

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Website: www.ijirset.com

Vol. 6, Issue 9, September 2017

Development, Formulation and Evaluation of Saracaindica Leaf Extract Tablets for Menorrhagia a Feminine Disorder

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ABSTRACT: The aim of the present study was to develop, formulate and evaluate the pharmaceutical parameters of saracaindica leaf extract. Formulation was prepared by saracaindica leaf extract, and it was optimized for better purity and acceptability of herbal medicine in the treatment of menorrhagia condition (an intrauterine disorder). Plant leaf was authenticated, cleaned, dried, and grinded and extraction was carried out for phytochemical screening. Later pre formulation and post formulation parameters were carried out. Preformulation characteristics like particle size, flow properties, angle of repose, porosity, bulk and tap density, compression and hardness ratio, were calculated to get a desired strength of 300mg. The quality of formulation was evaluated by weight variation, disintegration time (mean \pm S.D, 9.81 ± 2.65) and Dissolution (mean \pm S.D, 96.0 ± 3.721) and stability studies that indicated temperature and humidity had no significant effect on the prepared tablets. The conclusion of the study is that the herbal medicine can be used more conveniently and safely in various diseased condition, in case used in proper proportion and combination.

KEYWORDS: Pharmaceutical parameters, Saracaindica, Formulation, antimenorrhagial tablet.

I. INTRODUCTION

Indian is known for a rich tradition of ethno botanical medicine based remedial practices primarily involving medicinal plants and their products. The country accounts for sizeable biodiversity on the planet. Various treatment systems on the planet. Various traditional treatment systems such as Ayurveda, Unani, Siddha, etc. have been extensively practiced by locals since ancient times. Close to 25,000 effective plant based drug formulations have been reported in traditional Indian folk medicine. It is estimated that currently several thousand manufacturing units are involved in the production of natural health products and traditional plant-based formulations become global. Moreover, about two-third of Indian population is reported to rely directly or indirectly on herbal and other natural products for health needs. In a fast developing society like ours, it is hoped that with such a vast natural resources a traditional knowledge-base, we can rightfully aspire to leaders supplying safe, effective and economical health products to the international market[1].

Saracaindica has a drastic effect when used for treating feminine disorders. It has also used for the treatment of various skin disorders, obesity and has shown a powerful immune stimulant too[1,2].

II. MATERIALS AND METHODS

Instrumentation

Soxhlet apparatus (Eyela, Japan) was utilized for extraction with suitable organic solvent, Electronic microscope (Laboval-4, Germany), U.V spectroscopy (Wolfe, Germany) (λ max 254), Water bath with thermostat (Jiangsu Medical Instrument factory, China), Physical balance (Shimadzu), Blender, Disintegrator apparatus (Eureka, alpha), Dissolution apparatus (EurekaDt 600).

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Plant Materials

The leaves of the plant *Saracaindica* were collected from Sri Venkateshwara University, Andhra Pradesh, India. The sample was authenticated by Dr. Madhavchetty, Plant Botanist, Andhra Pradesh. The leaves were collected, shaded, sun dried and powdered and stored in desiccators until evaporation [2,3-5].

Preparation of Extract

The powdered leaves were passed through a sieve (No: 40) and stored in a desiccators. The powdered leaves were extracted by Soxhlet apparatus for 24 hours, by taking 1000 gm using suitable organic solvent like ethanol and excess waxy and fatty materials were removed by addition of Petroleum ether as successive solvent. Further the extract was dried in a hot air oven for 4 hours in 40 °C, dried powder was transferred in glass container and kept it for further procedures [6, 7-10].

Preformulation studies

The above mentioned plant parts were oven dried at 40 °C and grinded once more for fine powder and separated. The ethanolic extract powder was subjected for phytochemical studies to detect phytoconstituents optimizing the formulation with the ethanolic extract powder and for the study [11,12-14].

Preliminary Phytochemical Investigation

Alkaloids

Mayer's test: To 2-3 ml of the extract, few drops of Mayer's reagent (1.36 gm of mercuric chloride and 5 gm of potassium iodide in 100 ml of water) were added. Formation of cream color precipitate indicates presence of alkaloids.

Aminoacids

Millon's test: To 2 ml of the test extract above 2 ml of millon's reagent (mercury nitrate) was added. White precipitate indicating the presence of aminoacids.

Carbohydrate

Molish Test: To 2 ml of the extract, at first few drops of alcoholic alphanaphthol were added, then through side of test tube few drops of concentrated sulphuric acid are mixed with it. Purple or violet color ring appeared at the junction indicate the presence of carbohydrates.

Flavonoids

Alkaline reagent test: To 2 ml of test extract few ml of sodium hydroxide solution were added. At first intense yellow colour was formed which was consequently turned to colorless; on addition of few drops of dilute acid indicate the presence of flavonoids.

Glycosides

Brontrager's test: The test extract was boiled with 1 ml of sulphuric acid in the test tube for 5 min. While hot, it was filtered and then cooled. Shaking of the mixture was done with equal volume chloroform. Two layers of solution were formed. The lower layers of chloroform were separated. Then that layer was stunned with half of its volume of dilute ammonia. Production of rose pink to red colour suggested the presence of glycoside.

Saponin

Froth formation test: To 100 mg of extract was shaken dynamically with water in a test tube. Formation of constant froth indicated the presence of saponins.

Tannins

Gelatin test: To 2 ml of extract, 1% gelatin solution contains 10% sodium chloride was added. Creation of precipitate suggested the presence of tannins.

Protein

Warming test: 2 ml of extract was heated in a boiling water bath. Protein was coagulated due to heating.

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Steroids and Triterpenoids

Salkowski test: The test extract was treated with few drops of concentrated sulphuric acid. Red colors at lower layer indicate existence of steroids; whereas formation of yellow colored at the lower layer suggested the presence of triterpenoids [14, 15-18].

Pre compression parameters of Ethanolic leaf extract of Saracaindica powder

Screening of particles

In order to obtain the uniform particle size, powder material has to be passed through different series of sieves mesh #40 followed by #60 and #80, according to I.P. Uniformity of the particle is one of the important parameter for getting the optimum efficacy of the therapeutic moiety.

Flow properties

The flow properties of the powder result from many forces. Solid particles attract one other, and forces acting between particles when they are in contact are predominately surface forces. Flow is also crucial during mixing of different ingredients and packing. Flow ability of powder was checked by different methods.

Angle of repose of powder

The fixed funnel and free standing cone methods employ a funnel that is secured with its tip at a given height, H, above graph paper that is placed on a flat horizontal surface. Powder or granulation is carefully poured through the funnel until the apex of the conical pile just touches the tip of the funnel. Thus, with R being the radius of the base of the conical pile [19-21].

$$\tan \alpha = H/R$$

Where, α is the angle of repose.

Porosity of powder

To check the porosity of powder, a cylinder was freely filled up to 100ml (bulk volume of powder). Then the cylinder was tapped for 100 times on smooth surfaces in order to obtain the pack volume of powder.

Porosity was calculated by formula:

$$\epsilon = \text{porosity of powder} = \frac{V_b - V_p}{V_p}$$

Where V_b is bulk volume and V_p is packed volume

Bulk Density and Tapped Density

Bulk density of a compound varies substantially with the method of crystallization, milling or formulation. Usually, bulk density is of great importance when one considers the size of high dose product or homogeneity of the low dose formulation in which there are large differences in drug and excipient densities.

$$\rho_{\text{bulk}} = m / V_b$$

$$\rho_{\text{tapped}} = m / V_p$$

Where m is the weight of the powdered drug

Compressibility Index and Hausner Ratio

The bulk and tapped densities were used to calculate the Carr's compressibility Index and the Hausner ratio to provide a measure of the flow properties and compressibility of powders.

$$C.I = \rho_{\text{tap}} - \rho_{\text{bulk}} / \rho_{\text{tap}}$$

Formulation of ethanolic leaf extract powder of Saracaindica

For better patient compliance, a pharmacist generally chooses the smallest tablet containing the prescribed dose. Size of the tablets should be encapsulating at least 250mg or 500mg (blended extract) [22, 24, 25].

Further the ethanolic leaf extract powder is directly compressed to tablet without any external adjuvant in it.

Post compression parameters

Weight variation test

In this method, a composite weight of 210 tablets is determined and these tablets are weighed throughout the compression process. The composite weight when divided by 10 gives the average weight of the individual tablet. In the method, overweight and underweight are ignored [26].

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Disintegration

It is method to evaluate the rate of disintegration of solid dosage forms of tablets. Disintegration rate of tablets kept in stated experiment conditions within the predetermined time. A tablet is placed in a every glass tube and the basket containing these glass tubes is positioned in the beaker containing the required fluid such that all the tablets dip properly. The apparatus is then operated for specific time. The tablet passes the disintegration test when none of the drug particles remain o the mesh/ wirescreen [27, 28]

Dissolution

It is an official method to determine the dissolution rate of a solid dosage form. The bioavailability depends on the drug depends upon the dissolution rate of its dosage form.It is closed compartment apparatus. It consists of a cylindrical vessel made up of borosilicate glass or suitable transparent material with hemispherical bottom. It consists of a small wire mesh to hold the dosage form. The basket is lowered into the dissolution vessel containing dissolution medium such that it is at a height of 23-27mm from the bottom of the vessel. For dissolution six tablets were taken to determine the rate at which the active drug substances dissolved in the fluid of gastrointestinal tract[27,28].

Stability

Tablets are subjected to stability testing to anticipate their shelf life or expiry date under normal storage condition. For the tablets studies, were exposed to environmental fact ors temperature and Humidity.

Temperature

The effect of temperature for tablets was checked through four different temperatures.i.e. ambient, 35°C,55°C,65°C and observed the effect with ½, 1,3 and 6 hours intervals[28].

Humidity

In humidity studies powdered samples was evaluated at 30%, 50%, 70% and 90%.

III. RESULTS

There are several herbs utilized in the world in the form of curative agents and as an alternative medicine. For preliminary phytochemical screening of the extracts, were performed tests for alkaloids, aminoacids, flavonoids, glycosides, saponins , tannins and triterpenoids were detected. Uniform dosage from ethanol extracts of powder was converted to tablet form for clinical efficiency.

Table 1: Phytochemical Screening of Ethanolicleafextract of Saracaindica powder

P h y t o c h e m i c a l s	P r e s e n c e
P r o t e i n s	-
L i p i d s	-
A l k a l o i d s	+
G l y c o s i d e s	+
T r i t e r p i n o i d s	+
T a n n i n s	+
S a p o n i n s	+
S t e r o i d s	-

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Table 2: Flow characteristics of Ethanolic leaf extract of Saracaindica powder

S l . n o	Angle of repose	P o r o s i t y	Bulk Density	Tapped Density	Compressibility Index	Hausner Ratio
1	2 7 . 6 0	2 6 . 0 1	0 . 4 8 5	0 . 6 8 5	0 . 2 6 5	1 . 3 5 2
2	2 8 . 6 2	2 6 . 3 5	0 . 4 6 2	0 . 6 5 2	0 . 2 8 5	1 . 3 8 5
3	2 8 . 5 1	2 5 . 9 8	0 . 4 8 5	0 . 6 1 8	0 . 2 5 8	1 . 3 4 8
M e a n	2 8 . 5 1	2 6 . 5 2	0 . 4 5 8	0 . 6 2 1	0 . 2 6 8	1 . 3 5 2

Table 3: Disintegration and Dissolution of Ethanolic leaf extract of Saracaindica powder

N o . o f t a b l e t s	Disintegration Time(min)	Extent of Dissolution %
1 ^s T a b l e t	7 m i n	9
2 ⁿ d T a b l e t	9 m i n	9 4 . 5 6
3 ^r d T a b l e t	1 0 m i n	9 0 . 2 1
4 ^t h T a b l e t	1 1 m i n	9 1 . 0 5
5 ^t h T a b l e t	1 2 m i n	9 8 . 0
6 ^t h T a b l e t	1 3 m i n	9 6 . 2 8
M e a n X	9 . 5 8	3 . 4 5 8
± S . D	2 . 5 1	3 . 1 9 7

Table 4: Effect of different temperature on powdered tablets

Temperatures	A m b i e n t	3 5 ° C	5 5 ° C	6 5 ° C
H o u r s	½ 1 3 6	½ 1 3 6	½ 1 3 6	½ 1 3 6
E f f e c t	- - - -	- - - -	- - - -	- - - -

Table 5: Effect of Humidity on the stability of tablet drug

Temperature	H u m i d i t y 30%	H u m i d i t y 50%	H u m i d i t y 70%	H u m i d i t y 90%
A m b i e n t	-	-	-	-
3 5 ° C	-	-	-	-
5 5 ° C	-	-	+	+
6 5 ° C	-	-	+	+

(-) No change, (+) Degradation

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IV. CONCLUSION

The rate and extent of absorption of a drug into the blood stream is an important quality characteristic of dosage form. In vitro dissolution studies and in vivo bioavailability studies are very much important in optimizing the quality of the dosage form. We found that ethanolic extract of *Saraca indica* was tannins, glycosides, alkaloids, saponins were found. Blended powder directly punched to form tablets, precompression parameters like porosity, angle of repose, compressibility, Hausner's ratio and density as shown in table 2. Post compression parameters carried out to blended powder like weight variation, disintegration, dissolution shown in table 2, 3, 4, good results to convey them into perfect formulation and studies carried out further in vivo studies for more accuracy, stability and safety of patient to rectify their compliances.

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