Research Article

Formulation and Evaluation of Herbal Lozenges Containing Nutmeg Oil

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ABSTRACT

The history of herbs and spices is as long as the history of mankind. People have used these plants for medicinal purposes since the earliest times, and the knowledge of herbs has been handed down from generation to generation for thousands of years. Nutmeg is a well-known remedy for diarrhoea in herbal systems, but lesser known is its usefulness in cases of insomnia. In fact, it is one of the best treatments for insomnia. Nutmeg is one of our most powerful herbal sedatives. It possesses potent medicinal properties that can help calm the nerve and release serotonin which induces sleep. The present study focuses on the formulation and evaluation of herbal lozenges incorporating nutmeg oil. Research work involved extraction of nutmeg oil. formulation of lozenges and its evaluation. The results suggest that nutmeg oil containing lozenges could serve as an effective and safe remedy for insomnia. This study underscores the potential of herbal-based treatments in managing sleep disorders, offering a promising alternative to conventional medications.

Keywords: Insomnia, Nutmeg oil, Jaiphal, Lozenges.

INTRODUCTION

Lozenges are solid preparations that contain one or more medicaments, usually in a flavoured, Sweetened base, that are intended to dissolve or disintegrate slowly in the mouth. They can be prepared by moulding (gelatin and/or fused sucrose and sorbitol base) or by compression of sugar-based tablets. Moulded lozenges are sometimes referred to as pastilles, whereas compressed lozenges may be referred to as troches. Types of lozenges: 1. Hard candy lozenges 2. Soft lozenges 3. Chewable Lozenges.

Insomnia is a prevalent sleep disorder affecting millions worldwide, often leading to significant physical and psychological consequences. Traditional pharmacological treatments can have adverse effects, prompting the need for safer, natural alternatives. Herbal remedies used in treatment of insomnia are a type of confectionery designed to deliver herbal ingredients known for their calming and relaxing properties. These lozenges are formulated as hard candies, allowing for slow dissolution in the mouth, which aids in the gradual release and absorption of the active herbal compounds. The key components typically include natural relaxant myristicin which is traditionally used to promote relaxation and reduce stress.[1-3]

MATERIALS AND METHODS

Extraction of Nutmeg Oil (*Myristica fragrans*)

The hydro distillation method had been used for the extraction of essential oils from nutmeg. Nutmeg which is kernel of Myristica fragrans were grounded into fine powder. The distillation flask of 500 ml contained water about 2/3 of its volume and 50 gm of the powder. The operation proceeded by heating the flask at 100˚ C, heat was applied to the flask and the volatile oil was carried with the steam to a cold condenser, the lighter oil rises to the top of the separator. The essential oils collected was dried over anhydrous sodium sulphate, weighed and stored in a sealed vial of dark umber colored at 4˚C. The yield percentage of essential oil was determined.[3]

Thin Layer Chromatography of Extracted oil

TLC chamber prepared by adding a specific amount of the solvent system (ethyl acetate: Toluene 13.28:1) to the bottom. Ensure that the level of the solvent is below the marked line on the TLC plate when it is placed in the chamber. Prepared sample of nutmeg oil by, dissolving it in a suitable solvent (Di chloral hydrate) to create a solution of known concentration. Spot the TLC plate with sample using a spotter or capillary tube. Place small spots near the bottom of the TLC plate, ensuring that the spots are evenly spaced. Place the TLC plate in the developing chamber, ensuring that the spots are above the level of the solvent. Cover the chamber to prevent solvent evaporation. Allow the TLC plate to develop until the solvent front reaches near the top of the plate. Remove the TLC plate from the chamber and mark the solvent front with a pencil. Visualize the separated compounds on the TLC plate. Used UV lamp to visualize compounds that fluoresce under UV light, or an iodine chamber to visualize non-fluorescent compounds. Calculate the Rf value of myristicin by measuring the distance travelled by the compound from the origin (spot) to the centre of the spot, and dividing it by the total distance travelled by the solvent front. Compare the Rf value of myristicin to known standard.

Preparation Hard Candy Lozenges

Lozenges were prepared by heat and congealing method. In this method, sugar syrup was prepared by blending sugar and water. Sugar was dissolved in a little amount of

water and warmed it to 110°C till sugar breaks down totally forming clear thick syrup. The sugar syrup was warmed to 160°C till the colour changes to brilliant yellow. The temperature was decreased to 90°C, nutmeg oil and other excipients was then included. The entire preparation was then filled in the cavities of Molds. The lozenges formed were enclosed by aluminium foil and kept in desiccators to prevent moisture uptake.[4]

Table 1: Formula for Lozenges

Sr no.	Excipients	Weight in Gram
1	Drug	1ml
2	Powdered sugar	82gm
3	Corn Syrup	32gm
4	Water	q. s
5	Coloring agent	q. s

Figure 1: Prepared Hard Candy Lozenges

Evaluation of Lozenges: [5,6]

Physical observations

Physical observations like colour, odour, taste and solubility of prepared lozenges determined

Table 2: Physical observation of Lozenges

Physicochemical Study	Observation
Colour	Brown
Odour	Aromatic
Taste	Sweet and spicy
Solubility	Sparingly Soluble in Water

Weight variation:

Ten lozenges were randomly selected from each batch and individually weighed. The average weight and standard deviation of 10 lozenges were calculated. The batch passes the test for weight variation test if not more than 2 of the individual lozenges weight deviates from the average weight.

Thickness uniformity: Six lozenges were selected randomly from each batch and thickness was measured using Vernier calliper.

Hardness: Hardness or crushing strength (F0) is the force required to break a lozenge in a diametric compression using Monsanto Hardness Tester. For each formulation, the hardness of six lozenges was determined. The lozenges were held along its oblong axis in between the two jaws of the tester. At this point, reading should be 0 kg/cm2 Then, constant force was applied by rotating the knob until the lozenges fractured. The value at this point was noted in kg/cm2.6

Moisture content: Moisture content determined by the gravimetric method, 1 gm sample was weighed and placed in an oven at 60–70°C. Final weight was determined to utilize a delicate muslin fabric and its weight was rechecked.

Moisture content = $(initial\ weight – final\ weight)\ /initial\ weight$ X 100

Friability: Friability was determined by using a Roche friabilator. 10 lozenges were weighed and placed in the Roche friabilator and all the parameters set on the friabilator. The apparatus was rotated at 25rpm (100 rotations) for 4 minutes. After revolutions the lozenges were deducted and weighed again. The maximum mean weight loss samples are not more than 1.0 %. The percentage friability was measured using the formula:

$$\% F = W0 – W$$

Where, % F = Friability in percentage,

W0 = Initial weight of lozenges

W = Final weight of lozenges after revolution

Drug content: Drug content determined by UV spectroscopy. 5 mg of lozenges were placed in 50 ml of phosphate buffer solution of pH 6.8 for 4 hr on rotary shaker. The filtered solution was measured using a UV–visible spectrophotometer.

RESULT AND DISCUSSION

Percentage yield of nutmeg oil: -Amount of essential oil recovered- 6ml and amount of plant material distilled-50g.

$$\% \text{ Yield} = Amount\ of\ essential\ oil\ recovered(g)/ amount\ of\ plant\ material\ distilled \text{ X } (100g)$$

$$\% \text{ Yield} = 6ml\ /50gm \text{ X}100$$

% Yield (%) = 12%

Table 3: Physicochemical Study of Nutmeg oil

Physicochemical Study	Observation
Colour	Light Brown
Odour	Aromatic
Solubility	Sparingly Soluble in Water
TLC (RF Value)	0.72

Table 4: Weight Variation

Sr.no	Weight (gm)
1	1.97
2	1.98
3	1.94
4	2.0
5	2.1
6	2.09
7	2.1
8	2.11
9	2.0
10	1.96
Standard avg weight range	**1-5**
Average weight:	**2.0**

Table 5: Thickness uniformity

Sr.no	Thickness (mm)
1	10.60
2	10.70
3	9.10
4	9.90
5	9.20
6	10.90
Standard avg thickness	**8-15**
Average Thickness	**10.00**

Table 6: Hardness

Evaluation parameter	Result (Mean±SD) (n=6)
Hardness	4.9±1kg/cm^2
Standard Range	4.0 – 5.0kg/cm^2

Table 7: Moisture content and Friability

Sr. No	Friability	Moisture content
1	2.91±0.008	0.95±0.05
2	2.98±0.005	0.91±0.05
3	2.95±0.006	0.85±0.06
4	2.87±0.008	0.88±0.04
Standard avg.	2- 3%	0.5-1%
Average	**2.83±0.007**	**0.86±0.05**

Table 8: Drug content

Sr. No	Drug content (%)
1	98.5±0.04
2	98.3±0.05
3	94.8±0.04
4	97.6±0.04
Standard range	Up to 99%
Average	**96.7±0.03**

CONCLUSIONS

The present study was attempted to prepared herbal hard candy lozenges. The lozenges were prepared by using nutmeg oil which is extracted by hydro distillation method. The physico-chemical evaluation parameter shows percentage yield-12%, weight variation-2.0gm, thickness uniformity- 10.00mm, friability- 2.83±0.007, moisture content- 0.86±0.05. So concluded that prepared formulation has physical stability and safe to use as an alternative remedy to treat insomnia due to the presence of myristicin which is active constituent of nutmeg oil which have sleep producing activity.

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