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Preparation and Evaluation of Herbal Cough Lozenges: Corid-Cough Pearls

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Abstract

Traditional Indian system of medicine has different herb- based formulations to cure different aliments. Soreness of throat and cough are painful condition in throat infection. The soothing agents like cough syrup and lozenges can give symptomatic relief. Ayurveda reveals use of herbs such as *Khadira* (*Acacia catechu*), *Javitri* (*Myristicafragrans*), Kankol (*Piper cubeba*), Pomegranate rind (*Punica granatum*), *Karpura* (*Cinnamomumcamphora*) etc, as soothing agents in soreness of throat. Current research project was aimed at development and evaluation of polyherbal cough lozenges containing these herbs using natural excipients. Thoroughly dried and finely powdered herbs such as *Khadira* (*Acacia catechu*), *Javitri* (*Myristica fragrans*), Kankol (*Piper cubeba*) and Pomegranate rind (*Punica granatum*) mixed together homogeneously and Clove oil was added to it. The homogeneous mass was dispersed in molten mass of jaggery base. The prepared mixture was then poured in moulds to get desired shape. Prepared formulation was further evaluated for organoleptic characteristics, weight variation and other pharmacopoeial parameters.Oval shaped, brown coloured sweet lozenges with average weight of 1.5gm were prepared and foundto be as per standards laid down in the Pharmacopoeia. The lozenges were presented under brand name Corid-cough pearls. The prepared cough lozenges 'Corid-cough pearls' can be used for treatment of initial stages of cough and throat infection.

Keywords: Cough, Throat Infection, Corid-Cough Pearls Lozenges.

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Introduction

Coughing occurs as a defensive reflex due to stimulation of reflex arc. Coughing causes clearance of secretions and particles as a reflex action. It is protective action against foreign particles and certain pathogens. It is also important to clear secretions associated with inflammation and infection. Though Cough has role of protection, productive cough causes trouble and harm to mucosal layer of airways. Initiation of coughing happens due to irritation of cough receptors present in oropharyngeal cavity. (Polverino *et al*2012). For the early treatment of cough and bronchial complaints lozenges are usually taken as soothing agents (Pothu, R*et al* 2014). Lozenges are easy to administer. Due to pleasant taste these are placed in mouth for longer time and sucked the drug released over a period of time to have local effect. It needs minimal equipment and hence cost of production is less. In market there are four types of lozenges available. They are medicated lozenges with base of caramel, hard candy lozenges, soft lozenges and compressed tablet lozenges (Pothu, R *et al* 2014). Cough lozenges are special lozenges whichdissolve slowly to release the drugs and soothe soreness of throat due to infection or irritation (Umashankar S *et al*2016).

In the present research paper formulation and evaluation of herbal hard candy lozenges prepared by molding for treatment of cough are discussed. For the current study *Acacia catechu*, mace of *Myristica fragrans, Piper cubeba,* and *Punica granatum* rindwere selected as the active ingredient and jaggery as base formation agent.

Acacia catechu, It is also known as black catechu. Chemical constituents are catechins, tannins and quercetin. For the current study heart wood extract of plant that is khadira is used. Khadira is well known for its astringent and anti-cough property. It is commonly usedfor treatment of hoarseness of voice, relaxed sore throat and toothache (Kirtikar K R and Basu *et al* 1935).

Mace of *Myristica fragrans,* Dried red lacy arillus surrounding nutmeg seed is known as mace of nutmeg. It contains volatile oil and known to possess anti-inflammatory andexpectorant action (Nadkarni's K M1954).

Piper cubeba, It is also known as kabab-chini or kankola. It contains pleasant essential oil and important alkaloid piperine. It possesses carminative, stimulant and expectorant activity which justifies its use in cough syrups (Nadkarni's K M 1954; Alam MA. *et al* 2013).

Pomegranate rind, *Punica granatum* rind is known to possess antitussive action. Action might be due to tannins and astringent principle present in the drug (Bhowmik, D et al 2013).

In current article we have prepared and evaluated herbal lozenges containing above potent herbs using jaggery as base for the treatment of sore throat.

Materials and Methods

Procurement of plant material

All the raw plant materialswere procured from local market of crude herbs in Mumbai. Identification of plant material was done by botanist of local market and the specimens of plant material is deposited at institutional laboratory.Jaggery used as base for the lozenges was procured from local market.

Processing of plant material

The material was cleaned and thoroughly dried in oven at temperature not exceeding 60^0C. All the plant materials were powdered individually using simple mixer blender available in lab and stored in airtight containers away from light till further use.

Chemicals and instruments

All the chemicals and reagents used for this work were of analytical grade and procured from SD fine chemicals. For quality assessment of formulation different instruments used available in central instrumentation room of institute. Silicone moulds used for preparation of lozenges were procured from local market in Mumbai.

Methodology of Formulation

Hard candy lozenges were prepared using molten jaggery as base. The technique used was "Melting and molding technique" as reported by Yamsani M *et al* 2014.

All powdered materials were weighed (Table 1) and mixed homogenously. Weighed quantity of jaggery was melt on water bath. Powder mixture was added to molten mass while it was hot. Once mixture was thoroughly dispersed clove oil was added to it with continuous stirring. The mixture was poured into silicone molds (Figure 1) and allowed to cool at room temperature.

Table 1: Formula for Herbal Lozenge

Ingredients	Qty
Black catechu	125 mg
Mace of nutmeg	32 mg
Piper cubeba	32 mg
Rind of Pomegranate fruit	32 mg
Clove oil	q.s.
Jaggery base qs to	1.5 gm

The prepared lozenges (Fig.2) were evaluated for different pharmacopoeial parameters and packed in butter paper and paper packaging material and labeled (Fig.3).

Evaluation of Formulation

Formulation developed was sampled and evaluated for different parameters such as organoleptic properties, uniformity of weight, friability and disintegration.

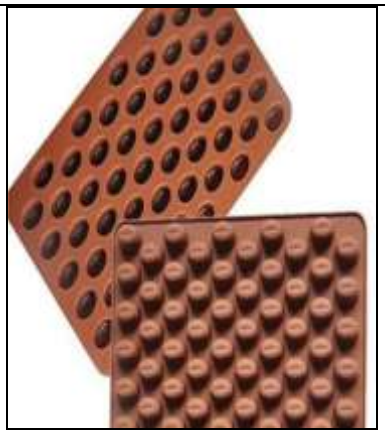

Fig.1: Moulds Used For Lozenges

Fig. 2: Hard Candy Oval Shape Lozenges

Fig. 3: Packed and Labeled Lozenges; Corid-Cough Pearls

Organoleptic properties- These were determined by visual observation for physical appearance and identity. Other organoleptic characteristics such as taste, color uniformity, dimensions also were evaluated. Length and thickness of twenty lozenges samples were determined using Vernier caliper and observations are as in the Table 2, for average dimensions indicating uniformity in size of lozenges.

Uniformity of weight- Twenty lozenges were randomly sampled and weighed individually on high precision balance (Mettler Toledo, USA). Average weight as well as % deviation for weight from the average weight for the twenty lozenges was determined.

Hardness test- The Hardness testing was done by using Pfizer hardness tester for sampled lozenges and average hardness was determined and the results were indicated as kg/sq. cm

Friability- The friability of the prepared lozenges was determined with a Friability Test Apparatus of Veego, Mumbai, India. Twenty lozenges were collected at random and weighed on a precision balance (Metler Toledo, USA). Lozenges were placed into drums of the apparatus which is then set for 100 revolutions. After the test the lozenges were deducted and

weighed again. The % friability was calculated using following formula;

$$\% \, Friability = \frac{Initial\ weight - Final\ weight)}{Initial\ weight} \, X\ 100$$

Disintegration time- Disintegration test of the prepared lozenges was performed according to monographic procedure given in USP34, using a disintegration tester in phosphate buffer (pH 6.2) maintained at 37 ± 0.5ºC as disintegration medium**.** Six lozenges were placed in the cylindrical glass and the time required for complete disappearance of a lozenge or its particles from the tester net was recorded as disintegration time.

Results and Discussion

The prepared cough lozenges "Corid-cough pearls"was a polyherbal cough relieving formulation containing *Khadira* (*Acacia catechu*), *Javitri* (*Myristica fragrans*), Kankol (*Piper cubeba*) and Pomegranate rind (*Punica granatum*) and Clove oilas active ingredients. All of these components are well known for their pharmacological action as an anti-inflammatory, anti- infective and analgesic. The acrid ingredients and pungent ingredients are indicated for sore throat in traditional system of medicine. *Acacia catechu* is extract of heartwood of tree. It is a source of catechins and tannins. These tannins are known to be useful for checking mucous discharge and in inflammation of pharynx and larynx. (Naik G Het *al* 2003; Lakshmi T *et al* 2011). Mace of *Myristica fragrans* used in preparation is a spice. It is aromatic in nature. It contains terpenes, essential oil 7 to 14%. These aromatic essential oil of mace of nutmeg are known to possess anti-inflammatory and analgesic activity (Jinous A *et al* 2012). *Piper cubeba* is having essential oil and alkaloid like piperine. It has antiseptic, antihistaminic, anti-inflammatory, astringent and sedative action (Alam M A. *et al.* 2013). *Punica granatum rind* and fruit is known traditionally for treating sore throat and cough. It has phytoconstituents such as phenolic acid, catechin, quercetin, gallic acid, which contribute to pharmacological action of the drug (Bhowmik D *et al*, 2013). Clove oil serves as flavoring agent as well active constituent. Clove oil is the essential oil obtained from flower buds of plant *Syzygium aromaticum.* It contains mainly Eugenol (72-90% approximately). Eugenol, an active constituent of clove oil has aromatic odour and indicated for treatment of cough, toothaches, headache etc. Clove oil is approved for its use as a topical antiseptic and local anesthetic (Bhowmik D *et al*, 2012).

Jaggery used to form the base of lozenges by melting. Molten jaggary helps to suspend the herbal powders and also imparts hardness to the lozenges after congealing. Additionally, it serves as a flavoring agent in the formulation.

After cooling glassy and smooth lozenges were obtained. These hard lozenges prepared uniformly dissolve and release drugs locally for the treatment of sore throat and cough (Pothu, R *et al*, 2014).

Organoleptic parameters- The lozenges were found to be oval in shape with smooth texture. This oval shape was due to molds used for preparation. The taste of the lozenges was determined using human volunteer panel of 10 people and was sweet and acrid in taste. The sweet taste could be attributed to the use of jaggary as base and acrid taste due to other ingredients. The odour of prepared lozenges was aromatic and agreeable and can be attributed to the presence of clove oil and other crude drugs known to contain essential oils. Colour of lozenges was brown due to base ingredient jaggary and crude drugs which were dark coloured. All these results are represented in Table 2.

Uniformity of weight- Average weight for twenty lozenges was found to be 1.5±0.07gm. The no. of lozenges deviating from the average weight were within limit of 5% specified in the monograph. The uniformity in weight can be correlated with uniformity in dosing. The results are given in Table 3.

Hardness test- The hardness determination is one of the required parameters in quality assessment for lozenges. This indicates the strength of the formulation and ability to withstand the impacts during transportation and handling. The transport and handling may cause chipping of the lozenges. Hence to determine the ability of the formulation to prevent fracturing, hardness testing was performed using Pfizer hardness tester. The average hardness for twenty lozenges was found to be 9 ±0.2 kg/cm^2.

Friability-The additional test to confirm the impact resistance of the formulation, friability testing was performed on the twenty lozenges. The % loss in weight estimated was found to be 0.34% which indicates that the formulation passes the test as the limits specified in Pharmacopoeia indicates that the value should be not more than 1.0% (Table 3).

Disintegration time- Ideally this test is not official for the formulation expected to be dissolved slowly in the mouth and hence the limits are not specific. Still the test was performed to find whether the lozenge dissolves in mouth and how much time it takes to dissolve completely so that the faster and localized onset of action can be obtained. The test was performed as per the procedure given in the monograph for uncoated tablets. The medium used was phosphate buffer pH 6.2 to simulate the pH of oral fluid.Sampled six lozenges revealed average disintegration time of 4±0.5 min (Table 3).

All the results shows that prepared lozenges "Corid-cough pearls" comply with the pharmacopoeial standards. Thus, the developed lozenges meet the desired quality.

Table 2: Organoleptic Parameters

Parameter	Observation
Color	Brown
Odor	Aromatic
Taste	Sweet and acrid
Texture	Smooth
Shape	Oval
Average Thickness	5mm*
Average Length	1.2 cm*

*Number of sample twenty n=20

Table 3: Evaluation of Formulated Lozenges

Parameter	Observation
Average weight*	1.5 gm±0.07gm
Average Hardness*	9 ±0.2 kg/cm^2
Friability	0.34%
Average Disintegration#	4 min±0.5 min

*Number of samples twenty n=20; #Number of samples six n=6

The herbal cough lozenges containing potent drugs of natural origin with brand name "Corid-Cough Pearls" were successfully prepared and evaluated. These cough lozenges are helpful for treatment of early symptoms of cough and throat infection.

Conflict of Interest- None

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