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A REVIEW ON VATI KALPANA WITH SPECIAL REFERENCE TO GUDA VATIKA-A CHEWABLE TABLET IN AYURVEDA

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ABSTRACT

The recent years in *Ayurveda* has been the years of advanced pharmaceutical studies to develop new dosage forms with enhanced safety, efficacy and convenience in terms of palatability, portability and shelf life. The drug delivery system in *Ayurveda* involves various dosage forms which aims to provide therapeutic amount of the drug at the site of action, throughout the period of therapy and then to maintain the desired drug concentration. *Vati Kalpana*[1] or the tablets in *Ayurveda* is one among the best and advanced form of medicine which can be incorporated with modern technologies to facilitate enhanced efficacy. In *Vatikalpana* different medicinal substances are used to make tablets (*vati*) and pills (*gutika*) either by cooking the powder of a drug with jaggery, sugar or *guggulu* or without cooking. There are numerous formulations in *ayurveda* literature which are enlisted under the roof of *Vatikalpana*. *Acharya Sharangdhara* also has mentioned various *Vatikalpanas* in the treatment if various diseases. One of them is ***GudaVatika***(गुड वटिका) which is explained in the seventh chapter of *Madhyama Khanda*. Here is an attempt to prepare this formulation in various methods and to standardize the same.

Keywords: GudaVatika, Vati, Chewable tablets

Introduction: *Ayurveda* is a treasure of various dosage forms which has been gifted from our acharyas as a means to achieve the basic target of *Chikitsa*. The success of this achievement can be attributed to quality of raw materials as well as the selection and making of the dosage form. *Vati*[1] or tablets has been one of the most convenient and palatable forms of oral administration of medicines, keeping the shelf life intact and also easy targeting of the site of action, which can be modified by altering the disintegration time.

Sharangadhara Samhitha is an important treatise in *Ayurveda* which is one of the *LaghuTrayis* and forms the basis of Ayurveda pharmacology. The book explains the various dosage forms in detail including the *Vatikalpana*[1]. There are many simple formulations explained by the author, which can be adopted in day-to-day clinical practice. One among them is *GudaVatika*[3] which is indicated for *Shwasa* and *Kasa*. The uniqueness of his formulation is that it is a chewable form of medicine.

Review on Vati Kalpana:

Definition:

Vati[1]: *Gutika/ Vati* is defined as a pill made up of powdered drugs by triturating them with specified liquids and rolling into round mass. It is also considered as the outcome of *kalka kalpana.*

A Tablets is defined as the solid unit dosage form of medicament or medicaments with suitable excipients. It comprises of a mixture of active substances and excipients, usually in powder form, pressed or compacted into a solid dose[3].

***Synonyms*[2]**: The synonyms of *Vati* described in *Sarangadhara samhitha* are *Gutika, Vati, Modaka, Vatika, Pindi, Guda, Varti* etc.

***History and development of tablet manufacturing*[4]**:

- Around 4,000 years ago, medicines were generally liquid preparations. Pills date back to roughly 1500 BC, first referenced in ancient Egyptian. In this period medicinal plants were reduced to powders, and other active ingredients, and then be mixed with certain substances which would bind the powder, then little balls, or pills, were made manually. Early ingredients of pills included saffron, myrrh, cinnamon, tee resins and many other botanicals.
- a carved stone in the British Museum shows a Roman pill-making equipment
- 1843, English scientist, William Brockedon invented a pill form where powder was placed in a tube and then compressed with a mallet, until solidified.
- Later added with disintegrating agents to aid tablet dispersion once swallowed and also binders, such as starch and cellulose.

***Types of Vati*[3]**: There are two types of Vati, based on the method of preparation as explained in *Ayurveda* Pharmaceutical texts, they are (i) *AgnisadhyaVati* and (ii) *AnagnisadhyaVati.*

***Agnisadhya Vati*[3]**: *Agni Sadhyavati* is prepared when sugar or Jaggery*(guda)* or *Guggulu* is made into *Paka / lehya* on mild fire then the powders of the ingredients are added to it to be rolled into circular pills.

Anagnisadhya Vati[3]: In case of *AnagnisadyaVati*, the powders of ingredients are either pounded with *Guggulu* and *guda*, after adding any suggested liquid or honey to prepare *vati* or triturated with any suggested liquid or honey to be made into *vati*.

General method of preparation of Vati[5]: The raw materials/drugs of plant origin are dried and separately made into fine powders, the minerals mentioned are made into *Bhasma* or *Sindura* and *Parada* and *gandhaka* triturated to form *Kajjali* form unless otherwise mentioned according to the formulation. These are taken in a *Khalvayantra* and triturated to form a homogenous soft paste with the prescribed fluids added in succession specific to the formulation. *Sugandhadravyas* are added and grounded again. The mixture is to be made into a paste so that, it should not stick to the fingers when rolled in between them. Pills may be dried in the shade and collected and stored in airtight and sterilized containers.

Ratio of essential drugs in the preparation of *vati*[6]*:* The ratio the essential ingredients in relation with fine powder of medicinal drugs is as follows.

- *Sita* – 4 times
- *Guda* – 2 times
- *Guggulu and madhu* – equal
- *Jala* or any other liquid preparation – 4 times

Dose of Vati Kalpana[7]- 1 *karsha* is the general dosage of the vati. *Anupana* for *vati*[4]: *Vati* is administered along with water, honey, milk or any other suitable liquid preparation.

Saveeryataavadhi of vati[7]- Two year is the **shelf life** of pills prepared from herbal drugs and indefinite time period for the pills made of mineral drugs.

Types of tablets[4]**:**

- **A. Fast Dissolving Tablet [FDT]:** Fast dissolving tablets are designed to first disintegrate and then swallowed without the need of water. Its advantage is ease of administration; rapid dissolution and absorption of the drug and increased bioavailability.
- **B. Rapid Disintegrating Tablets - [RDT]:** Speedy disintegrating tablet is advantageous in the administration to the patients who cannot swallow, such as the elderly, bed-ridden patients, patients affected by renal failure and patients who refuse to take tablets such as pediatrics, geriatric and psychiatric patients. It is used to achieve increased bio-availability, convenience for administration

especially for travelers and busy people and give good mouth feeling and prevent risk of choking and suffocation, thus providing improved safety.

Granulation[8]: Granulation is a size enlargement process, in fine or coarse particles converted into physically stronger and larger agglomerates having good flow property.

The advantages are:

- better compression characteristics and uniformity
- prevent segregation of the blend components
- improve content uniformity
- eliminate excessive amounts of fine particles.

Size of granules has a size range of 0.2 to 4. 0 mm, depending on their utility. Size of the granules depends on the quantity and feeding rate of granulating liquid.

Types of Granules[4]**:**

A. **Effervescent Granules:** Effervescent forms of granules substitute liquid forms because the active ingredients which are not stable in liquid form are often more stable in effervescent form. The administration is easy in children, who feel difficulty swallowing capsules or tablets.

The significance being:

- They help to mask the bad taste of certain drugs,
- help to avoid the gastric side effects of certain drugs,
- shorten the drug absorption rate with quicker therapeutic effect
- physical properties are appealing to consumers.

B. Rapid Release Granules[4]**:** Rapid release granules benefit the class of compounds where absorption is highly dependent on the dissolution of the drugs in the GI tract. Rapid release granules enhance the dissolution of bioactive compounds to increase the bioavailability of poorly water-soluble compounds.

Factors that influence the choice of manufacturing process used during tablet formulation:

In general, the choice of formulation process employed during tablet manufacture is dependent upon such factors as:

- Compression properties of the Active Pharmaceutical Ingredient (API)/ drug substance.
- Physical and chemical stability of the API during the manufacturing process.
- Particle size of the formulation ingredients.
- Availability of the necessary processing equipment and Cost of the manufacturing/formulation process

Manufacture of the tableting blend[4]: In the tablet pressing process, if a sufficiently homogenous mix of the components cannot be obtained with simple blending processes, the ingredients must be granulated prior to compression to assure an even distribution of the active compound in the final tablet. Two basic techniques are used to granulate powders for compression into a tablet:

Steps Involved in Tablet Formulation/ Procedure for Manufacturing Tablets[9]:

1. **Sizing:** Formulation ingredients must be in finely divided form
2. **Powder blending:** Powders are mixed with excipients using a suitable blender to obtain a uniform and homogeneous powder mix.
3. **Granulation:** Here small powder particles are gathered together into layers and permanent aggregates to render them the free-flowing states.
4. **Drying and dry screening:** Screened wet granules need to be dried for a particular time period in tray dry or fluid bed dryer at controlled temperature not exceeding 55^0C. Dried granules are screened through the appropriate mesh screen.
5. **Tablet compression:** This step involves the compression of granules into a flat or convex, round, oblong, or unique shaped, scored or unscored tablets; engraved with an identifying symbol and/ or code number using tablet press.
6. **Coating:** Tablets and granules are coated with coating solutions, if there is need to mask the unpleasant taste/odour of some drug substance,to increase the aesthetic appeal and as well as to modify the release or control the release of drug substance from tablets.
7. **Dispensing:** Each ingredient in the tablet formula is weighed and accurately dispensed as per dose. This is one of the critical steps in any type of formulation process and should be done under technical supervision.

Slugging: The powder of the ingredients is compressed into soft large flat tablets of about an inch in diameter is called Slugging. Then the slugs are broken by hand or milled to produce granules of required size. Then lubricants are added and the granules are then compressed into tablets.

Roller Compaction*[8]*: In this method, the ingredients are mixed and are passed between high- pressure the oppositely rotating rollers compress the powder at 1-6 tons of pressure. The compacted material is then milled to a uniform granule size and compressed into tablet after addition of lubricants.

Below table depicts difference between dry and wet granulation methods after milling and mixing the ingredients:

Wet Granulation	**Dry Granulation**
Preparation of binding solution and mixing with the ingredients to form wet mass	Primary compression to prepare Slugs
Screening of the wet mass through suitable mesh to obtain wet granules	Screening of slug
Drying and Screening of wet granules through suitable mesh to obtain dry granules	Mixing with lubricants and disintegrating agents
Mixing dry granules with lubricants and disintegrants	Tablet compression
Tablet compression	

Table 1.Difference between wet granulation and dry Granulation

Hot melt extrusion[8]: Hot melt extrusion is utilized to enable delivery of drugs with poor solubility and bioavailability. The process involves the application of heat, pressure and agitation to mix materials together and 'extrude' them through a die. The extruded particles are then blended and compressed into tablets or filled into capsules.

Granule lubrication[8]: After granulation, a final lubrication step is used to ensure that the tableting blend does not stick to the equipment during the tableting process, with a powdered lubricant, such as magnesium stearate or stearic acid.

Excipients used in Manufacture of the tablets[9]: The excipients can include diluents, binders or granulating agents, glidants (flow aids) and lubricants to ensure efficient tableting, disintegrants to promote tablet break-up in the digestive tract, sweeteners or flavours to enhance taste pigments to make the tablets visually attractive or aid in visual identification of an unknown tablet. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or to enhance the tablet's appearance.

Tablet compaction simulator[9]: This is a computer controlled device that can measure the punch positions, punch pressures, friction forces, die wall pressures, and sometimes the tablet internal temperature during the compaction event. Optimised standardized formulation can be performed by Numerous experiments with small quantities of different mixtures using this equipment.

Tablet presses[9]: The Ideal Tablet presses must have the following

- allow the operator to adjust the position of the lower and upper punches accurately,so that the tablet weight, thickness and density/hardness can each be controlled. This is achieved using a series of cams, rollers, and/or tracks that act on the tablet tooling (punches).
- Have Mechanical systems incorporated for die filling, and for ejecting and removing the tablets from the press after compression.
- Be required to be easy to clean and quick to reconfigure with different tooling

These machines range from small, inexpensive bench-top models that make single-station presses, with only around a half-ton pressure, to a large, computerized, industrial models (multi-station rotary presses) that can make hundreds to millions of tablets an hour. Common manufacturers of tablet presses include Natoli, Stokes, Fette Compacting, Korsch, Kikusui, Bosch-Manesty, B&D, PTK, Sejong, IMA and Courtoy.

There are 2 main standards of tablet tooling used in pharmaceutical industry: American standard 'TSM' and European standard 'EU'.Modern tablet presses reach output volumes of up to 1'700'000 tablets per hour.

Tablet coating[11]: An enteric coating is used when the active ingredient of a tablet is sensitive to acid, or is irritant to the stomach lining.Enteric coatings are also used for medicines that have unpleasant taste and those which can be negatively affected by taking a long time to reach the small intestine where they are absorbed.The coating used is resistant to stomach acid and dissolves in the less acidic area of the intestines. Tablet coatings are also useful to extend the shelf-life of components that are sensitive to moisture or oxidation and also can enhance brand recognition.

Tablet coatings are polymers and polysaccharide based, with plasticizers and pigments included.

Pill-splitters: It is sometimes necessary to split the tablets into halves or quarters. Tablets are easier to break accurately if scored, but there are devices called pill-splitters which cut unscored and scored tablets.

TABLET MANUFACTURING EQUIPMENT/ MACHINES:

Common equipment used in pharmaceutical tablet manufacturing include[8]:

1. **Size reduction equipment/ communition equipment** e.g.:hammer mill, end-runner mill, edge-runner mill, cutter mill and ball mill.
2. **Weighing balance/ balances** e.g:bulk weighing balance (weighs in kilogram), electronic weighing balance (weighs in grams and milligrams).
3. **Mixing equipment** e.g.: pneumatic mixers (air-mix mixer or air-driven mixer), diffusion/ tumbling mixers, convective mixers

4. **Granulators** e.g. rotating shape granulators, mechanical agitator granulators (e.g., ribbon or paddle blender, sigma blade mixer, planetary mixer, orbiting screw mixers), high-shear granulator, fluidized bed granulator, dry granulator etc.
5. **Dying equipment** e.g. spray dryer, rotary dryer, fluidized bed dryer etc.
6. **Tabletting machine** – single punch tablet press and multi-station/ rotary tablet press
7. **Quality control equipment** e.g., disintegration equipment or Erweka multiple unit disintegrating apparatus, USP Dissolution Tester, Tablet Hardness Tester, Tablet Thickness Tester, Tablet Friability Testers etc.
8. **Coating and polishing machines for coated tablets** e.g.: standard coating pan, perforated pan, fluidized bed/ Air suspension coating system etc.
9. **Packaging machines** e.g.: blister packaging machines, strip packing machine, aluminium foil packaging machine, etc

Chewable tablets[12]: Chewable tablets are a widely used **dosage form** for the delivery of pharmaceutical and nutraceutical. Chewable tablets is defined as tablets that are designed to be processed by chewing to facilitate release of the active ingredient(s). As a dosage form, chewable tablets have the advantages of conventional tablets in terms of manufacturability, dosing accuracy; portability, and long-term stability. Additionally, chewable tablets facilitate swallowing as the product is initially broken down into particles in the oral cavity. This is a useful patient-centric advantage for populations such as pediatrics for whom swallowing of conventional tablets is a concern .As water is not required for their administration, there is a benefit of convenience when dosing.

Chewable tablet guidance by FDA:

Hardness	Less than 12 kp (higher is allowed if justified)
Disintegration	Same as immediate release tablets
Dissolution	Same as immediate release tablets. Does not apply to modified chewable modified release products.
Others	Chewing difficulty index has to be referred
	Size shape thickness friability should be within normal limits
	Specific to individual product.

Table 2. Guidance by FDA on chewable tablets.

Advantages of Chewable Tablets[13]:

- The tablets are not expected to swallow intact.
- Improved patient acceptance -provides proper unit dosage form of medication which can easily be administered to children or to the elderly who have difficulty in swallowing and also provides pleasant taste
- Better bioavailability through bypassing disintegration(that increase dissolution)
- Need no water for swallowing
- Possible to use as a substitute for liquid dosage formswhere rapid onset of action is essential
- Faster absorption of drug
- Product distinctiveness through marketing prospective
- The large size of the dosage form is difficult to swallow. In such cases chewable tablet offers advantages over it
- Effectiveness of therapeutic agent is improved by thereduction in size that occurs during mastication action in the mouth before the tablet being swallowed.

Materials and Methods: *Guda Vatika* is a simple tablet with only 4 ingredients viz, *Shunti, Shiva, Musta and Guda.* As the proportions or quantity is not mentioned in the reference; the *anukta mana*[5] for preparation of *Vati* i.e 2 parts of *Guda* and 1 part of the *churna* was taken.

Thus ,the ingredients and quantity were taken as enlisted below:

Ingredient	Quantity
Guda	6 parts.
Shunti –Zingiber Officinale	1 part
Shiva-Terminalia Chebula	1 part.
Musta-Cyperus rotendus	1 part

Table 3.Ingredients of Guda vatika

Materials required: Stove, *KhalwaYantra,* Vessels, Cloth.

Samples were prepared in both *Sagni* and *Niragni* method.

Method of preparation:

1- *Sagni* method –

- *Guda*(jaggary) is taken in a clean vessel of measured quantity is added with sufficient quantity of water and heated over mild fire with frequent stirring.
- When *paka* of three thread consistency is obtained the ingredients are added and stirred well.
- Once a homogenous mixture is obtained, the mixture is rolled into pills.
- The prepared pills are dried under shade and stored in air tight containers.

Fig 1.*Guda vatika* prepared in *Sagni* method

2- *Niragni* method –

- The drugs are powdered and filtered through mesh no.120 and taken in the required quantity.
- *Guda(jaggery)* is pounded well and mixed with the powdered drugs.
- Mixture is triturated well to get a homogenous drug mass.
- The mixture is rolled into pills.
- Pills are dried and stored in air tight containers.

Fig.2.*Guda vatika* prepared by *Niragni* method

Precautions :

- In *Sagni* method, consistency of *Guda Paka* should be monitored carefully.
- In *Niragni* method, trituration should be continued till all the ingredients become a homogenous mixture.
- Powder of the ingredients should be very fine in both of the ingredients.

Discussion:

Guda Vatika is one of the specific formulations in Ayurveda which is explained as Chewable form of *Vati Kalpana*. The concept of chewable tablets in Ayurveda has wide prospects. Hence this formulation was taken up for study. The explanation of the formulation in the treatise includes the ingredients and indication and the administration method. The method of preparation is not mentioned which was the basic reason for trying the formulation in two different methods as per the classical reference. While preparing the formulation *sagni* method was more promising and easy with respect to rolling of pills and quality of the pills as an end product. Whereas the *niragni* method requires more time and pills rolled were fragile. Also the surface was not uniform and smooth. The pills prepared with *sagni* method was tastier and palatable with better dissolving experience in the mouth while chewing.

Conclusion:

Gudavatika explained in *Sharangadhara samhitha* is a formulation which can be easily prepared and administered in *Kasa* and *shwasa*. The ingredients and in chewable form makes it even more acceptable in terms of portability, administration, absorption and assimilation. Concept of Chewable tablets and lozenges in *Ayurveda* has immense scope in terms standardization and development of standard operating procedures to facilitate large scale production. Clinical and other research studies in this aspect is the need of the hour which can facilitate these kinds of formulations to be modified as lozenges. These projects can bring about remarkable changes in the field of pharmacy in *ayurveda* to make the dosage forms more palatable without compromising the efficacy.

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