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FORMULATION AND EVALUATION OF HERBAL COUGH SYRUP

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ABSTRACT

In recent years there is a spurt in the interest regarding survival of Ayurvedic forms of medication. In the global perspective, there is a shift towards the use of medicine of herbal origin, as the dangers and the shortcoming of modern medicine have started getting more apparent, majority of Ayurvedic formulation are prepared from herbs. Syrup is very popular dosage form of cough and cold medications, ease of patient compliance. The objective of this study is to develop a polyherbal cough syrup and evaluate the physicochemical parameter along with turbidity/ homogeneity were compared with the changes in accelerated stability testing. Quality of final herbal syrup was evaluated with the parameters: pH, density, total solid content. Three batches were formulated with simple syrup 40%, 50%, 60% w/v .as sugar base. All the batches were evaluated for physicochemical parameters, colour, odour, taste, spec. gravity, pH, total solid content. i.e. Specific gravity (1.24 – 1.36), pH (4.8- 5.0), solid content(37-56.75%). The formulated batches under gone stability studies and microbial test, no turbidity were observed for three months studies and no microbial growth were seen. All the batches assure the reproducibility and each parameter were complying with specifications.

KEY WORDS: Quality of final herbal syrup was evaluated with the parameters: pH, density, total solid content.

INTRODUCTION

In recent years, plant derived products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics and are available in health food shops and pharmacies over the counter as self-medication or also as drugs prescribed in the non-allopathic systems. Herbal medicines widely used in health-care in both developed and developing countries are complex chemical mixtures prepared from plants and are limited in their effectiveness because they are poorly absorbed when taken orally.

According to an estimate of the World Health Organization (WHO), about 80% of the world population still uses herbs and other traditional medicines for their primary health care needs. Herbal formulations have reached widespread acceptability as therapeutic agents for diabetics, arthritics, liver diseases, cough remedies, memory enhancers and adoptogens.[1]

As per WHO definition, there are three kinds of herbal medicines: raw plant material, processed plant material and medicinal herbal products. Herbal drugs are finished labeled products that contain active ingredients such as aerial or underground parts of plant or other plant material or combination thereof, whether in the crude state or as plant preparations.[2]

There is an increasing interest in use of plants in health care for its claimed safety and benefits. Clinical relevance and evidence have been the basis of phytomedicine developments in the past. [3]

Solutions are evenly distributed, homogeneous mixtures of dissolved medication in a liquid vehicle. Molecules of a solid, liquid, or gaseous medication are equally distributed among the molecules of the liquid vehicle. Because the medication is already dissolved in the solution, it is absorbed from the stomach, skin, or other site of administration more quickly than other medication dosage forms.

Cough Syrup is liquid dosage form; the oral use of liquid pharmaceutical has generally been justified on the basis of ease of administration to those individuals who have difficulties in swallowing solid dosage forms. Syrup is a concentrated mixture of sugar and purified water. The high sugar content distinguishes syrups from other types of solutions. Syrups may or may not contain medication or added flavoring agents. Syrups without a medication, but with a flavoring agent, are called non-medicated or flavored syrups. Flavored syrups are often used as vehicles for unpleasant tasting medications: the result is medicated syrup. The high amount of sugar present in syrups predisposes them to bacterial contamination, so they often contain a preservative.

Advantages of liquid dosage form:

- Homogeneous liquid.
- Drug is in solution, immediately available for absorption.

- Ease of administration.
- Oral liquid dosage forms usually are faster acting than solid dosage forms. Medications are absorbed into the bloodstream in a dissolved state. The medication in a liquid dosage form is already dissolved or is present in small particles so it can readily be absorbed. In contrast, tablets must dissolve before they can be absorbed so it takes more time for the medications to be absorbed.
- For patients who have difficulty swallowing, oral liquid medications may be easier to take then an oral solid dosage form.
- Liquid medications may be used where solid dosage forms are not practical to administer. For example, medications that need to be placed directly into the ear or eye may be more practically administered as a liquid rather than a solid.

Advantages of syrup

- Ability to disguise the bad taste of medications.
- Syrups are thicker than aqueous solutions, therefore only a portion of the medication dissolved in the syrup comes in contact with the taste buds. The remainder of the medication is held above the tongue by the thick syrup so it is not tasted as it is swallowed.
- The high sugar content of syrups gives them a sweet taste that helps conceal the bad taste of the medicine. This is why syrups are commonly used for pediatric medications.
- The thick character of syrups also has a soothing effect on irritated tissues.

Rational of preparation of cough syrup

The ingredients of the routinely used cough syrups mostly contain those ingredients, which cause:

- Drowsiness,
- Irritability or dryness in mouth.
- The requirements differ from person to person yet, faster symptomatic relief and trouble-free nature of the product remains supreme.[4]

Cough is a defensive reflex of the respiratory tract which is important to clear the upper airways and should not be suppressed indiscriminately. Cough is thought to be caused by a reflex. It occurs due to stimulation of mechano-or chemoreceptor in throat, respiratory passage or stretch receptor in the lungs. The sensitive receptors are located in the bronchial tree, particularly in the junction of the trachea. These receptors can be stimulated mechanically or chemically e.g. by inhalation of various irritants than nerve impulses activate the cough center in the brain. Traditionally cough is classified as either productive, i.e. producing mucus usually with expectoration, or nonproductive (dry). Therefore, the use of an effective antitussive agent such as Dextromethorphan or Codeine to suppress the debilitating cough suffered by such patients seems Appropriate. Non-Narcotic antitussive agents anesthetize the stretch receptor located in respiratory passages, lungs and pleura by dampening their activity and thereby reducing the cough reflex at its source. [5]

Cough as symptom is often nagging and entails a faster relief from problems that make the life miserable, be it just the sound effect or, a feeling of ‘something stuck in throat caused by the thickened mucus. Cough is sometimes due to:

- ✓ environmental pollution, sometimes as a
- ✓ result of self-inflicted injuries as is seen in smokers.

Cough could be of different types:

- ✓ productive,
- ✓ dry,
- ✓ spasmodic etc
- ✓ Most families prepare home remedies such as tea with honey or a mixture of one part lemon juice and one part honey. Several other ingredients are also common: tamarind, ginger and eucalyptus. Recipes vary widely. Traditional medicines derived from plants have been and will continue to be used for respiratory infections in many parts of the world. There have been few efficacy studies of traditional medicines as therapy for the common cold.[6]

MATERIALS AND METHOD

Various materials used in the preparation of polyherbal cough syrup were procured from Bacfo pharmaceutical India Ltd.

Table: 1 Material and source of cough syrup.

S. No.	Ingredients	Source
1.	Mulethi	Arya vastu bhandar, Dehradun
2.	Vasa	Arya vastu bhandar, Dehradun
3.	Kapoorkachri	Arya vastu bhandar, Dehradun
4.	Pushkarmool	Arya vastu bhandar, Dehradun
5.	Pippli	Arya vastu bhandar, Dehradun
6.	Kali mirch	Arya vastu bhandar, Dehradun
7.	Sonth	Arya vastu bhandar, Dehradun
8.	Tulsi	Arya vastu bhandar, Dehradun
9.	Potassium sorbate and sodium benzoate	Orchid chemicals, Powai
10.	Sabaroud dextrose agar	Titan biotech, Azadpur
11.	Soya casein digest agar	Titan biotech, Azadpur
12.	Mannitol salt agar	Titan biotech, Azadpur
13.	Bismuth sulphite agar	Titan biotech, Azadpur
14.	Nutrient broth agar	Titan biotech, Azadpur
15.	Mcconkey broth	Himedia laboratories pvt ltd
16.	Salt meat broth	Titan biotech, Azadpur
17.	Distilled water	In house
18.	Potassium dihydrogen phosphate	Scientific fische,Hosur
19.	Sodium hydroxide	Scientific fischer,Hosur
20.	Nutrient agar	Titan biotech

PREFORMULATION OF RAW HERBS

Determination of foreign matter

Method: Weighed 500 g or the quantity specified of the original sample and spread it out in a thinner layer. Inspect the sample with the naked eye or with the 6X lenses and separate the foreign organic matter manually as completely as possible. Weighed and determine the % of foreign organic matter from the weight taken.

Moisture content

Weighed 2 g of sample & glass petri dish separately, then heated in hot air oven at 105˚C for 1 hour. Then put off the petri dish from oven and allowed to cool. Percentage moisture content was calculated using following formula:

CALCULATION

(Weight of petri dish + Weight of Sample – Dried weight) X 100 / Weight of Sample

pH analysis

Prepared 1% w/v solution/suspension of sample in distilled water, mixed it properly. Checked the pH with pH meter at 27 ± 2 ºC.

Read the pH value when temperature and pH reading remains constant on display.

Determination of Ethanol Extractive Value

Macerated 5gm of air dried, shaken coarsely powdered drug with 100 ml of ethanol of 95% in a closed flask for 24 hrs. Shaken frequently for first 6h and allowed to stand for 18 hours, thereafter filtered rapidly taking care of loss of ethanol. Evaporated 25 ml of filtrate to dryness in a flat bottomed petridish, dry at 105 ºC and weighed. Calculated the percentage of ethanol soluble extractive with reference to the air dried drug using following formula.

CALCULATION

(Weight after drying - Weight of petridish) x 100 x 100 / weight of sample x volume of filtrate

Determination Of Water Extractive Value

Macerated 5gm of air dried drug coarsely powdered with 100 ml of chloroform water (2.5 ml chloroform in 1000ml water) in a closed flask for 24h, shaken frequently for first 6h and allowed to stand for 18 h, thereafter filtered. Evaporated 25 ml of filtrate to dryness in a flat bottomed shallow dish, dry at 105ºC and weigh. Calculated the percentage of chloroform soluble extractive with reference to the air dried drug, using following formula:

CALCULATION

(Weight after drying - Weight of petridish) x 100 x 100 / weight of sample x vol. of filtrate

Determination Of Total Ash

Incinerated about 2 g accurately weighed, of the ground drug in a tared platinum or silica dish at a temperature not exceeding 450 ºC for 5 hours, until free from carbon, cooled and weighed.

Calculated the percentage of total ash with reference to the air dried drug, using following formula:

CALCULATION

(Weight after drying - Weight of crucible) x 100 / weight of sample.

Determination Of Acid Insoluble Ash

Mixed the ash obtained above in 3.2.6 with 25ml of 2M HCl, collected the insoluble matter on an whattman ash less filter paper 60 mm , washed with hot distill water till fitrate is neutral to litmus paper, ignited for 15 min at temperature not exceeding 450 ºC. Cooled in a desiccator and weighed. Calculate the acid insoluble ash with reference to the air dried drug.using following formula:
(Weight after drying - Weight of crucible) x 100 / weight of sample

Determination Of Moisture Content (Loss On Drying)

Placed about 10 g of drug (without preliminary drying) after accurately weighing (accurately weighed to within 0.01 g) it in a tared evaporating dish. Dried at 105º for 5 hours, and weighed. Continued the drying and weighing at one hour interval until difference between two successive weighings corresponds to not more than 0.25 per cent. Constant weight is reached when two consecutive weighings after drying for 30 minutes and cooling for 30 minutes in a desiccator, show not more than 0.01 g difference.

Determination Of Total Solid Content

Accurately weighed, syrup sample was placed on the empty petri dish. Sample was evaporated on the water bath and further dried at low temperature. Then the dried petri dish was weighed again.

Formula

(b-a / sample weight) X 100

where, b = weight of petri dish after drying, a = weight of empty petri dish

3.5.3. Preparation of liquid oral

To prepare liquid oral form of plant extract of herbs following steps were carried out. It was prepared by decoction method.

3.5.3.1. Method of preparation of decoction

5-2 gm each of herbs was taken. herbs was mixed with 500 ml of water. The material was boiled ,until total volume become one fourth of previous. After boiling liquid was cooled and filtered. Filtrate was taken to prepare final liquid oral form.

3.5.3.2. Method of preparation of simple syrup :

60 gm, 50 gm, 40 gm of sucrose was dissolved in sufficient water to get 100 ml of concentrated simple syrup each. Then the solution was filtered .There simple syrup was used as vehicle.

3.5.3.3. Method of preparation of final liquid oral form

To prepared final liquid cough syrup, one part of decoction was mixed with five parts of simple syrup **(1: 5)v/v.**Solubility was checked by observing the clarity of solution visually. The final liquid dosage form was then subjected to evaluation of production quality as per official standards.

3.5.3. Methodology For Herbal Cough Syrup

Herbal cough syrup was prepared by the following steps :

1. Crude herbs were taken in quantity as mentioned in table 3.12.
2. All the herbs were taken in beaker and added sufficient water and boiled till 1/3rd part was left.
3. Syrup solution of varying concentration (40%, 50%, 60%w/v) was prepared.
4. Filtered both aqueous extract of herbs and syrup solution by filter paper whattman..
5. Slowly by continous stirring, added sugar solution to filtered extract.
6. Volume was made upto 100 ml.
7. Added preservative and flavor and evaluated it.

Table: 2 Formulation of cough syrup

Ingredients / Formulations	Mulethi (gm)	Vasa (gm)	Kapoor-kachari (gm)	Pushkar-mool (gm)	Pippli (gm)	Kali mirch (gm)	Sonth (gm)	Tulsi	Sugar base %	Pepper-mint %
F1	4	2	2	2	1	1	1	2	40	0.02
F2	4	2	2	2	1	1	1	2	50	0.02
F3	4	2	2	2	1	1	1	2	60	0.02

RESULT AND DISCUSSION

Table:3 Preformulation study results of cough syrup

PARAMETERS / INGREDIENTS	Liquorice	Vasaka	Kapur kachari	Pushkar mool	Pippli	Kalimirch	sonth	tulsi
Foreign matter (%)	0.05	0.23	0.05	0.05	0.04	0.04	0.01	0.2
Moisture (%)	5.5	6.0	5.2	5.8	7.3	3.0	4.2	3.2
Water soluble extractive (%)	27.2	26.1	6.9	32.6	8.8	7.5	11.7	15.6
Alcohol soluble extractive (%)	11.6	3.56	2.67	13.45	6.12	8.56	4.56	10.12
Total ash (%)	8.4	16.4	7.21	3.42	4.25	3.33	4.76	15.34
Acid Insoluble ash (%)	1.84	0.33	1.23	0.25	0.23	0.26	0.76	1.56

Post-formulation evaluation results

Table: 4 General Evaluation Result for Cough Syrup

S. NO.	TEST	FORMULATION		
		F1 (40%)	F2 (50%)	F3 (60%)
1.	pH Value	4.83	5.0	4.8
2.	Specific Gravity (wt/ml)	1.24	1.34	1.36
3.	Total Solid Content(%)	37	45.56	56.75
4.	Thermal stability	Ok	Ok	Ok
5.	Degradation product	No	No	No

Table: 5 Organoleptic Evaluation of Cough Syrup

S. NO.	SPECIFICATIONS	FORMULATION		
		F1 (40% sugar base)	F2 (50% sugar base)	F3 (60% sugar base)
1.	Physical Appearance	Viscous liquid	Viscous liquid	Viscous liquid
2.	Colour	Brownish	Brownish	Brownish
3.	Taste	Sweet	Sweet	Sweet
4.	Odour	Sweet aromatic	Sweet aromatic	Sweet aromatic

Table: 6 Micro-biological parameters

S.NO.	After 1-day	After 30- days	After 60 -days	After 90 –days
Formulation no.1 (SUGAR BASE 40 %)	TMC: less than 100 YMC: less than 100 E. coli: Ab S.typhi: Ab P. aeruginosa: Ab S. aureus: Ab	TMC: less than 100 YMC: less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab	TMC: less than 100 YMC less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab	TMC: less than 100 YMC: less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab
Formulation no.2 (SUGAR BASE 50%)	TMC: less than 100 YMC: less than 100 E. coli: Ab S.typhi:Ab P. aeruginosa: Ab S. aureus:Ab	TMC: less than 100 YMC: less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab	TMC: less than 100 YMC: less than 100 E. coli: Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab	TMC: less than 100 YMC: less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab
Formulation no.3 (SUGAR BASE 60%)	TMC: less than 100 YMC: less than 100 E. coli: Ab S.typhi:Ab P. aeruginosa: Ab S. aureus:Ab	TMC: less than 100 YMC: less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab	TMC:less than 100 YMC: less than 100 E. coli: Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab	TMC: less than 100 YMC: less than 100 E. coli:Ab S.typhi:Ab P. aeruginosa:Ab S. aureus:Ab

Table: 7 Accelerated Stability Study data for cough syrup :

MONTHS/ TESTS	F1				F2				F3			
	Initial month	After 1 month	After 2 month	After 3 month	Initial month	After 1 month	After 2 month	After 3 month	Initial month	After1 month	After 2 month	After 3 month
Physical appearance	Viscous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid	Vis-cous liquid
Texture	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Colour	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown
Odour	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic	Sweet aromatic
pH Value	4.83	4.81	4.85	4.94	5.0	5.06	5.05	5.07	4.86	4.85	4.82	4.8
Specific gravity	1.24	1.22	1.22	1.22	1.34	1.32	1.34	1.34	1.36	1.33	1.34	1.34
Thermal stability	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Degradation of product	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Microbial count (cfu/gm)	less	less	less	less	less	less	less	less than	less	less	less	less than

	than 100	than 100	than 100	than 100	than 100	than 100	than 100	100	than 100	than 100	than 100	100

CONCLUSION

The present study "develop and evaluate polyherbal cough syrup" revealed certain conclusion.

The preformualtion studies were within the in house specification. The physicochemical property of polyherbal cough syrup finished product were :Specific gravity (1.24 – 1.36), pH (4.8- 5.0), solid content(37-56.75%) The colour (brown), odour (sweet aromatic), and taste (sweet) of polyherbal cough syrup was satisfactory in physical appearance.

Among all the formulations F3 were considered best as it has appropriate concentration of sugar according to IP. and good preservative. The pH (4.8), Density (1.36gm/ml), and solid content (56.75%).

The herbal product is in high demand because of the least possibilities of side effect. The present studies help to develop a herbal cough syrup with 60% w/v base syrup, which is effective and safe.

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Conflict Of Interest

We declare that there is no conflict of interests regarding the publication of this paper.

REFERENCE

1. Moore Michael, "Herbal Formulas For Clinic and Home", Bisbee, AZ 85603, 1995; 1-34.
2. Neeraj Choudhary and Bhupinder Singh Sekhon, "An overview of advances in the standardization of herbal drugs", J Pharm Educ Res., 2011; 2(2): 55-70.
3. Tanuja Nesari, B. K. Bhagwat, Jasmin Johnson, Narenda S. Bhatt, and Deepa Chitre, "Clinical Validation of Efficacy and Safety of Herbal Cough Formula: Study of Herbal Cough Syrup", Journal of Herbal Pharmacotherapy, 1-12.
4. S Satam, R Jain, J Dagaonkar, C Chotalia, A Suthar, and R Joshi, "Evaluation of Clinical Efficacy and Tolerance of Khasceeze –SF Cough Syrup", International Journal of Pharmaceutical Sciences and Drug Research, 2011; 3(1): 67-68.
5. A.Kesari, G.Kaushal, T.K.Mohapatra, R.R.Nayak, T.Satapathy, and B. Meher, "International Journal of Universal Pharmacy and Life Sciences "; International Journal of Universal Pharmacy and Life Sciences, 2011; 1(2): 325-330.
6. Department of Child and Adolescent Health and Development World Health Organization "Cough and Cold Remedies For The Treatment Of Acute Respiratory Infections In Young Children", Switzerland, 2001; 1-33.