

FORMULATION AND EVALUATION OF ANTIEMETIC *H. spicatum* LOZENGES

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ABSTRACT

Hedychium spicatum also called as Kapoorkachri or Shati is a rhizomatous, fragrant leafy herb with robust stem belonging to Zingiberaceae. Rhizomes have strong aromatic odour and bitter camphoraceous taste. *Hedychium spicatum* is traditionally used for its stimulant, carminative, stomachic and expectorant properties. Shati rhizomes have mention in Ayurvedic text for its use in Hairloss, Digestion and Respiratory problems, Cleansing Teeth, Cardiac Health, Headache, Joint pain and Hiccups. Rhizomes are usually used in the form of powder or formulated in syrups or tablets. Rhizome is reported to contain sitosterol and its glucosides, P-methoxy cinnamic acid ethyl ester, furanoid diterpene-hedychenone and 7-hydroxy hedychenone and essential oil contains Cineole, terpinene, limonene, phellandrene, p-cymene, linalool and terpineol which contribute to its activity. Paediatric patients have low patient compliance towards drug formulations like tablets because of unpalatable taste. On the other hand, children can easily accept and swallow sweet lozenge with additive flavour. In order to provide better patient compliance we have formulated lozenges using shati rhizome extract specially for paediatric patients. Aim of this study involves design, preparation and evaluation of medicated lozenges. Methodology includes extraction of drug with cold maceration method using aqueous : ethanolic extract (1:1) proportion. Lozenge base was made with Sugar and corn syrup followed by addition of drug extract. Ginger juice was added as natural flavour and for additive antiemetic and antitussive property. Lozenges were made by casting method where in the resultant hot mix was poured in moulds. This lozenges are evaluated by pharmaceutical methods like moisture content, friability test, disintegration test which complies with IP.

Keywords: *Hedychium spicatum*, antiemetic, paediatric, Ayurvedic text.

INTRODUCTION

Emesis is defined as action or process of vomiting, by virtue of which contents of stomach are thrown out via the mouth. Emesis is precipitated by several factors such as psychosocial stressors related to accomplishments and family, fiasco in context of expectation of parents, eating pathology, lack of exercise, medication and food poisoning. In addition to above precursors, emesis is also precipitated by sensory stimuli such as bad odour, ghastly sight, severe pain, fear and recall of an obnoxious event.

Emesis is prevalent among all age groups including paediatrics and geriatrics. Synthetic drugs for emesis have been used for its treatment. This is suitable for adults but often result in potential side effects and masking of underlying condition in children. Furthermore, rationale of designing a dosage form which is compatible to paediatrics is crucial. A low patient acceptance is seen for tablets and capsules due to large size, poor taste. Intravenous route is never preferred for paediatrics due to pain attributed with it.

On the contrary, lozenges which are disk shaped, pleasantly flavoured solid preparations dissolving in buccal mucosa are preferred over conventional dosage forms. *Hedychium spicatum* is an herbal drug which is used in ayurveda since ages for treatment of emesis. Rhizomes of *H.spicatum* are utilized for treatment of emesis.*H.spicatum* is also used as antiseptic, diuretic, anti inflammatory, aphrodisiac. Active ingredient of *H. spicatum* is para methoxy ethyl cinnamate. Apart from above active ingredient used in formulation, *H. spicatum* contains furanoid diterpene-hedychenone and 7-hydroxy hedychenone and essential oils such as cineole, terpinene, limonene, phellandrene, p- cymene, linalool, terpineol. The aim of this study was formulation of hard candy lozenges of *H. spicatum* and its subsequent evaluation.

MATERIALS

Hedychium spicatum (family - *zingiberaceae*) was obtained as a drug powder from authenticated source. Other solvents like acetone, water, n hexane, ether, 5% H₂SO₄ were of analytical grade and throughout the study distilled water was used.

EXTRACTION

For extraction, cold maceration technique is employed. Initially 100 gm of sample *Hedychium spicatum* was taken into round bottom flask (RBF). Later 400 ml ethanol water solution was added to Round bottom flask (RBF) containing powder. For obtaining uniform mixture this RBF is subjected to sonication, called as homogenization. 9 successive cycles of each 180 revolutions were carried out. It is kept aside undisturbed for 24 hrs. Filtered using filtration method, ethanol extract was collected and kept in vacuum oven for 10-20 mins at 80°C to get concentrated product which is further used during continuous process for candy preparation.

PREPARATION OF GINGER EXTRACT

Collect small sized fresh ginger. Make small sized pieces of ginger with the help of scraper. Subject it to squeezing through muslin cloth. Collect the juice. Keep it in refrigerator for separation of starch. Collect supernatant to use it as a additive.

PRELIMINARY PHYTOCHEMICAL SCREENING

Chemical tests were performed in the preliminary phytochemical screening to identify various secondary metabolites such as tannins and phenols, carbohydrates, glycosides, saponins, alkaloids, flavonoids and sterols using standard methods

Table 1: Physicochemical Constants

Phytoconstitue nts	Methanol	Aqueous
Alkaloids	+	+
Carbohydrate	+	+
Flavonoids	+	+
Gums & Mucilage	-	+
Glycosides	+	+

Phenolic compounds	-	-
Protein	+	+
Amino acid	-	-
Saponins	+	+
Steroids	+	-
Triterpenes	-	-
Tannins	+	+

FORMULATION OF HARD CANDY CHEWABLE LOZENGE:

To provide ease of drug administration, the lozenges are formulated into stable dosage form.

Table:2 Formulation table

Ingredients	Master formula(quantity for 20 lozenges)	Working formula(quantity for one lozenge)
Sugar	57%	0.8607%
Corn syrup	37%	0.5587%
Drug extract	5%	0.075%
Ginger extract	1%	0.015%

PROCEDURE:

Melting and Molding technique was utilized for formulation of lozenges. Required amount of sugar, corn syrup and water are mixed together with the help of heating at a constant temperature, followed by incorporation of drug extract into homogeneous candy base. Ginger extract is added to the formulation. Mixture is poured into mold having required size and shape. Candies are formed in plastic mold. Hard candies are wrapped into aluminium foil. Candies are stored in suitable plastic container.

EVALUATION OF LOZENGES

i)Weight Variation Test: Twenty lozenges were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one lozenge was determined from the collective weight. The weight variation test is a satisfactory method of determining the drug content uniformity. The percentage deviation was calculated using the following formula.

Sr.No.	Weight of Lozenge(gm)	Sr.No.	Weight of Lozenge(gm)
1	1.51	11	1.53
2	1.49	12	1.57
3	1.45	13	1.51
4	1.57	14	1.49
5	1.53	15	1.45
6	1.57	16	1.53
7	1.53	17	1.45
8	1.51	18	1.57
9	1.49	19	1.49
10	1.45	20	1.51

Total weight of 20 Lozenges=30.2gm

Average weight of Lozenge=30.2/20=1.51 gm

±5% Deviation applied as average weight is greater than 250mg

Range=(1.434-1.585)

INFERENCE-It passed the test as no lozenge is deviating from the range as per Indian Pharmacopoeia 2010 acceptance criteria for test(Not more than 2 lozenges deviates from range limit)

ii)Hardness:Hardness of lozenge is defined as the force applied across the diameter of the lozenge in order to break the lozenge. The resistance of the lozenge to chipping, abrasion or breakage under condition of storage, transportation and handling before usage depends on its hardness. For each formulation, the hardness of 3 lozenges was determined using Monsanto hardness tester and the average was calculated and presented.

Sr.No.	Hardness(Kg/cm ²)
1	5.4
2	5.3
3	5.5

Average hardness of Lozenge=(5.4+5.3+5.5)/3=5.4Kg/cm²

INFERENCE-It passed the test as acceptable hardness should be 5Kg/cm² or greater.

iii)Friability:It is a measure of mechanical strength of lozenges. Roche friabilator (Electrolab, Mumbai, India) was used to determine the friability by following procedure. Pre-weighed lozenges (20 lozenges) were placed in the friabilator. The lozenges were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the lozenges were re-weighed; loss in the weight of lozenges is the measure of friability and is expressed in percentage as:

% Friability = [(W1 – W2) / W1] × 100

Where W1 = Initial weight of 20 lozenges

W2 = Weight of the 20 lozenges after testing.

W1=30.200gm, W2=29.898gm, W1-W2=0.302gm

% Friability =(0.302/30.2)×100=1%

INFERENCE-It passed the test as per Indian Pharmacopoeia 2010 acceptance criteria for test(it should not be greater than 1%)

DETERMINATION OF PHYSICAL PARAMETERS OF *Hedychium spicatum*

i. Macroscopical Evaluation: For determination of organoleptic properties of the formulation, it was evaluated based on its visual observation.

Table:3 Macroscopical evaluation table

S.N.	Parameters	Observations
1	Colour	Dark brown
2	Odour	Ginger flavour
3	Taste	Sweet and spicy
4	Texture	Smooth and transparent
5	Shape	Round

ii. Ash Values: Residue remaining after incineration is the ash content of drug. It is useful criterion to judge identity and purity of drug.

Types of Ash value	Value
Total Ash	5.15% w/w
Water Soluble Ash	1.738% w/w
Acid Insoluble Ash	1.6% w/w

iii. Swelling Index: The swelling index is the volume in ml taken up by the swelling of 1gm of plant material under specified conditions. It's determination is based on addition of water as specified in the test procedure for each individual plant material. Using a glass stoppered measuring cylinder, the material is shaken repeatedly for 1 hour and then allowed to stand for required period of time. The volume of mixture is then noted. It was found to be 5ml.

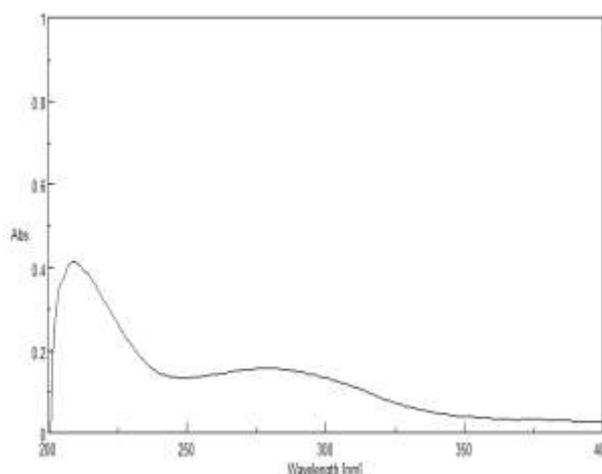
iv. Determination of extractable matter: This method determines the amount of drug constituents that can be extracted with solvents like water and ethanol. The extractive values were determined as per the procedure given in Indian pharmacopoeia 2010.

Water soluble extractive value	1.2% w/v
Ethanol soluble extractive value	0.2% w/v

v. Determination of Moisture Content: Moisture content is the ratio of mass of water in a sample to the mass of solids in the sample expressed as a percentage. For the determination of this parameter, the weighed amount of the formulation was kept in hot air overnight at 105°C and moisture content was calculated.

Sr.No	Dosage form	Moisture content
1	Lozenges	3.2%

UV Spectrophotometry: Aqueous solution of extract of *Hedychium spicatum* was prepared and subjected to UV analysis to detect presence of active ingredient Para methoxy ethyl cinnamate. Presence of para methoxy ethyl cinnamate was detected at 210nm.



UV curve for detection of para methoxy ethyl cinnamate at 210 nm

RESULT AND DISCUSSION

Lozenges were formulated using Melting and molding technique, with the combination of sugar and corn syrup as a base. Evaluation of lozenges which encompasses test for weight variation and friability were done as per procedure mentioned in Indian Pharmacopeia 2010. For Determination of physical parameters ash value, swelling index, extractable matter, moisture content were calculated and UV analysis was carried out. On investigation, it was found out that formulation passes evaluation test as per inference mentioned in Indian Pharmacopeia 2010. In UV analysis, para methoxy ethyl cinnamate was detected. Lozenges should be stored at low humidity and at low temperature, as at room temperature absorbance of moisture by formulation was observed.

CONCLUSION

Lozenge is most preferred dosage form over other solid dosage forms like tablets and capsules. This is due to fast onset of action and high patient compliance particularly in paediatrics. Herbal lozenges are prepared by using candy base of sugar and corn syrup by melting and molding technique. Sugar serves purpose of taste masking and drug *Hedychium spicatum* as antiemetic is incorporated as hydro alcoholic extract in candy base. Aqueous ginger extract is added as flavouring agent. Finally, it is poured into mold to get lozenges. Hence, formulation of lozenges is easy. Lozenge dissolve in buccal cavity and in turn bypass first pass metabolism. In additional production of lozenges is economical.

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