Formulation and Stability Studies of Herbal Suspension of Heliotropium Indium Powder

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ABSTRACT

The present study was focused on the stability study of herbal suspension of Heliotropium Indiumpowder. The suspension is useful in tuberculosis. Herbal medicine is the oldest form of healthcare known to humankind. Herbs had been used by all culture throughout history. It was an integral part of the development of modern civilization. Herbal medicinal products are defined as any medicinal products, exclusively containing one or more active substances. The WHO report 80% of the world population relies on the drug from natural origin.

Keywords: Herbal suspension, Heliotropium Indium, Stability study.

INTRODUCTION:

In improving the quality of human life plants have played a significant role. Herbal medicine is based on the principle that plants contain constituents that can promote health and alleviate illness. All over the world the plants research has increased and the collected evidences showed the immense potential of medicinal plants used in various traditional system. There are many medicinal plants generally used in ocular diseases which are easily available and possessbiological activity. Mycobacterium tuberculosis is a worldwide problematic, communicable pathogen causing both pulmonary as well as skin tuberculosis.

Heliotropiumindicum (HI) Linn (Family Boraginaceae)[1,2] is a medicinal plant. It has various medicinal uses in the treatment of disease conditions such as abdominal pains, amenorrhoea, skin rashes, wounds, hypertension, ocular infections, convulsion, dizziness and tuberculosis. Cold infusion of the leaves used as an enema, stops abdominal pains; this preparation also removes cataract in the eye; the juice from the leaves is squeezed into the eye to stop dizziness; decoction of the whole plant is used to treat convulsion in children. Other medicinal uses of HIcomprises the use of juice of the leaves as an antiseptic and anti- inflammatory agent when applied to wounds, sores, boils, gum boils and pimples on the face.Boiled with castor oil, it is applied to sores from scorpion bites and also locally used in treating Ophthalmic disorder. The volatile oil from the aerial parts isolated by hydrodistillation was studied for antituberculosis activity against Mycobacterium tuberculosis H37Ra in the Alamar blue assay system. The results revealed significant antituberculosis activity with an MIC of 20.8 µg/ml[3]

The oral rout of drug administration is the most important method of administrating drugs for systemic effects. Ayurvedic herbal formulations were also administered preferentially by oral route. Designing of oral herbal formulations is till date a challenge in modern pharmaceutics[4]. Suspension is coarse dispersion of finely divided solid particles of a drug dispersed in a liquid medium, in which the drug is not readily soluble. An aqueous suspension is a useful formulation system for administering an insoluble or poorly soluble drug[5].

Our aim of the project is to prepare and evaluate the oral suspension from HI leaf extract to treat against Mycobacterium tuberculosis.

MATERIAL AND METHODS:

Collection and preparation of plant powder:

The leaves of *H. indicum* were collected in the month of December from Nagercoil, TN anddried in shade. The plant was authenticated by Dr.D.Stephen, Madurai medical college, TamilNadu. The shade dried leaves were powdered to get a coarse powder. The powder was passed through sieve No. 40 and stored in an airtight container for further use.

Preparation of extracts:

The leaf of the plant were dried in shade for about 3 weeks and ground by using a mixer to a coarse powder.Powders of leaf were first extracted with the petroleum ether for defatting and then successively re-extracted with ethyl acetate and 70% acetone for 48 hrs. Obtained acetone extract was filtered and dried by usingrotary flash evaporator.

The 20gm of coarse powder of leaf was boiled in 400 ml of distilled water and were further heated at 60–70°C to a concentrated solution (~50 ml). Extracts were subsequently filtered through 0.22µm filters and concentrated to dry mass by using vacuum distillation. The percentage yield was calculated. The aqueous extracts were used for further study.

Preparation of herbal suspension dosage form:

The composition of formulation for preparing 100 ml of suspension of *H. indicum*powder was as shown in Table 1. The 100-mesh size fine particles of the drugs are properly mixed by triturating[6]. After that the drug mix in water and the different additive such as Tween-80, sodium carboxymethyl cellulose (CMC), sweetening agent, flavoring agent, and sodium benzoate used for its better stability during shelf life of formulation[7].

Table 1: Composition of herbal suspension

S.No.	Name of ingredients	Quantity taken		
		F1	F2	F3
1.	*H. indicum*powder	1g	1g	1g
2.	Tween 80	0.1w/v	0.1w/v	0.1w/v
3.	Sodium CMC	0.5%	0.7%	1.0%
4.	Sodium benzoate	1g	1g	1g
5.	Sugar™ Free gold	0.1g	0.1g	0.1g
6.	Lemon oil	1 ml	1 ml	1 ml
7.	Purified water q.s	100 ml	100 ml	100 ml

Sedimentation volume:

The sedimentation volume is the ratio of the ultimate height (Hu) of the sediment to the initial height (Ho) of the total suspension as the suspension settles in a cylinder under standard condition. It wasdetermined by keeping a measured volume of suspension in a graduated cylinder in an undisturbed state for a certain period of time and note that the volume of the sediment which is expressed as ultimate height.

Redispersibility:

The suspension was allowed to settle in a measuring cylinder. The mouth of the cylinder was closed and was interred through 1800 and the number of inversion necessary to restore a homogeneous suspension was determined.

Rheology:

The time required for suspension sample to flow through a pipette was determined the apparent viscosity was using the equation.

Flow rate = Volume of pipette (ml)/Flow time

Viscosity:
The viscosity of the sample was determined at room temperature using Brookfield viscometer at 50 rpm by using spindle no. 3.

pH: The pH of suspension was determined using pH meter.

Crystal growth:
Stability of suspension will also decrease because of crystal growth, which usually occurs from temperature fluctuation during storage and form broad particle size distribution. Crystal formulation was determined at 4°C, Room temperature (RT) and 47°C. The resulting parameters of suspension for all formulation are shown in Tables 3 and 4.

Table 2: Physical test for herbal suspension

S.No.	Parameter	F1	F2	F3
1.	Nature	Liquid	Liquid	Liquid
2.	Color	Slight brownish	Slight brownish	Slight brownish
3.	Odor	Pleasant	Pleasant	Pleasant
4.	Texture	Suspension	Suspension	Suspension

Table 3: Accelerated stability studies

S.No	Parameter	F1	F2	F3
1.	Redispersibility	1 inversion	1 inversion	1 inversion
2.	pH	6.5	6.5	6.5
3.	Flow rate	5ml/5.40 sec	5ml/22.40 sec	5 ml/1 min 25 sec
4.	Viscosity	70cPs	113cPs	285 cPs
5.	Sedimentation	3.21	1.51	0.92

Table 4: Crystal formation of formulation

S.No	Formulation code	Time duration (hrs)	Temperature (°C)	Crystal Formation
1.	F1	24	4°	No
2.	F2	24	RT	No
3.	F3	24	47°	No
4.	F1	48	4°	No
5.	F2	48	RT	No
6.	F3	48	47°	No
7.	F1	72	4°	No
8.	F2	72	RT	No
9.	F3	72	47°	No

RESULTS AND DISCUSSION:

Herbal suspension was prepared, and stability parameters were evaluated. The World health organization guidelines and parameters are now very essential for developing herbal products for various diseases. Moreover, pharmaceutical formulation in the form of suspensions many require preservatives, coloring, flavoring agents and other similar additives. Therefore, the necessity of adding a preservative at the desired level as well as its physical and chemical compatibility with other constituents of the medicinal product must be demonstrated. Sugar free

gold (zydus wellness) was selected as a sweetening agent and Tween 80 is polysorbate used as surfactant and also used to increase bioavailability in oral suspension and due to non-ionic nature, it does not change pH of the suspension. CMC improves viscosity and stability of suspension. Lemon oil was used as a flavoring agent in suspension. Sodium benzoate is used as a preservative. It is relatively non-toxic and least harmful preservative. The prepared suspension formulation was found to have redispersibility property with sedimentation studies showed that the sedimentation volume of formulation F3, which indicates that the formulation was optimum and acceptable. All stability parameter is optimum stable and acceptable at variable temperature. There was no significant change observed in physicochemical and Organoleptic behavior.

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