Oct 1;10(4):221.
- 11. Tan TY, Lee JC, Yusof NA, Teh BP, Mohamed AF. Malaysian herbal monograph development and challenges. Journal of Herbal Medicine. 2020 Oct 1;23:100380.
- Shepherd JV. Standard procedures for foreign matter and moisture analytical tests used in cotton ginning research. Agricultural Research Service, US Department of Agriculture; 1972.

- Lohar DR. Protocol for testing of ayurvedic, siddha and unani medicines. Pharmacopoeial Laboratory for Indian Medicine, AYUSH. Ministry of Health and Family Welfare.
- 14. Thakkar N, Upadhyay K, Gupta K, Kumbar P, Parappagoudra MM, Patharkar JJ. Pharmaceutical analysis of shivagutika: An ayurved formulation. International Journal of Pharmaceutical Research. 2020 Apr;12(2):31-36.
- 15. Savarikar SS, Barbhind MM, Halde UK, Kulkarni AP. Pharmaceutical and analytical evaluation of triphalaguggulkalpa tablets. Journal of Ayurveda and Integrative Medicine. 2011 Jan;2(1):21-28.
- 16. Liu K. New and improved methods for measuring acid insoluble ash. Animal Feed Science and Technology. 2022 Jun 1;288:115282.
- 17. Mazumder A, Das B, Sarma D. Preparation of Pippalyadi Gutika Anjana and its standardization. Journal of Medicinal Plants. 2022;10(4):211-3.
- 18. Mazumder A, Das B, Sarma D. Preparation of Pippalyadi Gutika Anjana and its standardization. Journal of Medicinal Plants. 2022;10(4):211-3.
- Dudhal NM, Wadkar KA, Kondawar MS, Lokapure SG, Mane TN. Standardization of marketed ayurvedic formulation: Lavangadi vati. Journal of Pharmacognosy and Phytochemistry. 2018;7(5):1082-5.
- 20. Dole M. The theory of the glass electrode. Journal of the American Chemical Society. 1931 Dec;53(12):4260-80.
- 21. Moore EW. Determination of pH by the glass electrode: pH meter calibration for gastric analysis. Gastroenterology. 1968 Apr 1;54(4):501-7.
- 22. Clark JW. An electronic analytical balance. Review of Scientific Instruments. 1947 Dec;18(12):915-8.
- 23. <u>https://www.ayush.gov.in/docs/guideline-drug-development.pdf</u>
- 24. Goodhart FW, Draper JR, Dancz D, Ninger FC. Evaluation of tablet breaking strength testers. Journal of Pharmaceutical Sciences. 1973 Feb 1;62(2):297-304.
- 25. Fairchild HJ, Michel F. Pfizer tablet hardness tester. Journal of pharmaceutical sciences. 1961 Nov 1;50(11):966-9.
- Al-Gousous J, Langguth P. Oral solid dosage form disintegration testing—The forgotten test. Journal of pharmaceutical sciences. 2015 Sep 1;104(9):2664-75.
- 27. Donauer N, Löbenberg R. A mini review of scientific and pharmacopeial requirements for the disintegration test. International journal of pharmaceutics. 2007 Dec 10;345(1-2):2-8.
- Shafer EG, Wollish EG, Engel CE. The "Roche" friabilator. Journal of the American pharmaceutical association. 1956 Feb;45(2):114-6.
- 29. Suvarapu LN, Baek SO. Determination of heavy metals in the ambient atmosphere: A review. Toxicology and industrial health. 2017 Jan;33(1):79-96.
- 30. Clark FE. Agar-plate method for total microbial count. Methods of Soil Analysis: Part 2 Chemical and Microbiological Properties. 1965 Jan 1;9:1460-6.



Available online at www.globalresearchonline.net

©Copyright protected. Unauthorised republication, reproduction, distribution, dissemination and copying of this document in whole or in part is strictly prohibited.

- Buck JD, Cleverdon RC. The spread plate as a method for the enumeration of marine bacteria 1, 2. Limnology and Oceanography. 1960 Apr;5(1):78-80.
- 32. Odds FC. Sabouraud ('s) agar. Journal of Medical and Veterinary Mycology. 1991 Nov 1;29(6):355-9.
- Gupta V, Iyer K, Shah S, Patil S. Standardization and detailed aspects of Marichadi Gutika. Journal of Medicinal Plants. 2019; 7(4):274-7.
- 34. Jain V, Jain T, Saraf S, Saraf S. HPTLC method for routine quality control of Ayurvedic formulation Drakshadi gutika. Asian Journal of Pharmaceutical Analysis. 2013;3(4):111-4.
- 35. Lehotay SJ, Cook JM. Sampling and sample processing in pesticide residue analysis. Journal of agricultural and food chemistry. 2015 May 13;63(18):4395-404.
- Abbas HK, Shier WT, Horn BW, Weaver MA. Cultural methods for aflatoxin detection. Journal of toxicology: Toxin reviews. 2004 Jan 1;23(2-3):295-315.
- 37. Stevens W. Good clinical laboratory practice (GCLP): the need for a hybrid of good laboratory practice and good clinical practice guidelines/standards for medical testing laboratories conducting clinical trials in developing countries. Quality Assurance. 2003 Apr 1;10(2):83-9.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

For any questions related to this article, please reach us at: globalresearchonline@rediffmail.com New manuscripts for publication can be submitted at: submit@globalresearchonline.net and submit_ijpsrr@rediffmail.com



©Copyright protected. Unauthorised republication, reproduction, distribution, dissemination and copying of this document in whole or in part is strictly prohibited.