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Development and Evaluation of Herbal (Guduchi) Hard Candy Lozenges

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ABSTRACT:-

Lozenges are the solid dosage form which are intended to slowly dissolved in the mouth. Lozenges were developed in 20th century and are still under commercial production. This dosage form can be adopted for local as well as systemic therapy and a wide range of active ingredient can be incorporated in them.

Guduchi is an herbal drug used in treatment of digestion, diabetes and inflammation. In the present study an attempt has been made to prepare and evaluate the sugar based medicated guduchi lozenges to improve bioavailability and increase patient compliance especially for those patients who have difficulty in swallowing. Lozenges/troches were prepared using sugar as base. The guduchi lozenges were prepared by heating and congealing method on laboratory scale.

All formulations prepared were subjected to various physicochemical parameters like hardness, weight variation, friability, etc. This Lozenges are completely herbal containing no synthetic ingredient is used in the preparation and it is economical.

Keywords:- guduchi, diabetes, inflammation, bioavailability, troches, congealing.

Introduction:

They are also called a troche or pastilles. The word "Lozenge" is derived from French word "Losenge" which indicates a diamond shaped geometry with four equal sides. Lozenges are flavoured medication dosages that are meant to be retained in the mouth or pharynx and typically contain one or more medications in a sweetened base. They have a regional or systemic impact. They are typically designed to hold in the oral cavity, are flavor-infused solid unit dosage forms for medication delivery, are moistened with saliva, and dissolve completely over time. It is utilised for both systemic actions like pain relief and antacid as well as local action of medications in the mouth and pharynx for sore throat or pharyngitis. Lozenges make it simple to deliver medications with high doses. The most popular method of drug delivery is by the oral route since it has several benefits, including simplicity of intake, discomfort avoidance,

The majority of lozenge preparations can be purchased without a prescription. Analgesics, anaesthetics, aromatics, astringents, corticosteroids, decongestants, and demulcents were among the medications frequently used in lozenges. Depending on the requirements of the individual patient, compound lozenges can be made from a single ingredient or several.

As a general tonic with antiperiodic, antispasmodic, antiarthritic, antiallergic, and anti-diabetic qualities, guduchi is frequently employed in Ayurveda and veterinary medicine. The primary purpose of guduchi is to strengthen the immune system and the body's resistance to illnesses. Guduchi aids in enhancing bodily immunity. Guduchi's antioxidant and antibacterial qualities cleanse the body of AMA poisons and protect it from a variety of microbiological ailments. Additionally, it cures urinary tract infections and enhances liver and kidney function.

History of Lozenges:

Around Egypt's Twentieth Dynasty in 1000 BC, candies composed of pure honey and flavoured with the juice of citrus fruits, various herbs, and certain priceless spices were used to relieve the throat. Some doctors in the 19th century used morphine and heroin made from opium, which has antitussive properties. At the time, the most popular formulations were Smith Brothers Cough Drops, which were first advertised in 1850, and

Luden's, which were created in 1880. However, later worries about the possibility of opioid dependence and addiction led to the development of alternative medications

Classifications at Lozenges:

Lozenges can be classified into various Classes based on various methods like

- A. According to the site of action.
- B. According to texture and composition.

A According to the site of action:

a) local effects:
ex: - Antiseptics, Antibiotics, Decongestants

b) systemic effects:
ex:- Vitamins, Nicotine

B. According to texture and composition:

- a) chewy or caramel based medicated lozenges.
- b) compressed-tablet lozenges.
- c) soft lozenges
- d) Hard Lozenges
 - centre filled Lozenges

a) chewy or caramel based medicated lozenges: -

These are the dose forms where the medication is combined with a caramel base and chewed as opposed to being dissolved in the mouth. The majority of formulations are based on the glycerinated gelatine suppository formula, which includes gelatin, glycerin, and water. To mask the bitter taste of the glycerine, these lozenges, which are sometimes very fruit-flavored, may have a mildly acidic flavour.



b) Compressed tablet lozenges:-

When the active ingredient is heat sensitive, compressed lozenges can be made. Compressed lozenges are flavor-enhanced, medicated solid dosage forms.



c) Soft lozenges: -

Either chewing or gradual drug release in the mouth is intended for them. They can be produced using PEG 1000 or 1450, chocolate, or a base of sugar and acacia. While some recipes for soft candies can also include silica gel and acacia.

In order to prevent components from settling to the bottom of the mould cavity during cooling, silica gel is employed as a suspending agent and acacia is utilised to add texture and smoothness. Only ingredients that can withstand heat should be included in the formulation, which calls for a heating process at roughly 50 °C.



d) Hard Lozenges:-

These are mixtures of sugar and other carbohydrates that are amorphous (not crystalline) or glassy in nature. They may also be thought of as sugary solid syrups. Hard candy lozenges should weigh 1.4–4.5 g and have a moisture level of between 0.5-1.5%. These shouldn't disintegrate; instead, they should dissolve or erode gradually and uniformly over a period of 5 to 10 minutes. The main body of these hard candy lozenges has a soft or liquid centre.



The hard candy lozenges further classified into following:

listed below are center-filled hard lozenges of the following varieties:

Sl. No	Type of centre filled lozenges	Composition	Fill weight (%)
1.	Liquid fill	Fruit juice, sugar syrup, hydro alcoholic solutions or Sorbitol solution.	10-20
2.	Fruit center	Jams and jellies whose viscosity has been modified with corn syrup or liquid sucrose	20-25
3.	Paste center	Granules and crystals formulated as paste	40
4.	Fat center	Medicament or flavor being suspended or dissolved in hydrogenated vegetable oil	25-32

Advantages: -

1. Both paediatric and elderly patients can easily receive it.
2. It has a pleasant taste and will prolong the amount of drug that needs to be in the mouth to cause local activity.
3. Drugs may be absorbed systemically through the buccal cavity.
4. It requires little in the way of equipment to prepare.
5. Sweeteners and flavours used in the formulation can mask the taste of the drugs.
6. It can be administered to patients who have trouble swallowing.
7. The flavour is delectable.
8. Administration should not require water intake.
9. The method is non-invasive, just like parenteral.
10. An improvement in bioavailability
11. First pass metabolism bypass.
12. A decrease in stomach irritation
13. Increase in onset of action.

Disadvantages:

1. It should be kept out of children's reach because they can mistake it for candy and eat it.
2. Possibility of medication and saliva flowing from mouth cavity to stomach.
3. No consuming anything or eating anything while using.
4. shouldn't be ingested.
5. only temporary relief, and a person needs competent care for long-term alleviation

About the herbal drugs: -

An herb is a plant or plant part utilised for its flavour, aroma, or medicinal benefits. Herbal medications are sold as dietary supplements and come in a variety of dose forms, including tablets, capsules, powders in the shape of tea bags, and solid extracts, which can occasionally be made from fresh or dried plants. People take herbal medications to preserve or enhance their overall health.



About the ingredients:

Guduchi:

Synonyms – giloy, amrita, gurijo, Heartleaved, Moonseed.

Scientific name: *Tinospora cordifolia*

Biological sources: It is consist of dried, matured pieces of stem of *Tinospora cordifolia* Miers

family - menispermaceae.

Distribution: It is an herbaceous Vine and indigenous to the tropical areas of India, Myanmar, shri lanka. The plant is a glabrous climbing shrub found throughout India, typically growing in deciduous and dry forests.

Macroscopy: -

leaves → Heart shaped

Bark → creamy white to grey with deep clefts spotted with lenticels.

Flower → yellow

Fruits → turning red when ripe

young steam → green in colour

Stern surface → smooth.

Taste → bitter



Chemical constituents: -

It belong to different classes of constituents such as diterpenoid lactones, glycosides, steroids, phenolics, aliphatic compound, polysaccharides, Columbine tinospora side, tetrahydrofuran.

alkaloids like palmatine, berberine, jatrorrhizine, tembeterine

Tinocordifolioside, cordifolioside A

Tinosporic acid, tinosporal, tino sporone.

Method of preparation:-

- The upper thin skin of Tinospora cordifolia is removed and bruised in a stone or a wooden mortar before being ground into a paste and being soaked in water for 6–12 hours.
- Straining later through cloth causes the material to be squashed, rubbed, squeezed, and separated from the fluid.
- The liquid evaporates in the sun, leaving behind pure "Guduchi Satva" as a residue.

Uses:-

- Rejuvenator
- Immunomodulator
- Blood Purifier
- Antipyretic
- Astringent
- Cardiotonic
- Antiasthmatic
- also used for skin conditions
- gout
- rheumatoid arthritis
- anaemia
- respiratory conditions
- diabetes

Hard Candy Lozenges :-

Raw Materials-

Several variables may influence the sorts of raw ingredients utilised in medicinal lozenges. The majority of medicated lozenges include the medication as well

as sugar, corn syrup, an acid, a colour, and a flavour.

(1) Sucrose:-

Sugarcane or beets are used to produce sucrose, a disaccharide comprising glucose and fructose. The decision to use cane or beet sugar depends on geography and the availability of both. Because of their importance as neutral sweeteners, easy solubility, and ability to act as a "drier" to lower the weight of the confection by crystallisation, sucrose and sucrose products are employed in medicinal lozenges.

(2) Invert sugar :-

The physical property of invert sugar, which is generated from sucrose, is particularly desirable since it prevents concentrated sugar solutions from crystallising and keeps the finished product fresh thanks to its humectant properties.

(3) Maple/corn syrup :-

Almost all confections employ corn syrup to prevent sucrose and dextrose crystallisation, which can cause crumbling.

An amorphous glass can be formed when corn syrup is combined with sucrose and dextrose in the right amounts, creating a sweet with a pleasing appearance.

When making medicated sweets, the physical characteristics of corn syrup such as density, dextrose equivalent (DE), hygroscopicity, sugar crystallisation, viscosity, freezing point depression, and osmotic pressure are crucial.

(4) Isomalt :-

The weight ratio of 6-glucopyranosyl-sorbitol (6-GPS) to 1-glucopyranosyl-mannitol (1-GPM), which makes up isomalt, can range from 43 to 57% to 57% to 43%. Isomalt possesses qualities similar to a binding substance. In other words, to a certain extent, it is able to create binding between the various components of the composition and further in the binding created during the kneading step of making a lozenge. Isomalt is a good softener in addition to being a binding agent. Lozenges made with a binding agent that includes isomalt are softer than lozenges without isomalt.

(5) Colorants :-

For appearance, product identification, and to cover up physical deterioration, colourants are added to medicinal lozenges.

(6) Dyes and other organic colorant:-

Before choosing, it is important to consider the compatibility of the dyes and other organic colourants with the drug, excipients, and process conditions. Dyes and other organic colourants may degrade by heat or light via oxidation, hydrolysis, photo oxidation, etc. The latest regulatory status of colourants can be found from colour suppliers, who are a great source of information.

(7) Acidifiers :-

Medicated lozenges frequently contain acidulants to enhance and reinforce their flavour. The most widely utilised organic acids are citric, malic, fumaric, and tartaric acids. The most typical formulations use tartaric acid alone or in conjunction with citric acid. Acids are also used in medicinal lozenges to change the pH in order to preserve the potency of the medication.

The pH range of regular conversion corn syrup is 5.0 to 6.0. When a weak organic acid is added to increase flavour, the pH is lowered to 2.5–3.0, where several medications have the greatest durability. Some medications can be stabilised if necessary by bringing the pH level to 7.0–8.0 using an appropriate weak base, such as calcium carbonate.

According to several studies, using acidic lozenges too frequently Paraphrase without limits.

(8) Flavors:-

The flavours used in medicated lozenges must be both compatible with the medication and its excipients and strong enough to endure the rigours of manufacture.

Numerous compounds that interact with excipients or medications or breakdown in the presence of heat or light make up flavours. Drugs and aldehydes, ketones, and esters may interact. A main amine medication (benzocaine, phenylpropanolamine) and an aldehyde containing flavour elements like cherry, banana, etc. interact in a way that leads to the creation of a Schiff base, drug breakdown, and loss of potency. Adjusting the pH of the lozenge base to emphasise certain flavours, like citrus, may make some medicines incompatible (eg, benzocaine)

(9) Recover :-

Salvage from lozenge batches that were rejected due to flaws in the shape or size, the presence of air bubbles, or an undesirable medication concentration makes up the final main ingredient in lozenges. If cooked correctly, salvage can be utilised again in final goods without changing their colour, texture, lozenge base composition, or medication concentration.

Before any salvage can be used as a component of a medicated lozenge base, it should be adjusted to a pH of 4.5–7.5 to prevent the excessive and uncontrolled formation of reducing sugars. Additionally, the stability of the medication during cooking cycles should be determined.

Formulation of guluchi Lozenges:

formula for 30 lozenges (hard Candy Lozenges):-

guduch	1 gm
Powdered sugar	42 gm
Corn syrup	16 gm
H2O	24 ml

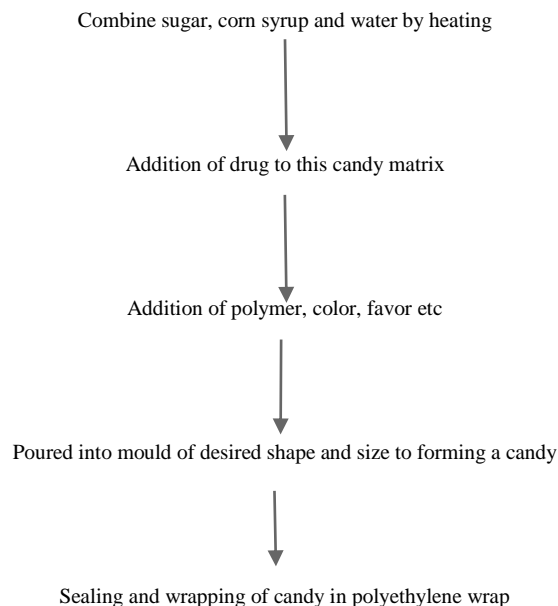
mint extract 12 ml

colour

Preparation method of guduchi Lozenges

Method of preparation of medicated Lozenges

Technique used heating and congealing.



EVALUATION OF FORMULATIONS:

1. Measurement of thickness:-

Vernier callipers were used in order to measure the thickness of guduchi lozenges. Average values were determined using lozenges from each batch.

2. Weight variation:-

The weight uniformity of the guduchi lozenges underwent testing. Formulas were weighed both collectively and individually. The average weight was determined from the total weight. The weight of each lozenge was then compared to the average weight to determine if it was within the allowed limits or not.

3. Hardness:-

The force needed to break a lozenge by compression in the opposite direction is known as the lozenge crushing strength. The power needed to break the guduchi lozenges was recorded when the hardness of the lozenges was assessed using a Monsanto Hardness tester. The unit of measurement is kg/cm².

4. Friability:-

The friability of the lozenges was evaluated using the friability test instrument. The device held pro weighted guduchi lozenges for 4 minutes at 25 rpm. The lozenges were then weighed again. Using the formula, the percentage of friability was calculated.

Friability is calculated as Initial Weight - Final Weight multiplied by 100.

Friability= (Initial Weight - Final weight) x 100 / Initial weight

5. Drug content:-

From each batch, guduchi lozenges were chosen, weighed individually, and crushed in a mortar. We used 100 cc of distilled water to extract the drug. At 285 nm, the drug concentration was measured spectrophotometrically using a reference sample of blank lozenge extract.

6. Disintegration test:-

USP determined how long guduchi lozenges would last before disintegrating. In a pH 6.4 buffer at 37°C, the disintegration equipment and disintegration time were noted

7. Stability test:-

According to ICH recommendations, the chosen formulation was stored in an airtight, dark container at a relative humidity of 40/75% for six months in order to conduct an accelerated stability study.

Conclusion :-

The technique for making lozenges is quick and simple. Guduchi is one of the many herbal medications that can be utilised to make herbal lozenges that are hard candies. In Ayurveda, guduchi is a very popular plant that is widely used to treat fever, respiratory issues, diabetes, anaemia, and cardiac diseases, among other conditions. For patients who are children, lozenges will be the best dosage form. There are numerous varieties of soft compressed hard candy lozenges on the market. You may make guduchi lozenges out of hard candy. Guduchi powder can be combined with additional excipients, such as corn syrup, colourant, flavour, sugar, etc. to create guduchi herbal lozenges. Different characteristics are used to evaluate guduchi herbal lozenges, including weight variation, hardness. Lozenges currently have a significant role in pharmacy and

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