Research Article
AMERICAN JOURNAL OF PHARMACY AND HEALTH RESEARCH

www.ajphr.com
2020, Volume 8, Issue 4
ISSN: 2321–3647(online)

Formulation and Evaluation of Polyherbal Anti-Tussive Syrup

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ABSTRACT

Now a days the synthetic and novel drugs are the major source of curing any type of disease, although these chemically synthesized drugs are harmful hazardous and shows toxic effect on the human body, this research formulation is a Polyherbal product (expectorant) which is useful and effective to treat the acute as well as chronic cough mainly chronic cough in patients of all ages. The prolonged chronic cough which last for several months or even years (in some patients) so to treat this "polyherbal anti-tussive syrup" is best mode, this syrup consist of some prominent and effective naturally occurring drugs or medicinal plants like, cinnamon, clove, black paper, Tulsi , honey (as base), and menthol (as cooling agent expectorants). This particulate combination of drugs is very effective for the treatment of cough, although this syrup can also be used for the treatment of the common cold respiratory disorders or nasal problems.

Keywords: Anti-tussive, Medicinal Plants, Polyherbal Formulation, Expectorants, Cough Syrup

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Received 10 March 2020, Accepted 01 April2020

Please cite this article as: Rajmane RB *et al*., Formulation and Evaluation of Polyherbal Anti-Tussive Syrup. American Journal of Pharmacy & Health Research 2020.

INTRODUCTION

Nature has been a source of medicinal agents for thousands of years, and an impressive number of modern drugs have been isolated from natural sources, particularly plants and with many based on their use in traditional medicine. By using medicinal chemistry and combinatorial chemical and biosynthetic technology, novel natural product needs will be optimized on the basis of their biological activities to yield effective chemotherapeutic and other bioactive agents.[1]

During the past decades, public interest in natural therapies, namely herbal medicine, has increased dramatically not only in developing countries but mainly in industrialized countries.[2] Cough associated with the acute and chronic conditions is commonly in patients of all ages, common cause of cough are bacterial or viral infection on the upper respiratory tract, air pollution cigarette smoking, foreign body, asthma and eosinophilic bronchitis. Only controlling the etiology of cough may not be effective treatment but also addition of desensitizing of cough pathways is also essential.[3] Treatment of cough depends on function the cough is serving, when cough indicates an under an underlying illness but treatment should also attempt to control, prevent or eliminate using the cough suppressive agents. In these situations the use of expectorants and anti-tussive agents are indicated not only to alleviate the cough but also to eliminate the more serious events occurring.[4] During the past decades, public interest in natural therapies, namely herbal medicine, has increased dramatically not only in developing countries but mainly in industrialized countries.[5] In this research article poly herbal anti- tussive syrup formulation containing some of the natural drugs like Clove (*Eugenia aromatica*), Cinnamon (*Cinnamomum cassia*), Black pepper (*Piper nigrum*), Tulsi (*Ocimum sanctum*), peppermint (menthol) & Honey (as a base) were formulated and evaluated. These particulate combinations of natural drugs which have cough repellent property are made in form of syrup. These are nontoxic not harmful does not show any of side effect on human body and most superior than of OTC drugs. List of drugs used with their Biological name were shown in Table 1.

Table 1: Names of Drugs (List of drugs used with their biological name & family)

Sr.No.	Name of drug	Biological name	Family
1)	Clove	*Eugenia aromatica*	Myrtaceae
2)	Cinnamon	*Cinnamomum cassia*	Lauraceae
3)	Black pepper	*Piper nigrum*	Piperaceae
4)	Tulsi	*Ocimum sanctum*	Lamiaceae
5)	peppermint	Menthol/ mentha	Mint
6)	Honey	-----	-----

MATERIALS AND METHOD

Clove

Ripped dried flower of Clove (*Syzygium aromaticum*) was used. These are easily available in the market in the dried form but it requires drying in sun light for nearly 4 to 5 hrs. Then nearly 20 to 30 g of dried clove was taken for formulation purpose.

Cinnamon

Ripped dried bark of cinnamon (*Cinnamomum cassia*) was used. These are also easily available in market in dried form it also requires a sun light drying for removal of total moisture. Then nearly 20 to 30g of the cinnamon was taken for the formulation.

Black paper

Dried ripped fruit part of black paper (*Piper nigrum*) was used. These are small black coloured bean shaped cleaned and cleared. These are also available in market like other drugs. Nearly 10-15g of drug was taken for formulation.

Tulsi

Fresh plucked leaves of tulsi was used which should be weighed nearly 20-25g was taken for formulation.

Peppermint

Menthol crystals which are easily available in the market, just crushed it into powder, and nearly 0.2-0.5g was taken for formulation.

Honey

Any of the marketed branded product honey can be used (Marketed preparation of Dabur honey of 250 ml was used) which is already purified and stabilized, nearly 40-50ml of honey was taken for formulation.

Preparation method for Syrup

Preparation of drug powder[6]

The required amount of the each dried crude drug (clove, cinnamon, black paper) about 20-40g, was taken and crushed into fine powder using the mortar and pestle, the each drug was powdered separately, then each drug was collected in separate vessel and weighed, each drug should full fill the required amount. Clove and cinnamon should weigh nearly 20-40g and black paper nearly 10-15g.

Extraction by maceration

The each powdered drug was taken for the process of maceration, Each drug is socked separately in different beaker containing 400-500ml of distilled water, or slightly alcohol treated water nearly

5% alcohol (2-4ml alcohol in 100ml water). The adequate amount of water was added that means 13-14 times the quantity of drug, and then these beakers were put for nearly 17-24 hours for undisturbed condition.

Preparation of Tulsi leaves decoction

Firstly, the fresh green leaves of Tulsi should weigh nearly 30-40g was taken and washed and cleaned properly and added in a beaker and soaked with 400-500ml distilled water (nearly 3-4 times more quantity of drug), then kept aside undisturbed for nearly 4-5 hours, then after 4-5 hours boiled it until the quantity of water remain less than small portion or one third of original nearly 20-25 ml. Then it was taken and filtered with muslin cloth and stored well.

Preparation decoction of macerated drugs

The powdered drugs which were macerated earlier collected and boiled separately at constant temperature for 1-1.5 hour, up to when the quantity of water remains less than small portion or one third original nearly 10-20ml, then decoction was filtered with muslin cloth and stored separately.

Preparation of final poly herbal syrup

In a of 100ml beaker nearly 50ml of honey was taken as the honey is itself syrup so no need to prepare any syrup as it is a drug constituent as well as the syrup, then it was kept aside. Then the prepared decoction of all drug constituents (which should be as clove-15ml, cinnamon-15ml, Tulsi-15ml, black paper-10ml) was taken and mixed well. And while mixing nearly 0.3gm of menthol was added. Finally the prepared mixture was added in the beaker containing the honey, and then the mixture was shaken to produce one phase, and kept for stabilization. Lastly final volume of syrup was made upto 100ml with the water.

Consistency comparison

Formulation F1 & F2 were prepared. F1 contains less concentration of honey as compare to F2 (formulation of F1 & F2 were listed in table -2), the F1 was the syrup which was not passed the viscosity, density and some other physiochemical parameters because of its poor consistency and unbalanced stability, then by observing the drawbacks of the first formulation F1 the second formulation F2 was designed and its formula was structured, which was successful and final, in first formulation F1 mainly the viscosity and density of syrup were not as the syrup must consist of the slightly less than the normal values because of less concentration of base Honey which is responsibility of high viscosity, and then in second formulation F2 the concentration of honey was increased which was then stable and finalized.

Table 2: Formulation of F1 &F2 formulation

Sr.No.	Drugs	Formulation (F1) (per 100ml)	Formulation (F1) (per 100ml)
1	Clove	20ml (decoction)	15ml (decoction)
2	Cinnamon	20ml (decoction)	15ml (decoction)
3	Tulsi	20ml (decoction)	15ml (decoction)
4	Black paper	15ml (decoction)	10ml (decoction)
5	Honey	25ml (marketed)	50ml (marketed)
6	Menthol	0.3g (Crystals)	0.3g (Crystals)
7	Propyl paraben	-	0.2mg

EVALUTION TEST FOR THE POLY HERBAL SYRUP:

Physiochemical parameters of syrup[7-8]

The herbal syrup was evaluated for various physicochemical parameters such as physical appearance (colour, odour, taste), pH, Density and Specific Gravity.

Colour Examination

Five ml final syrup was taken into watch Glass and placed against white back ground in white tube light. It was observed for its colour by naked eye.

Odour examination

Two ml of final syrup was smelled individually. The time interval among two smelling was kept 2 minutes to nullify the effect of previous smelling.

Test examination

A pinch of final syrup was taken and examined for its taste on taste buds of the tongue. Or simply a pinch of syrup was put on tip off tongue for determining test.

Determination of pH

Placed an accurately measured amount 10 ml of the final syrup in a 100 ml volumetric flask and made up the volume up to 100 ml with distilled water. The solution was sonicated for about 10 minutes. pH was measured with the help of digital pH meter.

Determination of density

Density of the syrup was determined by using the density bottle method by measuring the weight and the volume, by the density bottle average density was found to be 1.43g/ml.

Specific gravity at 25°C

A thoroughly cleaned and dry Pycnometer was selected and calibrated by filling it with recently boiled and cooled water at 25°C and weighing the contents. Assuming that the weight of 1 ml of water at 25^0C when weighed in air of density 0.0012g/ml was 0.99602g. The capacity of the Pycnometer was calculated. Adjusting the temperature of the final syrup to about 20°C and the Pycnometer was filled with it. Then the temperature of the filled Pycnometer was adjusted to 25°C,

any excess syrup was removed and weight was taken. The tare weight of the Pycnometer was subtracted from the filled weight. The weight per ml was determined by dividing the weight in air, expressed in g, of the quantity of syrup which fills the Pycnometer at the specified temperature, by the capacity expressed in ml, of the Pycnometer at the same temperature.

Determining the viscosity of syrup

The viscosity of the syrup was determined by using viscometer mainly capillary viscometer, the average viscosity of any syrup at 21-30°c temperature is 700-1300 centipoise or cp, the determined viscosity of syrup was 880cp.

Stability testing [9-10]

Stability testing of the prepared poly herbal syrup was performed on keeping the samples at accelerated temperature conditions. Six portions of the final syrup (A1 A2 A3, B1 B2 B3, C1 C2 C3), In these batches A1, A2 & A3 are the syrups without added preservatives and B1 B2 B3 & C1 C2 C3 are the syrups with added preservatives like ethyl paraben, methyl paraben, were taken in amber cooled glass bottles and were kept at accelerated temperature at 7°C, Room temperature (Nearly 23-27°c) and 48°C respectively. The samples were tested for all the physicochemical parameters, turbidity and homogeneity at the interval of 24 hr, 48 hr and 72 hr to observe any change.

Antimicrobial Activity [11-12]

The antimicrobial activity of the poly herbal syrup was tested by using the cup plate method, & using the agar media, in that four different testing plates were prepared as F1, F2, Control and blank, the F1 plate consist of the syrup without preservatives, F2 plate consist of the syrup with preservatives and control plate consist of the any of standard antimicrobial preparation (Marketed Adulsa syrup containing preservative like methyl paraben & propyl paraben) & the blank, (The microbial culture used is *Escherichia-coli* bacteria). The antimicrobial activity was determined by measuring the diameter of zone of inhibition.

RESULTS AND DISCUSSION

Physiochemical parameters of syrup

The physiochemical parameters such as colour, odour, taste p^H, density, specific gravity viscosity of syrup were performed. The evaluation parameters results were listed in Table -3. The prepared Poly herbal anti-tussive syrup is Brownish red, sweet in taste with neutral p^H & having good pourabilty.

Table 3: Physiochemical parameters

Sr. No.	Physiochemical parameters	Observed values (F2)	Observed values (F1)
1	Colour	Brownish red	Brownish red
2	Odour	Aromatic	Aromatic
3	Taste	Sweet aromatic	Sweet aromatic
4	pH	6.98pH	6.51pH
5	Density	1.43g/ml	1.20g/ml
6	Specific gravity	1.39g	1.19g
7	Viscosity	880cp	799cp

Antimicrobial activity

The anti-microbial activity was successfully performed for F1 & F2 syrup. The antimicrobial activity was determined by measuring the diameter of zone of inhibition. The results obtained in the evaluation of the antibacterial activity of both F1 & F2 syrup were depicted in table no.4. It is observed that the F1 plate syrup without added preservatives were shown less antimicrobial activity and less zone of inhibition as compared to the F2 plate syrup with added preservatives, hence there is prominently need to add preservative in poly herbal syrup, the results of anti-microbial activity were shown in the photographic manner in figure-1-3.

Figure: 1. Anti-bacterial activity of polyherbal syrup (Control plate, F1 &F2 plate)

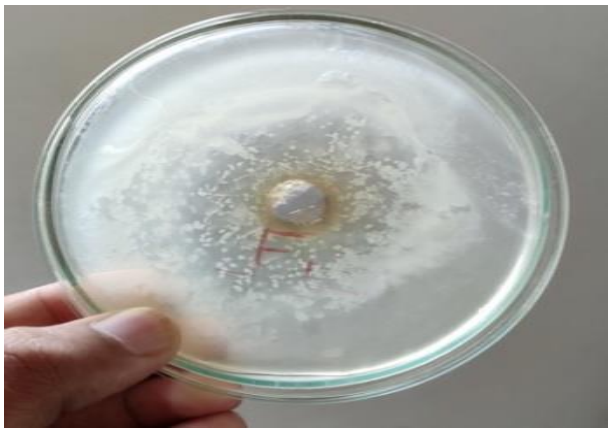

Figure: 2. Plate without added preservative

Figure: 3. Plate with added preservative

Figure: 4. Control plate

Table 4: Antimicrobial activities of F1 & F2 syrup

Sr. No.	Test micro-organism	Zone of inhibition (mm) F1	F2	Adulsa Syrup
1	*Escherichia coli*	7.91	10.13	10.37
2	*Staphylococcus aureus*	10.76	15.91	16.50

Stability testing[10]

The stability testing was performed by keeping final formulation under variation of temperature of 7°C, 27°C & 43°C for different duration of time as 24hrs, 42hrs, & 72hrs respectively, The results of stability studies were shown in Table -4. This proves the syrup has passed the accelerated stability studies. It is observed that polyherbal syrup was homogeneous & does not show any turbidity & there was no any change in colour, odour, taste & pH under 7°C, 27°C & 43°C.

Table 4: Stability studies through physiochemical parameters

Sample code	Time duration (in hr)	Temperature in °C	Parameters						
			Color	Odour	Taste	pH	Density	Specific gravity	Turbidity/ Homogeneity
A1		7°C	NC	NC	NC	6.98	1.43g/ml	1.39g	No turbidity
A2	24 hrs	RT	NC	NC	NC	6.98	1.43g/ml	1.39g	OC
A3		48°C	NC	NC	NC	6.98	1.43g/ml	1.39g	Homogeneity
B1		7°C	NC	NC	NC	6.98	1.43g/ml	1.39g	No turbidity
B2	42 hrs	RT	NC	NC	NC	6.98	1.43g/ml	1.39g	OC
B3		48°C	NC	NC	NC	6.98	1.43g/ml	1.39g	Homogeneity
C1		7°C	NC	NC	NC	6.98	1.43g/ml	1.39g	No turbidity
C2	72 hrs	RT	NC	NC	NC	6.98	1.43g/ml	1.39g	OC
C3		48°C	NC	NC	NC	6.98	1.43g/ml	1.39g	Homogeneity

RT= Room temperature, OC= original condition, NC= No change, hrs= hours

CONCLUSION

The present study concluded that by giving a comprehensive view of herbal drugs for the treatment of cough as crude drug as well as poly herbal formulations is good alternatives of modern cough drugs which are having a lot of side effects. In the present research polyherbal anti-tussive syrup containing medicinal plants like, cinnamon, clove, black paper, tulsi, honey (as base), and menthol (as cooling agent expectorants) were formulated & prepared evaluated successfully. According to present study it was concluded that the prepared polyherbal anti-tussive syrup shows good physical characteristics, exhibit antimicrobial activity & good accelerated stability study. This research successfully concluded that the formulated poly herbal anti-tussive syrup shows its maximum effect and also decrease in the severity of cough, the good tolerability profile of the syrup makes it particularly useful in patients with cough. Individual ingredients of the syrup have broad spectrum activity like anti-tussive, expectorant, anti-histaminic, bronchodilator and nasal-decongestant anti-allergic, anti-bacterial, and anti-viral supported by the scientific studies. The effectiveness of this poly herbal syrup daily dose of one to two teaspoons to patients with sore throat, hoarseness of voice and condition like chronic bronchitis asthmatic bronchitis, and acute upper respiratory tract infection in patents of all ages.

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