"ATTRIBUTE OF BIXA ORELLANA SEEDS TO MAKING HERBAL LOZENGES"

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ABSTRACT

Bixa orellana the sindur plant belonging to Bixaceae family and has a phytochemical and pharmacological uses. The extraction of essential oil and the chemical composition of oil from the bixa orellana seed are described along with antimicrobial, antibacterial and other uses.

Bixin can be use as a decoction or an infusion to treat bacterial infections, according to the literature.
Soxhlet extraction was used to carry out Extraction on dried seed.

The lozenges were prepared by molding method with sucrose, peppermint oil, gelatin, honey, turmeric etc. The prepared medicated lozenges were characterized for Hardness, weight variations, moisture content method.

These activities was done against various pathogens bacteria such as E.coli,streptococcus aureus and other l, these activities was investigating using disc diffusion method

Keywords: lozenges, throat infection, bixa orellana seeds,antimicrobial activity.

INTRODUCTION

ORAL RUTE OF DRUG ADMINISTRATION

This is the most common and accepted route of drug administration. Following oral administration, drug reaches the systemic circulation and is widely distributed across all tissues. Oral route has advantages of being safe, painless, and convenient for repeat and long-term use. Moreover, through this route, drug can be self-administered and does not require professional assistance. However, oral route has few limitations like slow onset of action, and thus cannot be given in emergencies, unpalatable/irritant drugs (e.g., chloramphenicol), unabsorbable drugs (e.g., neomycin), drugs with high first-pass metabolism (e.g., lignocaine), medications destroyed by digestive juices (e.g., insulin). Other drawbacks included are they cannot be given in unconscious/uncooperative/unreliable patients and those having vomiting and diarrhea.

Many dosage forms are available for oral administration; for example, solid forms like tablets, capsules, and liquid preparations such as

syrups, elixirs, and suspensions. Tablets are made by compressing powdered drug along with binding agents and excipients, whereas capsules contain shell of gelatin, which is a tasteless natural substance. Two types of capsules are available-hard gelatin capsule (contain drug in solid form) and soft gelatin capsule(drug as an oily liquid form). In case of pediatric patients, swallowing of tablets/capsules is often problematic; in such cases, oral liquid preparations can be used.[1]

LOZENGES

A lozenge is a solid medication that includes a drug and a flavoring agent. It's designed to dissolve slowly in the mouth, providing either local or systemic effects. The term "lozenge" originates from the French word for a four-sided diamond shape. They can be made using molding or compression techniques, with molded pastilles being one type and troches being compacted lozenges. These have been produced in pharmacies since the twentieth century and arestill commercially available.[2]

A lozenge is a potent and solid substance taken orally that dissolves in the mouth or throat. It contains one or more active ingredients and is formulated in a sweet, sugary base. Lozenges are used to treat oral irritation or throat conditions and can also aid in the absorption of drugs into the body. They have both local effects on the throat, such as soothing and cooling, and systemic effects if the medication is absorbed through the buccal linings or ingested.[3]

Lozenges are designed to be placed in the mouth, and buccal lozenges are commonly used due to their size and shape, as they can be positioned between the gums and the cheek. The duration of the lozenge's effect can vary, depending on the individual, but it can last up to 30 minutes. By controlling the rate of dissolution and absorption, patients can regulate the amount of medication delivered each time they use a lozenge. Sucking on the lozenge and increased saliva production can lead to dilution and swallowing of the medication.[4]

TYPES OF LOZENGES

- Hard Lozenges
- Soft Lozenges
- Chewable Lozenges

Bixa Orellana

Bixa orellana is a tiny evergreen tree native to Central, South, and North America. Achiote or annatto is other names for it. Carotenoids bixin and norbixin, which are found in abundance in red seeds, are utilized to make annatto, commonly used red to yellow color. Dye is used to color clothing as well as variety of foods such as rice, butter, cheeses, soups, and soft beverages. Bixa leaves, decoctions (teas), and extracts have been used by indigenous peoples for many years as medical and folkloric treatments to cure headaches, dysentery, fever, different microbiological illnesses, heartburn, and indigestion, as well as astringent and to cure different skin disorders. Bixa leaf and root preparations are used to cure jaundice, diabetes, and hypertension in Trinidad and Tobago, according to ethnobotanical interviews. According to previously published scientific findings, plant has antivenom, antibacterial, anticonvulsant, analgesic, anti-diarrheal, enzyme producing, hypoglycemic, and antimutagenic properties. Plant is utilized as coloring ingredient in traditional Filipino cookery. It's also used to tint butter, margarine, cheese, drinks, and meat and fish. Bixa dye, often known as annatto dye, is made from outer layer of Bixa orellana seeds.[5]

Fig. 1 Bixa Orellana, plant and seeds

PLANT DESCRIPTION

This plant stands alone in its family as a profusely fruiting shrub that can grow up to about 20 meters[2].

It is a tropical plant, hence requires warm 32-38°C, dry climate and cannot tolerate wet and foggy climate, and in a wide range of soils from loam to lateritic soils.[6]

These are in many with a scarlet covering[2] sized 5mm in diameter[1]o and are ovate in shape[2]. Generally Seed maceration or capsules are used.

Traditionally it is used as expectorant, ground seed powder in small dosages of 10-20 mg daily is used for high cholesterol and hypertension, insect repellant, wound healer24. In tropical regions seeds are used to soothe an irritated stomach that is suffering from excessively spicy food.

Leaves are large green, 5-15 cm long, 4-11 cm wide and are pointed. Generally the infusion of leaves is used. It is documented to act as aldose reductase inhibitor linked to diabetic complications, antibacterial and antihemorrhagic.

SYNONYMS

Anatto, Lipstick tree, Achiote, Kesumba, Jarak Belanda, Annato dye plant, Sindur.

PART OF PLANT USED

The aerial part of plant (seed) are used to rxtract the active phytochemical.

Drug and Excipients

- For the study fresh seeds of bixa orellana were selected.
- The seeds of bixa orellana was procured from my home backyard.
- All the ingredients like sucrose,gelatin,peppermint oil,menthol,citric acid,honey were supplied from the college laboratory of pharmaceutics and pharmacognosy MIBP COLLEGE, GONDIA.
- All the chemical used in the study were of analytical grade.

MATERIAL AND METHODS

Collection of plant:

The fresh and dried seeds were collected from naturally occurring plant of bixa orellana which found in my home backyard. Identification and confirmation were done by Botnay Department of D.B Science college Gondia. Specimen was sent to college is Herbarium.

Preparation of Bixa orellana seed extract

- 200 gm dried seed taken in soxhlet apparatus containing solvent.
- The extraction was carried out in a soxhlet apparatus for 24 hrs with the help of distilledwater.[9]

Procedure:

- Herbal lozenges (solid) formulation was formulated.
- A sucrose was dissolved in a small amount of purified water and heated upto 110°c until it formeda clear viscous syrup.[10]
- The bixin oil and other ingredients were added (peppermint oil, elatin, honey, ginger, menthol).
- After mixing all the ingredients the mixture was poured into a molds to creat a lozenges.
- To protect from the moisture they were wrapped

in aluminum foil.[11]

Table No.1 :- The Formula for the Composition of Lozenges is given below:

Sr. No.	Ingredients	F1	F2	F3
1	Bixin oil (API)	1ml	1ml	1ml
2	Sucrose	30gm	25gm	20gm
3	Peppermint oil	3ml	2ml	2ml
4	Ginger oil	4ml	3ml	2ml
5	Honey	5ml	4ml	3ml
6	Gelatin	5gm	5gm	5gm
7	Menthol	2gm	2gm	1gm
8	Turmeric	2gm	3gm	1gm
9	Citric Acid	2gm	2gm	1gm
10	Purified Water	Q.S	Q.S	Q.S
11	Colour	Q.S	Q.S	Q.S
12	Flavor	Q.S	Q.S	Q.S

EVALUATION TEST

EVALUATION TEST FOR BIXIN OIL

1) REFRACTIVE INDEX:-

Begin by assembling the necessary tools, including a refractometer, Bixa orellana oil sample, and a well-lit environment. Before testing the oil, calibrate the refractometer using distilled water. Place a drop on the refractometer's glass surface and adjust the device until the water's boundary line is in focus. Take a clean glass slide and place a small drop of Bixa orellana oil on it. Ensure the oil is spread evenly across the slide. Gently place the glass slide with the oil onto the refractometer's glass surface. Close the refractometer's cover plate to avoid air bubbles. Look through the refractometer's eyepiece and adjust the focus until the boundary line between the oil and air appears sharp and well-defined. The refractometer typically has a scale that directly indicates the refractive index of the substance. Record the value displayed. To enhance precision, repeat the process multiple times and calculate the average refractive index. Active index values can be temperature-dependent. If possible, note the temperature during measurements and correct the values if necessary. Validate your results by comparing them with published refractive index values for Bixa orellana oil. This step helps ensure the accuracy of your measurements. Record your findings, including the methodology, measured refractive indices, and any observations. Analyze the data for consistency and reliability. Remember, precision and attention to detail are crucial when using a refractometer to determine the refractive index of any substance, including Bixa orellana oil.

2) VISCOSITY

Ensure the viscometer is calibrated using standard calibration fluids. This step is crucial for accurate viscosity readings.Prepare your sample according to the specifications for your particular viscometer. It may involve controlling temperature or adjusting the sample's rheological properties. Choose an appropriate spindle based on the expected viscosity range of your sample. The viscometer's user manual or guidelines can help you make this selection. Mount the selected spindle on the viscometer. Set the instrument to the desired speed and temperature based on the sample requirements. Before immersing the spindle into the sample, ensure the instrument reads zero in the air. Adjust if necessary.

Lower the spindle into the sample, ensuring it is fully submerged and there are no air bubbles. Start the viscometer. Allow the viscometer readings to stabilize. The time required for stabilization depends on the nature of the sample. Record viscosity readings displayed on the viscometer. If the instrument has multiple speed settings, you may need to perform the test at different speeds for accurate results. After completing the measurements, clean the viscometer and spindle thoroughly to avoid contamination between samples.

3) pH

Take a small amount of oil in a clean container. If the oil is too thick, you may need to dilute it with a suitable solvent like ethanol or isopropyl alcohol. If you're using a pH meter, ensure it's properly calibrated according to the manufacturer's instructions. Dip the clean pH electrode into the oil sample. Make sure the electrode is fully submerged but not touching the container's bottom. Allow the pH meter to stabilize, then record the pH reading displayed on the meter. Rinse the pH electrode with distilled water between measurements to prevent contamination. Dispose of the oil sample and any other materials used according to local regulations.

4) Acid Value

A known quantity of oil sample was taken and mixed with a 10 to 12 mL mixture of methanol/chloroform solution followed by the addition of 0.5 g charcoal. A clear layer of lipid was collected from the mixture. Afterward, 2-3 drops of phenolphthalein indicator were added and titrated against 0.01 N KOH solution. The volume of the solution was noted at the point of color change Black-violet and repeated the same procedure for three times. The following equation was used to calculate the acid.

Phytochemical Screening of Bixin oil

- **Carbohydrate**

Equal amounts of Fehling's A and B were added to test tubes containing one milliliter of each of the various extracts. For 10 to 15 minutes, the tubes were heated in a water bath at 65 °C.Carbohydrates were detected in the redbrick precipitate.[12]

- Alkaloids

Four to six drops of Wagner's reagent were added to one milliliter of extracts in test tubes. The presence of alkaloids was revealed by the radish-brown precipitate.

- **Glycoside**

In test tubes, 1 mL of glacial acetic acid was added with 1 mL of extracts. Then a solution of 1% ferric chloride was added approximately 5–6 drops. Glycoside was present as shown by the browncolor ring that formed at the top.

- **Tannins**

Four to five drops of 1% ferric chloride were added after one milliliter of extracts had been mixed with one milliliter of distilled water. The presence of gallic tannin was indicated by the color blue, while cathecholic tannin was shown by the color greenish-black.

- Phenols

To 1 mL of extracts, 1 mL of ethanol was added. Then, each tube had 6-7 drops of a 1% ferric chloride solution. Green, blue, or purple color formation suggested the presence of phenol.

- Proteins

A few drops of concentrated HNO3 were added to one milliliter of the extract for treatment. Proteins were present as indicated by the development of a yellow color.[13]

EVALUATION TEST FOR LOZENGES

1. Determination properties of organoleptic

The determination of organoleptic properties involves a visual inspection of the lozenges to assess their appearance, color, and shape. This evaluation is done to ensure that the lozenges meet the desired visual characteristics and quality standards. The determination of organoleptic properties involves a visual inspection of the lozenges to assess their appearance, color, and shape. This evaluation is done to ensure that the lozenges meet the desired visual characteristics and quality standards.[14]

2. Weight variation

Weight variation testing involves randomly selecting eight lozenges from a batch and individually weighing them. The average weight and standard deviation of these ten lozenges are calculated. To pass the weight variation test, no more than two individual lozenges' weights should deviate from the average weight. This test ensures that the lozenges in the batch are consistent in terms of weight, meeting quality and dosage standards.[14]

3. Thickness uniformity

In the evaluation process, six lozenges were randomly selected from each batch, and their thickness was measured using vernier calipers.[15]

4. Hardness

Hardness or crushing strength (Fo) of a lozenge is the force needed to break it in diametric compression using a Pfizer hardness tester. To determine the hardness for each formulation, six lozenges were tested. The lozenges were held between the two jaws of the tester along their oblong axis. Initially, the reading should be 0 kg/cm². Then, a constant force was applied by rotating the knob until the lozenges fractured. The value noted at this point represents the hardness of the lozenge and is measured in kg/cm². This test provides valuable information about the lozenges' mechanical strength and durability, ensuring their quality and integrity duringhandling and use.

5. Diameter

The diameter, size, and shape of lozenges depend on the molds selected. The lozenges of various sizes and shapes can be prepared, but generally, they are circular with either flat or biconvex faces.

6. Moisture content

By the gravimetric method, 1 g sample was weighed and placed in an oven at 60-70°c for 12-16

h. Final weight was determined to utilize a delicate muslin fabric and its weight was rechecked.

Percentage friability is given by the equation.[14]

% f = (initial weight-final weight/initial weight) × 100.

7. Friability

Determined by roche friabilator operated at 25rpm for 4min.

8. Stability studies

The stability studies for lozenges were performed for optimized formulation (f7) at 40°c and 75% rh for some days as per ich guidelines. The lozenges were assessed for various parameters such as hardness, weight variation, moisture content, and according to procedures mentioned previously by analyzing the

samples after some days.

9. Antimicrobial Activity

Prepare nutrient agar plate inoculated with test organism, with a depth of 4-5mm and then allow it to solidify. Divide the NA plate into four equal portions. Then with the help of a sterile borer make four cavities one in each portion. Then fill three cavities with antibiotic solution and in one fill the standard solution. Slowly incubate the plates at 37°C for 24 hours. After incubation measure the zone of inhibition.

RESULT AND DISSCUSSION

Evaluation test of oil

1. Refractive index

Normal range:-	1.456 to 2.326)
Result:-	1.45)

2. Viscosity

Result:-	low viscosity (32.6cp)

3. pH

Normal Range:-	(5-6)
Result:-	(5.99)

4. Acid Value

Sample weight = 2g

Normality of KOH = 0.1 N

Weight of empty weighing Bottle = 38.10 gm

Weight of oil and weight bottle =40.10gm

Oil weight = 40.10-38.10 =2 gm

Volume of KOH Solution = Final Burette Reading – Initial Burette Reading

= 3.4-0.0 =3.4 ml

Normal Range:- (1 to 10mg KOH/gm)

= 9.53 mg/g

Table 2:- Phytochemical screening of oil

Sr. No.	Phytochemical	Water extract
1	Carbohydrate	Present
2	Alkaloid	Present
3	Glycoside	Present
4	Tannin	Present
5	Phenol	Present
6	Protein	Present

Table 3:- Evaluation Test of Lozenges

Properties	Observation
Colour	Reddish orange
State	Solid
Odor	Aromatic
Texture	Smooth
Shape	Circular

Table 4:- Weight variation (in gm)

Formulation	Initial Day	7 Day	15 Day
	F1	F2	F3
1	3	3	2.9
2	2.9	3	3
3	3	3	2.9

Table 5:- Thickness (in mm)

Formulation	Initial Day	7 Day	15 Day
	F1	F2	F3
1	6.3	6.8	7.1
2	6.5	6.4	6.8
3	7	7.2	6.4

Table 6:- Hardness (in kg/cm^2)

Formulation	Initial Day	7 Day	15 Day
	F1	F2	F3
1	8	7.5	7.9
2	8	8.2	8.5
3	7.9	7.8	8

Table 7:- Diameter (in mm)

Formulation	Initial Day	7 Day	15 Day
	F1	F2	F3
1	12	12.2	13
2	11.5	11.9	12
3	11.9	12	11.6

Table 8:- Moisture Content

Formulation	Initial Day	7 Day	15 Day
	F1	F2	F3
1	0.95	0.91	0.88
2	0.95	0.88	0.90
3	0.89	0.93	0.91

Table 9:- Friability

Formulation	Initial Day	7 Day	15 Day
	F1	F2	F3
1	1.90	2.10	2.15
2	2	2.10	1.9
3	1.95	2	2

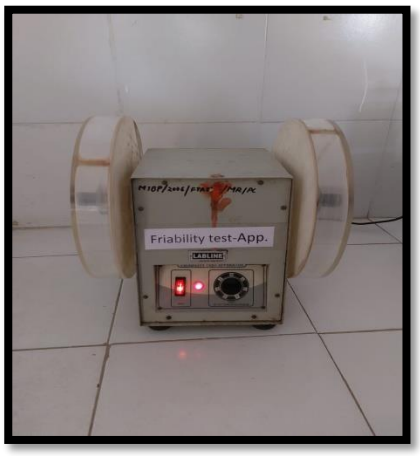
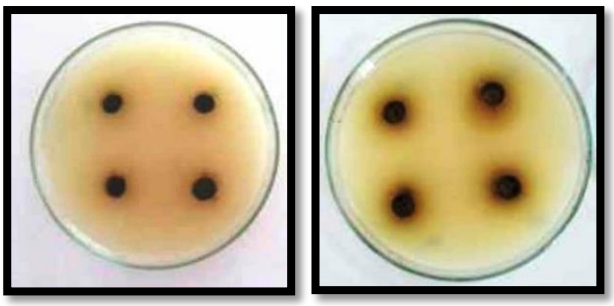


Table 10:- Stability study

Evaluation parameter	Optimize formula (F1)		
	10 days	20 days	30 days
Hardness	8	7.9	8
Weight variation	3	2.9	2.9
Moisture content	0.95	0.95	0.93
Friability	1.90	1.90	2.10

Table 11 :- Antimicrobial Activity

Sr. No.	Zone of Inhibition	
	Marketed Formulation(Ampicillin)	Herbal Preparation (Lozenges)
F1	18 mm	15 mm
F2	20 mm	15.5 mm
F3	21 mm	16.2 mm



Zone of Inhibition

CONCLUSION

From the study it can be conducted that prepare of herbal lozenges using bixin oil is suitablefor treat or prevent the throat infection.

Herbal lozenges are ideal dosage form for children due to ease of administration, patient compliance and comfort during treatment and hence reduce the side effects and throat infection of humans.

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