Design Development and Evaluation of Polyherbal Lozenges

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Abstract :Lozenges are one of the very popular and better innovative dosage form and oral confectionary products. Lozenges have been in use since 20th century and are still in commercial production. Lozenges have bright future as a novel method of delivering drugs for local action and systemic effect in the oral cavity. The "lozenges are solid medicated, flavored and sweetened base dosage forms intended to be sucked and hold in the mouth/ pharynx". The benefits of the medicated lozenges is they increase the retention time of the dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. The acceptance for lozenges as a dosage form is high by adults and also more by children. Different types of lozenges available in market are compressed lozenges, hard lozenges & soft lozenges and their methods of preparation along with ingredients used in their preparation are discussed. The present review covers more or less all aspects associated with lozenges and also throws light on the applications of lozenges. It includes various researches performed till date, formulation and evaluation parameters, packaging and applications of lozenges.

Key word : Tulsi leaves, pudina leaves, turmeric rhizome, fenugreek seeds , Beal fruit, jaggery, Honey, Ghee

INTRODUCTION

Lozenges are solid doses form intended to dissolve in mouth for long duration with soothing effect. They contain one or more herbal medicament with a wide range of effect. This is used to treat cough, sore throat, throat infection, fever etc. [1] Even it is use as a source of immune boosting. Patient are recommending lozenges because of swallowing problem of solid doses form and so lozenges are designed such that it releases the medicament slowly in the oral cavity and it bath the throat tissue with the drug solution.[2]

Plant with multiple benefits to boost immunity are used are as follow. Tulsi contains Volatile oil, eugenol, neroli etc. and use as expectorant, carminative, bronchitis, flavouring agent [3]. Pudina consist of limonene, carvone, butyric and caproic and use as flavouring agent, digestive, carminative, stimulant, spasmolytic [4]. Turmeric consists of curcuminoids and essential oil and use as aromatic, anti-inflammatory, uretic, stomachic, stimulant, tonic, blood purifier, carminative, antiperiodic, coloring agent, cold and cough [5]. Fenugreek seed is a good source of calcium, iron, minerals, vitamins like A and D, β-carotene, and dietary fiber and diabetes, constipation, stimulates, balance cholesterol level, cures joint pains, flu and cold, improves heart health, reduce menstrual discomforts [6]. Bael fruits contain xanthotoxin, β-sitosterol, imperatorin, alloimperatorin, tannins and it use for in diarrhea, diabetes, dysentery.[7]

Classification of Lozenges:
According to texture:[2]

- Chewy or caramel based medicated lozenges.
- Compressed tablet lozenges.
- Soft lozenges.
- Hard sweets lozenges.

LITERATURE REVIEW

Doddapaneni Mohana Naga Ravi Prakash, Vardhanapu Sunny et.al. [2022]:
There are three different types of dosage forms used in pharmaceutics, each including an API and a unique excipient to treat a different ailment. However, every dosage form has a particular preference in conditions for the patient's acceptance. To eliminate the demerits, dosage forms have been created of earlier dosage types. The lozenges are study dosage forms that are created using both methods. API coupled with sweetening and flouring agents integrated into it. These are utilized for both local and systemic infections, too.

Tripathi Devika and Verma Shashi et.al. [2015]
The western half of Bareilly is home to many Ocimum (Lamiaceae) species, including Ocimum basilicum Linn. and Ocimum sanctum. The current study examines the physical constants, morphological characteristics, and microscopical features of leaves from distinct Ocimum species, as well as the estimation of drying loss, ash values, and extractive values. The introductory various leaf extracts were

also subjected to phytochemical screening, and the results revealed the presence of various polysaccharides, flavonoids, protein and amino acids, tannins, phytosterols, and saponins are examples of phytoconstituents. The antibacterial properties and phytochemicals are present in the plant sample's leaves retrieved were examined.

Methaq Nazhan Mahmooda, Isra Khald Yahyab et.al.[2017]
The primary phytochemical, nutritional, and active group content of fenugreek seeds powder (Trigonella foenum graecum) were examined using the aqueous extract and the alcoholic extract. Active groups in extracts underwent preliminary testing. (Alkaloids, flavonoids, steroids, carbs) appeared to be present. Phenolic compounds, free amino acids, tannins, saponins, glycosides, trepenes, and saponins) are present. The quantitative and qualitative content of the extracts varied according to the active groups. The quantity of crude protein concentration, total ash, total oil, crude fibre, carbohydrate, and nitrogen content. The alkaloids, flavonoids, steroids, tannins, free amino acids, and saponins were among the substances with estimated quantitative content.

R.S. Sawant and A.G. Godghate et.al.[2019]
The rhizomes of Curcuma longa, a plant in the ginger family (Zingiberaceae), are used to make the spice turmeric. The horizontal underground stems known as rhizomes produce both roots and shoots. Turmeric's vibrant colour is mostly caused by from the polyphenolic pigments known as curcuminoids, which are fat soluble. Plants exhibit healing due to the presence of phytochemical components. Constituents of plants that are not nourishing plant compounds with anti-disease abilities. The Curcuma rhizomes using solvents such as acetone, methanol, ethanol, and chloroform, longa was extracted to yield 16.10, yields of 15.42, 25.75, and 15.50%.[5]

AIM
The aim of this research project is to formulate and evaluate the herbal hard lozenges by using various herbs.

OBJECTIVE
1. To perform the physicochemical evaluation of herbs.
2. To formulate the polyherbal hard lozenges as energy booster.
3. To evaluate the formulated polyherbal hard lozenges.

MATERIAL AND METHODOLOGY

Requirements:
Materials: Tulsi leaves, Pudina leaves, Turmeric rhizome, Fenugreek seeds, Bael fruit, Jaggery, Honey, Ghee.

Apparatus: Beakers, Glass rods, Measuring cylinders, Hot air oven, Digital weighing balance, Spatulas, Petry plates, Thermometer, Tripod stand, Burner, Molds, Aluminium foil, Filter paper, Pipette.

Procedure:
Collection of Material:
- The Tulsi leaves has been taken from our own home.
- The Pudina Leaves, Turmeric rhizomes, Fenugreek seeds and jaggery has purchased from local shop.
- Honey of Patanjali brand is purchase from shop
- Bael fruits are received from farmer

Preparation of Decoction:[11]
a) Tulsi and Pudina leaves Decoction:
The Tulsi and Pudina fresh leaves have been taken and wash it by water separately.
Then the leaves of Tulsi and Pudina are placed separate on burner for boiling with water until total extract obtained in water. Now this both extracts are filter out.

b) Turmeric Decoction:
The Turmeric rhizomes are taken and make pieces of this rhizomes.
These pieces are place to boil with water until the yellow color extract is obtained. Now filter out the extract.

c) Fenugreek Decoction:
The seeds of Fenugreek have been taken wash it. These seeds are placed to boil with water until the extract is obtained. Now filter the extract.

d) Wood Apple Decoction:
The ripped fruit of Bael is taken and the pulp of it remove out and separate out seeds. This pulp is boiled with water until total extract is obtained. Now filter

out the extract.

Preliminary and Phytochemicals Evaluation:
Physicochemical studies:
It involves ash value and extractive value to determine the purity and quality of powder of Tulsi leaves, pudina leaves, turmeric rhizomes, fenugreek seeds, Bael fruit.
1) Determination of ash values:[7]
Crude drug incineration results in an ash residue having inorganic material.

a) Total Ash:
Place about 2-4 gm of dried drug crucible. Now place this crucible in muffle furnace and ignite it heat to 4500c. Until it gets white means absence of carbon. Cool it in desiccator and weight. Percentage of ash is calculated.

b) Acid Insoluble Ash:
Boil ash with 25 ml of dilute HCl for 5 minutes. Filter it with ashless filter paper to get Insoluble matter. Place it again to muffler furnace to get ash. Weight it and calculate acid Insoluble ash.

c)Water Insoluble Ash:
Boil ash with 25 ml of water for 5 minutes. Filter it with ash less filter paper to get Insoluble matter. Place it again to muffler furnace to get ash. Weight it and calculate water Insoluble ash.

2) Extractive Value:[7]
Take 5 gm of dried coarsely powdered of Tulsi and Pudina leaves, turmeric rhizomes, fenugreek seeds and Bael fruit pulp separately. Macerated it with 100 ml of water and ethanol for 24 hours in close 250 ml conical flask. During first 6 hours shake this all flask frequently and allow it to stand for 18 hours. After 18 hours filter it. Empty Petry disk should weight first. Take 25 ml of filtrate to evaporate in Petry disk under oven at 1050c.
After drying of Petry disk weight it again. Now solvent soluble extractive percentage is calculated with reference to air dried drug.

3) Phytochemical Screening:[8]
It is done to determine the secondary plant constituents. The decoction of Tulsi leaves and Pudina leaves, Turmeric rhizomes, Fenugreek seeds and Bael fruit pulp is taken. The test is performed on each decoction separately in test tube as follows.

A. Testing for reducing sugars:
It involved adding 5ml of a 1:1 mixture of Fehling's solutions IA and II (B) to 2ml of the extract and boiling the mixture in a water bath for 5 minutes. The presence of free reducing sugars was indicated by a brick-red precipitate.

B. Testing for Anthraquinone:
Anthraquinone presence should be checked: Shaking 10 ml of the benzene with 0.5g of the extract and was filtered, and the filtrate was then added to 5 ml of a 10 percent ammonia solution. A combination pink, crimson, or violet tint in the ammoniacal (lower) phase after shaking exhibited anthraquinones' existence.

C. Testing for Saponins:
A test tube containing 0.5g of the extract was dissolved in 10 ml of distilled water, sealed with a cork, and shaken violently for 30 seconds. The test tube was then let to stand for 45 minutes to determine the presence of saponins. the persistent foaming appearance that results from warmth. Saponins were present, which indicated.

D. Testing for Flavonoids:
Test for flavonoids by adding a few drops of 10% ferric chloride to a fraction of the dissolved extract. Addition of the remedy. Phenolic nucleus was seen as a green or blue tint.

E. Testing For Steroids or Terpenes:
A test for steroids or terpenes involved dissolving 0.5g of the extract in 2 ml of acetic anhydride, which was then thoroughly chilled in ice. After that, Sulphuric acid was carefully added. The existence of a steroidal nucleus was indicated by a color change from violet to blue to green.

F. Testing For Tanning:
0.5 g of the extract was dissolved in 5 ml of water, then a few drops of the solution were added. 10% ferric chloride is used. An indication of the would be a blue-black, green, or blue-green precipitate. Availability of tannins shows.

4) Chemical Test for Jaggery and Honey:
1. Solubility: Drug add in cold water and warm water. Prepare solution of honey and jaggery in water separately.
2. Reducing Sugar Test: In solution add

Fehling's solution A and B. Brick red color precipitate is form.

3. Molisch's Test: In solution add little Molisch's reagent. Purple color ring is formed at the junction of two liquid.

4. Seliwanoff's Test:In solution add some seliwanoff reagent heat it. Rose colour is obtained.

Preparation of lozenges:[1]

- Take the measured quantity of Tulsi leaves, Turmeric rhizomes, Pudina leaves, Fenugreek seeds and Bael fruit extract in container.
- Place it to heat until get one third quantity.
  Now add the measured quantity of jaggery to it.
- After getting thick consistency add required quantity of honey to it.
- Now pour this to the required shapes molds and place it to cool.

Evaluation test for lozenges:[9]

1) Organoleptic characteristics:

It involves color, odor, taste determination. The effectiveness and safety of produced herbal sweets must be determined by quality evaluation. The formulation was assessed using physicochemical and phytochemical comparisons to the standard criteria. sensory assessment was also carried out and characterized as a field of study that aimed to elicit, quantify, examine, and interpret responses to those food and material features as viewed through the senses of sight, smell, taste, touch.

2) Physicochemical Evaluation of Herbal Lozenges:

Molisch Test, Fehling's Test, Mayers Test, Hanger Reagent Test, Wagner Test, Salkowski Test, Aqueous sodium Hydroxide Test, Sulphuric Acid Test, Ferric Chloride Test are performed on the herbal lozenges.

3) Weight variation Test:

A suitable, previously calibrated balance was used to precisely weigh ten lozenges, and the average weight of each was noted. By adding together, the weight of all 10 lozenges and dividing it by 10, the average weight was determined.

4) Hardness Test:

A specific level of firmness or hardness is necessary for solid formulations, whether they be tablets or lozenges, to withstand mechanical shocks from manufacturing, packaging, and shipping handling. Using the Monsanto tablet hardness tester is another way to measure hardness; with this test, when lozenges is sandwiched between two anvils, the anvils are forced together with such crushing power that the candy just breaks is captured. Zero reading is taken before the experiment begins. Six sweets were tested for hardness in Kg/cm2, and the average toughness was recorded.

5) Testing for Friability:

Friability is a different indicator of a lozenge's durability. The Roche friabilator, a plastic circulachamber that rotates at 25 rpm and drops at 25 °C. The disintegration machine was turned on, and the amount of time needed to break up all six lozenges was noted, and the mean time was determined.

7) PH measurement:[10]A 1% W/V solution of lozenges was made by dissolving 1 g of lozenges in 100 ml of distilled water, and the pH of the solution was recorded. The alkalinity or acidity of a product is expressed by using a pH meter, a scale from 1.0 to 14.0.

CONCLUSION

The technique of preparing polyherbal hard lozenges is quick and simple. The prepared formulation is better received organoleptically, especially by pediatric patients, also it is beneficial for adult persons. It is effective therapy including low doses, fast start of action, reduced dosage regime, and economics, as well as patient compliance, convenience, and comfort. This will provide improved and beneficial doses form to improve the immunity. Lozenges currently have significant role in pharmacy and will do so in the future. The current study goal was to create polyherbal lozenges utilizing the heating and congealing procedure. Trails no. 7 of formulated polyherbal lozenges showed that it was successful in all terms of evaluation parameters. These multi-herbal lozenges are primarily used to improve immunity. The remaining study will perform in future in terms of preclinical trials and other evaluation.

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