



Formulation and Evaluation of Herbal Cubepops

Prasuna Sundari Pingali*, Sukesh Madhari¹, Sowmya Pujar², Gayathri Lingala³, Bhargavi Bandi⁴, Shivankitha Katttekola⁵.

*Professor, Sri Venkateswara College of Pharmacy, Madhapur, Hyderabad 500081, India.

^{1,2,3,4,5} B. Pharmacy 4th year students at Sri Venkateswara College of Pharmacy, Madhapur, Hyderabad 500081, India.

*Corresponding author's E-mail: jpspingali2014@gmail.com

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ABSTRACT

Cold and cough are seasonal occurrences and sometimes quite frequent in individuals with low immunity and people with reported allergies. Though not serious, their symptoms pose discomfort, affect attendance, decrease concentration at work and, if not attended to, might lead to secondary infections. Herbs are time tested and therefore would be effective as an initial remedy. In the pharmaceutical market, herbal formulations for cough and cold are available as syrups, tablets, lozenges etc. Lozenges offer better patient compliance. Cube pops are available in the US market. Cube pops differ from lollipops in their shape, texture and chewability. The aim of the present study was to formulate and evaluate hard candy cube lollipops. Literature review indicated that myrobalan, tulsi, turmeric, ginger, vasaka, betel etc. as effective remedies. Dried juices and decoctions of herbs were prepared. Placebo cube pops were prepared for the selection of suitable excipients. Drug loaded cube pops F1, F2 and F3 were prepared and evaluated for shape, color, uniformity, texture, chewability, other formulation characteristics, and stability at room temperature. The results obtained are in compliance with the limits specified in IP. The antimicrobial activity of the prepared cube pops was determined against *Staphylococcus aureus* and *Pseudomonas aeruginosa* using the agar-well diffusion method. Vicks Cough Drops (lozenge) were taken as standard. The zone of inhibition obtained indicated that F3 formulated using herbal decoctions was better, as it exhibited 19 ± 0.3 and 17 ± 0.4 (in mm) against *Staphylococcus aureus* and *Pseudomonas aeruginosa* respectively. F3 was found to be stable when stored at 40°C. However, further studies need to be carried out to determine its stability and suitability across all temperature zones.

Keywords: Cold, Cough, Myrobalan, Tulsi, Betel, Antimicrobial activity.

INTRODUCTION

Cold and cough are common symptoms that affect the upper respiratory system. Most often, viral and sometimes bacterial infections contribute to these conditions. Common cold is an acute, self-limiting viral infection of the upper respiratory tract involving the nose, sinuses, pharynx and larynx.¹ Cough is a protective mechanism that ensures the removal of mucus, noxious substances, and infectious organisms from the larynx, trachea, and large bronchi.² Though they are self-limiting in nature, they cause nasal congestion, sleep disturbances, physical, psychological emotional discomfort, impair daily activities, and will reduce the quality of life. These in turn drop attendance and productivity.³ Therefore, it becomes important that this condition be addressed in the initial stage itself. Herbs like turmeric, pepper, haritaki, betel leaf, vasaka, ginger, eucalyptus etc, are used in India for relief of cold and cough since decades. Literature review indicated many herbs which possess expectorant, mucolytic and antimicrobial activity to help in reducing the symptoms and also address infection if present. Most commonly herbal formulations for use in cold and cough available in the market are powders for herbal teas, infusions, decoctions, syrups, gargles, capsules and lozenges. Indian market holds place for number of herbal formulations for use in this condition (Arogyam Herbal Tea, Kasahari cough syrup, Restrec lozenges, Tragutan Tablets).

An alternative to these, lollipops are convenient to use and facilitate patient compliance across all age groups.

Lollipops are intended to be sucked and held in the mouth and contain one or more medicament usually in a sweetened base which can be consumed over a long period of time through licking. They are meant to dissolve slowly in the mouth of the patient and release the contents that might act locally to reduce oropharyngeal symptoms or to be absorbed through the buccal route and act systematically.⁴ Lollipops may include analgesics, antihistamines, cough suppressants, antimicrobial agents, or even certain vitamins or minerals.⁵ Medicated lollipop is designed to improve patient compliance, acceptability and increase oral retention time. Cube pops are similar to lollipops but differ in shape and texture. These are available in the US market, to exemplify differently flavoured cube lollipops (Espez, Vegas). Myrobalan and betel are traditionally used in the management of acute and chronic cough and helps expel mucus secretions. Tulsi is reported to be useful for cold and cough. They contain polyphenols due to which are antimicrobial in nature. The objective of the present work is to formulate and evaluate herbal hard candy cube pops to be beneficial in cold and cough.

MATERIALS AND METHODS

Myrobalan, Betel, and sucrose were procured from the local market. Homegrown tulsi leaves were used for the study. Corn syrup was purchased from Bakers villa, Pvt Ltd. All other chemicals used were purchased from SD Fine Chemicals Pvt Ltd. Cube silicon moulds were purchased from a local supermarket.



Experimental Methodology

Dried juices of the fresh / dried drug in course powder were placed in a mixer grinder together with water. The aqueous juice obtained was filtered, and the filtrate was evaporated to dryness. Decoctions were prepared by boiling 1:16 parts of water till the final volume is reduced to 1/8th of the initial volume.

Preparation of placebos:

Placebos were prepared to select the right proportions of binding/sweetening agent and polymer to achieve the desired texture that defines cubepop. A solution of binder was prepared in hot water, and solution of polymer in water was added to it. On cooling, the solution was transferred to mould for solidification. This was cooled and then poured into the talc coated silicone moulds. They were air dried for 24-36 hours and then demoulded and subjected to evaluation tests primarily for ease of demoulding, shape, texture, and feel of chewability. For placebo preparation, various gelling agents HPMC, CMC, Carbopol 934, gelatin, guar gum and agar were used.

Preparation of herbal cubepops

The herbal actives were included in cube pops either as a decoction or dried juice. Sucrose, and corn syrup were dissolved by heating over a water bath. Agar previously dissolved in water by boiling, was added and stirred continuously. Herbal extracts, flavouring agent, colouring agent and preservative were added and stirred thoroughly until they were uniformly distributed. This was then poured into the talc coated silicone moulds and allowed to air dry for 24 to 36 hours, demoulded and evaluated.

Table 1: Composition of formulated cubepops (200gms)

Composition	F1(gms)	F2(gms)	F3(gms) (decoctions)
Myrobalan	3.3	3.3	25ml
Tulsi	10	10	25ml
Betel	2	2	25ml
Sucrose	50	50	50
Corn syrup	50	-	-
Mannitol	-	50	50
Methyl paraben	0.03	0.03	0.03
Agar	8	8	8
Pineapple flavour	q.s	q.s	q.s
carmoisine	q.s	q. s	q.s

Evaluation of cubepops

The prepared cubepops were evaluated for shape, texture, chewability, and taste. Their weight variation, friability, hardness, thickness, and moisture content were also determined.

Weight variation: Total weight of 10 cubepops were noted and the average weight calculated. The individual weights

were compared with the average weight. The percent deviation was calculated using the formula:

$$\% \text{ Deviation} = \frac{\text{Individual Weight} - \text{Average Weight}}{\text{Average Weight}} \times 100$$

Friability: Friability was determined using Rosch friability apparatus. Weight of Ten cubepops was noted, placed in the drum of Roche friabilator and rotated at 25rpm for 4 mins and the final weight taken. Friability percentage was calculated using the formula:

$$\% \text{ Friability} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

Hardness test: Hardness was measured by placing weights over the cube pops. The weight at which the cube pop broke was noted as its hardness in kg/cm².

Thickness: Thickness was measured by using a screw gauge.

Moisture content: Cube pops were weighed and then placed in the hot air oven at a temperature of 105°C. Weight was measured at regular intervals. This procedure was continued until a constant weight was reached. The difference between the Initial weight and the final weight of cube pops determines the moisture content of the cube pops.

Determination of antibacterial activity: Agar well diffusion method was used to screen the antibacterial activity of medicated herbal cube pops against *Staphylococcus aureus* and *Pseudomonas aeruginosa*. 10% solution of cube pop formulations were used as a test samples. Vicks cough drops was used as standard for comparison. The plates were allowed to settle at room temperature for 30 minutes for diffusion of extracts and incubated at 37⁰±2⁰C for 18- 24 hours. The zone of inhibition was measured (in mm). The experiment was done in triplicate, and average values were recorded.⁶

RESULTS AND DISCUSSION

Physical characters of dried juices of dried juices

Table 2: Physical characters of herbal juices

Character	Myrobalan	Tulsi	Betel
Colour	Brown	Dark green	Green
Total yield (in gms)	10	23	10

Physical characters of decoctions

Table 3: Physical characters of herbal decoction

Character	Myrobalan	Tulsi	Betel
Colour	Light brown	Sap green	Green
% yield (in ml)	25%	25%	25%

Evaluation of placebos

The placebos were prepared using different sweetening agents and gelling agents.



The prepared placebos are evaluated for their shape, texture, flexibility, taste, hardness, and ability to demould from the silicone moulds. PF6 and PF7 formulated using sucrose & mannitol/corn syrup with 4% agar as gelling agents yielded a better product.

Evaluation of herbal cubepops

The prepared formulations F1, F2 & F3 are evaluated for their organoleptic characters, and the results are indicated below.

From the above table it indicates that F2 and F3 formulations are satisfactory in terms of, texture, chewability and demoulding.

The prepared cubepops are evaluated for their weight variation, hardness, thickness, friability and moisture content. Data obtained is indicated in below table.

Table 4: Characteristics of cubepops

Parameters	F1	F2	F3
Defined shape	✓	✓	✓
Texture	Soft	Hard	Hard
Chewability	✓	✓	✓
Taste	Sweet with herbal extract taste.	Sweet with herbal extract taste.	Sweet with herbal extract taste.
Demoulding	Good	Good	Good

Table 5: Evaluation data of F1, F2 and F3.

Parameter	F1	F2	F3
Weight variation	Within the limits	Within the limits	Within the limits
Hardness	4.5kg/cm ²	5.6kg/cm ²	5.6kg/cm ²
Thickness	10.3mm	10.6mm	10.3mm
Friability	0.02%	0.4%	0.6%
Moisture content	1.74gm	5.45gm	4.98gm

The values obtained are found to be in compliance with the pharmacopeial specifications.

Antibacterial Activity

The antibacterial activity was done using agar well diffusion method.

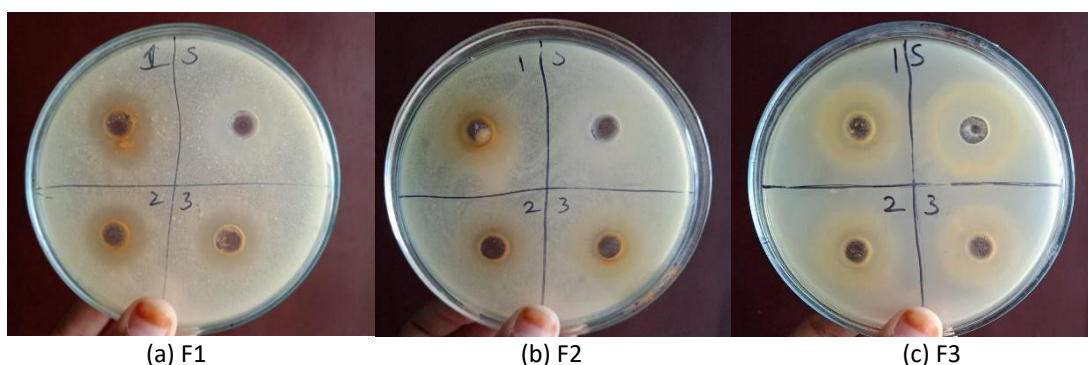


Figure 1: Zones of inhibition of (a) F1 (b) F2 and (c) F3 against *Staphylococcus aureus*

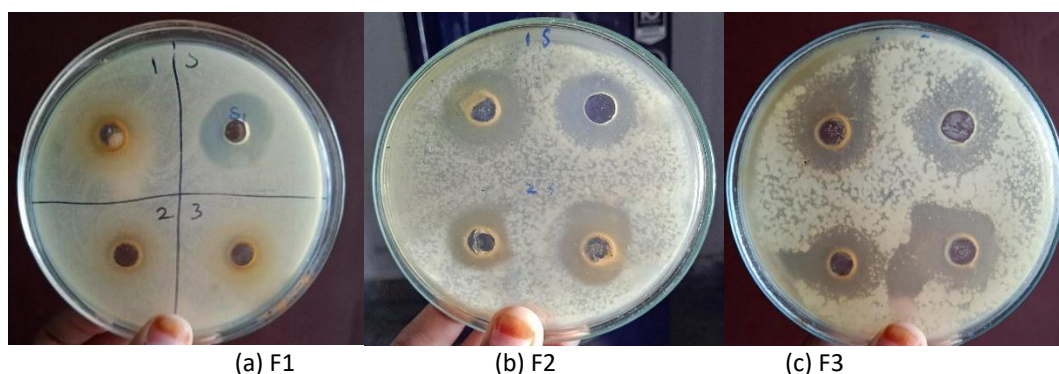


Figure 2: Zones of inhibition of (a) F1 (b) F2 and (c) F3 against *Pseudomonas aeruginosa*

Table 6: Zones of inhibition (mm) of F1, F2 and F3 against *Staphylococcus aureus* and *Pseudomonas aeruginosa*

Bacteria	Formulation	Zone of Inhibition (in mm)*
<i>Staphylococcus aureus</i>	F1	15 ± 0.4
	F2	16 ± 0.2
	F3	19 ± 0.3
	Vicks cough drops	20 ± 0.5
<i>Pseudomonas aeruginosa</i>	F1	14 ± 0.2
	F2	15 ± 0.3
	F3	17 ± 0.4
	Vicks cough drops	19 ± 0.2

* values are the mean of three readings

The above result indicated that the F3 formulated using herbal decoction and agar as gelling agents exhibited antimicrobial activity on par with vicks lozenges containing tulsi.

CONCLUSIONS

Most of the herbs are time tested and easily available. They can be used as medicine for primary ailments. 85% of the world population depends on herbal medicine. Cold and cough are seasonal ailments but if left unattended, they might lead to secondary infections. Myrobalan and tulsi have been reported to be useful in treatment and management of acute and chronic cough. Betel leaf and tulsi are useful in expelling oropharyngeal secretions. Cube

pops formulated with decoctions of these selected herbs exhibited better antimicrobial activity. However, stability studies need to be conducted to indicate storage conditions and shelf life.

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