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Formulation and Evaluation of Herbal Lozenges Containing Eucalyptus Oil and Coleus Aromaticus Oil

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ABSTRACT

The aim of this study was to extract Eucalyptus oil and Coleus aromaticus oil, and to formulate the lozenge tablets in order to investigate a profitable dosage form. Lozenge tablets were prepared using Roller compression method. The tablets also were evaluated for the physicochemical properties such as hardness, friability, weigh uniformity, thickness and disintegration time. The formulated product showed inhibitory activity against non resistant C.albicans infections thus providing a very good release matrix for the eucalyptus and coleus aromaticus combined extract**.** The results clearly indicate that the prepared lozenge tablets can be a good alternative for traditional forms.

Keywords: *Eucalyptus oil*, Coleus aromaticus. lozenge, roller compression, oropharyngeal inflammation.

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INTRODUCTION

Pharyngitis or sore throat is an inflammation of the oropharynx, which is one of the most common complaints seen by emergency physicians. Causes of sore throat include viruses, *Streptococcus*, mononucleosis, *Mycoplasma*, gonorrhea, and diphtheria. For a large group of patients, no cause can be established. Lozenges are flavored medicated dosage forms intended to be sucked and held in the mouth or pharynx. Also they are solid preparation that are intended to dissolve or dissolve or disintegrates slowly in the mouth. They contain one or more medicaments usually in a flavored, sweetened base. Lozenges are most often used for localized effects in the mouth. They may contain vitamins, antibiotics, anesthetics, antihistamines, decongestants, corticosteroids, astringents, analgesics, etc[1-4].

The oropharyngeal symptoms which lozenges are intended to relive are commonly caused by local infections and occasionally by allergy or drying of the mucosa from mouth breathing.

MATERIALS AND METHOD

The leaves of Coleus aromaticus were taken from the medicinal garden of Nazareth college of pharmacy. Othera, Thiruvalla. The leaves of Eucalyptus were taken from the garden of steel plant, Kozhikode. The plants were authenticated at Department of Bioscience in Marthoma college, Thiruvalla, Kerala.

Table: 1

Sl.no:	Materials	Suppliers
1	Magnesium stearate	Nice chemicals
2	Lactose	Nice chemicals
3	Mannitol	Spectrum reagents
4	Gelatin	-
5	Sucrose	-

Table 2: Equipments

Sl no:	Equipment	Model
1	Electronic balance	107
2	Friabilator	RKB 3258
3	Lozenge board roller and punch	-
4	Dissolution apparatus	ALMICRO
5	Monsanto hardness tester	-

MATERIALS AND METHOD

Extraction of Volatile Oil From Eucalyptus Globules[5-8]

The leaves of Eucalyptus were collected and shade dried for 7 days. The leaves were cut into small pieces (50gm) and the distillation was carried out in Clevenger apparatus using distilled water as a solvent (500ml) for 3-5 hrs. The oil obtained in the reservoir was stored in refrigerator at 2-8^{0}c.

The extraction was carried out twice.

Extraction of Volatile Oil from Coleus Aromaticus

The fresh leaves of Coleus aromaticus were cut to small pieces and the distillation was carried out in Clevenger apparatus using distilled water as solvent (500ml) for 3-5hrs. The oil obtained in the reservoir was stored in refrigerator at 2-8^{0}c.

Preparation of Lozenges [21]

Accurate amount of volatile oils were transferred to a beaker, and the mixture was mixed with accurately weighed lactose. Mannitol and sucrose were weighed and powdered thoroughly, drug mixture was added and mix well, then passed through sieve no. 60. The gelatin mixture was added and triturated to produce a mass of the required consistency. The mass was rolled on lozenge board and cut to required size. The lozenges were dried in a hot air oven.

EVALUATION TEST[9-18]

Physicochemical properties:

Physicochemical properties such as physical stability, colour, odour, taste etc. are done.

Weight variation test:

10 lozenges were taken and individual weights were noted, then average weight of lozenges was calculated by total weight divided by ten. Then it was compared with standard monographs.

Friability test:

Using Roche friabilator apparatus at a speed of 25 rpm.

Dissolution time:

Dissolution time was calculated using USP dissolution apparatus

3.5. In vitro antimicrobial evaluation of lozenges:[20]

25ml of sterile normal saline solution were transferred to 3 beakers. 3 lozenges (containing Eucalyptus oil, Coleus aromatics, combination of these two) was dropped into each beaker containing beads and placed on a magnetic stirrer. 1ml solution were withdrawn at a time interval of 5, 10 and 15 min. The samples were stored in sterile test tubes. The standard gentamicin solution (40mg/ml) was diluted to 0.6µg/ml.

A 0.1ml of microorganism (C.albicans) were pipetted into agar plates and allowed to solidify. Wells of 4mm were made and lozenges solution pippeted at various time interval was added to it. Standard gentamicin solution was used as control. Then it is incubated at 37°C for 24 hours and zone of inhibition is measured.

RESULTS AND DISCUSSION

Extraction of volatile oil from eucalyptus and Coleus aromaticus

Extraction of eucalyptus oil and coleus aromaticus oil were done using suitable solvent and suitable amount of oil used with other ingredients as in indicated by the formula.

Formulation development

Trail batches of 50 lozenges were taken (four formulations of eucalyptus alone (E_1-E_4), four with coleus aromatics alone (C_1-C_4) and four formulations containing both eucalyptus oil and coleus aromaticus (G_1-G_4) were taken and the formulas are given below.

Formulations containing Eucalyptus globules alone

Ingredients	E_1	E_2	E_3	E_4
Extracts of Eucalyptus globulus	1%	2%	3%	4%
Lactose	30 mg	30 mg	30 mg	30 mg
Gelatin	100 mg	75 mg	50 mg	60 mg
Mannitol	200 mg	200 mg	200 mg	200 mg
Sucrose	663 mg	688 mg	713 mg	703 mg
Magnesium stearate	7 mg	7 mg	7 mg	7 mg
Purified water	q.s	q.s	q.s	q.s

Formulations containing Coleus aromatics alone

Ingredients	C_1	C_2	C_3	C_4
Extracts of Coleus aromaticus	1%	2%	3%	4%
Lactose	30 mg	30 mg	30 mg	30 mg
Gelatin	100 mg	75 mg	50 mg	60 mg
Mannitol	200 mg	200 mg	200 mg	200 mg
Sucrose	663 mg	688 mg	713 mg	703 mg
Magnesium stearate	7 mg	7 mg	7 mg	7 mg
Purified water	q.s	q.s	q.s	q.s

Formulations containing both Eucalyptus globules and Coleus aromatics alone

Ingredients	G_1	G_2	G_3	G_4
Extracts of Eucalyptus globulus	1%	2%	3%	4%
Extracts of Coleus aromaticus	1%	2%	3%	4%
Lactose	30 mg	30 mg	30 mg	30 mg
Gelatin	100 mg	75 mg	50 mg	60 mg
Mannitol	200 mg	200 mg	200 mg	200 mg
Sucrose	663 mg	688 mg	713 mg	703 mg
Magnesium stearate	7 mg	7 mg	7 mg	7 mg
Purified water	q.s	q.s	q.s	q.s

Physical stability studies of formulations containing Eucalyptus globules alone

Evaluation test	E_1	E_2	E_3	E_4
Physical stability studies				
Color	NCC	NCC	NCC	NCC
Odour	„	„	„	„
Taste	„	„	„	„

Hardness	„	„	„	„

NCC- No characteristics change

Physical stability studies of formulations containing Coleus aromaticus alone

Evaluation test	**C_1**	**C_2**	**C_3**	**C_4**
Physical stability studies				
Color	NCC	NCC	NCC	NCC
Odour	„	„	„	„
Taste	„	„	„	„
Hardness	„	„	„	„

Physical stability studies of formulations containing both Eucalyptus globules and Coleus aromaticus

Evaluation test	**G_1**	**G_2**	**G_3**	**G_4**
Physical stability studies				
Color	NCC	NCC	NCC	NCC
Odour	„	„	„	„
Taste	„	„	„	„
Hardness	„	„	„	„

Evaluation test of formulations containing Eucalyptus globules alone

Evaluation test	**E_1**	**E_2**	**E_3**	**E_4**
Hardness	5	5	5	5
Weight variation	Fail	Pass	Pass	Pass
Friability	1.2	1.1	0.5229	0.5789
Dissolution time	12 min	13min	12min	15min
Anti microbial evaluation	-	-	15mm	20mm

Evaluation test of formulations containing Coleus aromaticus alone

Evaluation test	**C_1**	**C_2**	**C_3**	**C_4**
Hardness	5	5	5	5
Weight variation	Fail	Fail	Pass	Pass
Friability	1.4	1.2	0.4675	0.4555
Dissolution time	11 min	12min	12min	14min
Anti microbial evaluation	-	-	12mm	15mm

Evaluation test of formulations containing both Eucalyptus globules and Coleus aromatics

Evaluation test	**G_1**	**G_2**	**G_3**	**G_4**
Hardness	5	5	5	5
Weight variation	Fail	Pass	Pass	Pass
Friability	1.1	1.2	0.5454	0.5256
Dissolution time	15 min	15min	12min	15min
Anti microbial evaluation	12mm	12mm	20mm	22mm

Depending upon the evaluation parameters E_4,C_4,G_4 were found out as the best formulations and these formulations were used for the scale up batch.

Formula for scale up batch

Ingredients	E_4	C_4	G_4
Extract of Eucalyptus globulus	5%	-	5%
Extract of Coleus aromaticus	-	4%	5%
Lactose	30mg	30mg	30mg
Gelatin	60mg	60mg	60mg
Mannitol	200mg	200mg	200mg
Sucrose	703mg	703mg	703mg
Magnesium stearate	7mg	7mg	7mg
Purified water	qs	qs	qs

Physical stability studies of scale up batch

Evaluation test	E_4	C_4	G_4
Color	NCC	NCC	NCC
Odour	,,	,,	,,
Taste	,,	,,	,,
Hardness	,,	,,	,,

Evaluation test for scale up batch

Evaluation test	E_4	C_4	G_4
Hardness	5	5	5
Weight variation	Pass	Pass	Pass
Friability	0.5789%	0.4555%	0.5256%
Dissolution time	15min	14min	15min
Anti microbial evaluation	20mm	15mm	22mm

CONCLUSION

Extract of eucalyptus and coleus aromaticus has been successfully formulated as a lozenge for the purpose of taste masking, crude drug release and consequent antimicrobial activity. The formulated product showed inhibitory activity against non resistant C.albicans infections thus providing a very good release matrix for the eucalyptus and coleus aromaticus combined extract. Further studies are required to fully standardize combination for maximum antimicrobial activity without compromising the other desirable properties of both eucalyptus and coleus aromaticus, and screen various community strains of fungi and bacteria. Lozenges are of good quality with regards to characteristics like hardness, friability, weight variation and disintegration time. Thus it can be concluded that these lozenges can be used for various diseases and can be used either as lozenges containing single extract or lozenges containing both the extract and is a suitable dosage form for administration.

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