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Development of quality control parameter for Bhringrajaadi Churna: An ayurvedic formulation

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Abstract
The Bhingrajaadi churna is a solid dosage form which is described in the Bhaisajyaratnavali. Bhingrajaadichurna it is a polyherbal formulation consist of bhringraj (*Eclipta alba*), amla (*emblica officinalis*) and black seasame seeds (*Sesamum indicum*) the regular consumption of this churna helps to get rid of disease, lessen the impact of old age premature death attain hairs as the black clouds and it rejuvenates pale and worn out teeth. This study was aimed to development of quality control parameter for churna like organoleptic, phytochemical, physical evaluation and monograph analysis of crude drug and formulation as per WHO guidelines and it were found the following results i.e. foreign matter is not exist, extractable matter 48.75±0.11, alcohol soluble extractable matter 27.37±0.22, total ash 07.31±0.24, acid insoluble ash 4.16±0.10, foaming index is nil. The phytochemical test shows the presence of alkaloid, protein, carbohydrates flavonoids and tannins, it has poor flowability the qualitative estimation of gallic acid is also done with the help of HPLC mobile mobile phase is water: acetonitrile (80:20%v/v) and stationary phase C18 250x4.65 µmm at wavelength 272 nm.The results obtained may be considered as tools for assistance to the regulatory authorities scientific organization & manufacturer for developing standard formulation & great efficacy.

Keywords: bhingrajaadi churna, *eclipta alba*, *emblica officinalis*, *sesamum indicum*, phytochemical screening, ayurvedic formulation

Introduction
Herbal medicine is still the mainstay of about 75–80% of the world's population, mainly in developing countries, for primary health care because of better cultural acceptability, better compatibility with the human body and lesser side effects. It is estimated that approximately one quarter of prescribed drugs contain plant extracts or active ingredients obtained from or modeled on plant substances.
Ayurveda objective is to help the healthy person to maintain good health and the diseased person to regain good health. The practice of ayurveda is designed to promote human happiness at physical, mental and spiritual level. By the proper balance of all vital energies in the body, the processes of physical deterioration and disease can be reduced. This is accomplished through proper eating, thinking and living habits as well as the use of herbal remedies to treat illness.
Ayurvedic formulations are of multi component mixtures, containing plant and animal-derived products, minerals and metals. Most of the ayurvedic therapeutics is polyherbal formulations. This is based on the fact that the therapeutic efficiency of the herbal constituents of plants is enhanced by the synergistic efficacy of other the therapeutic efficiency of the herbal constituents of plants is enhanced by the synergistic efficacy of other plants. Ayurveda is a complex science in which all the components are equally important for the cure of disease and maintaining balance of body, mind, and consciousness.
Standardization of Ayurvedic formulations is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for production and manufacturing of herbal drugs. WHO specific guidelines for the assessment of the safety, efficacy and quality of herbal medicines as a prerequisite for global harmonization are of at most importance [1].
Standardization of herbal formulation requires implementation of Good Manufacturing Practices (GMP) (WHO guideline, 1996) In addition, study of various parameters such as pharmacodynamics, pharmacokinetics, dosage, stability, self-life, toxicity evaluation, chemical profiling of the herbal formulations is considered essential. Heavy metals contamination, Good Agricultural Practices (GAP) in herbal drug standardization are equally important[2].

Material and methods
Collection and Processing of Crude Drugs
The crude drug which is used in the formulations was collected from the local market of Ujjain. All the crude were authentified at Department of Botany, Vikram University, Ujjain. The specimens deposited at department of Pharmacognosy M.I.P.S. Ujjain.

Organoleptic evalution of Bhringrajaad Churna
The colour odor taste of churna were evaluated manually

Table 1: Organoleptic evalution

S.NO	Parameters	Observation
1	Colour	Dark brown
2	Taste	Tastless
3	Odour	Sour
4	Texture	Fine

Phytochemical Parameters
Ash values, extractive values, loss on drying, swelling index, foaming index was determined.

Table 2: Phytochemical Parameters

S.NO.	Parameters	Observation
1	LOD	100mg
2	P^H 1% w/v	3
3	P^H 10%w/v	2
4	Total ash value (%w/w)	0.71±0.57
5	Acid insoluble ash (%w/w)	4.16±0.10
6	Alcohol soluable extractive value(%w/w)	27.37±0.22
7	Water soluable extractive value (%w/w)	48.75±0.11

P^H

The determination of P^H of Bhringrajaadi churna was determined by the ph paper and ph meter, in that two concentration of churna is prepared they are 1% w/v and 10% w/v churna in water.

Loss on drying

Place about 2-5gm of the prepared air dried material, accurately weighed, on a previousaly dried and tared flat weighing bottle in an oven at 100-105ºC and dry until two conseccutive weighings do not differ by more than 5mg. calculated the loss on weight in mg/gm of air dried material.

Swelling Index

Introduce the specific quantity of the plant material concerned, previously reduced to the required fineness and accurately weighed (1gm) into a 25 ml glass stoppered measuring cylinder.

After that add 25 ml of water and shaken the mixture in every 10 minutes time interval for 1 hour then allowed to stand the mixture for three hours at room temperature, then measure the volume in ml occupied by the plant material include any sticky mucilage, and then the mean value was calculated.

Foaming index

Weight about 1gm of plant material powder finess by passing a sieve no.100, the fine powder was transferred to 500ml conical flask which contain 100ml of boiling water maintain at moderate boiling for 30 minutes after that cool the flask and filter the mixture in the 100ml volumetric flask add sufficient water to make volume up to 100ml after that the decoction was pour into 10ml stoppered test tubes in successive portion of 1ml, 2ml, 3ml, 4ml upto 10ml and then make up volume upto 10ml the test tubes were stoppered and shake them in a lengthwise motion for 15second, (two shakes per second) then allow to stand for 15 minutes and measure the height of foam.

Extractable Matter

4gm of coarsely ground air dried material was accurately weighed in a glass stoppered iodine flask. Then 100ml of solvent was added in the flask shaken occasionally for 6 hours, then the flask was allowed to stand for 18 hours filter it rapidly then transfer 25ml of filtrate to a tared flat-bottom dish and evaporate to dryness on a water bath then dry it at 105ºC for 6 hours, cool in a desiccator for 30 minutes weigh without delay. Calculated the content of extractable matter in mg/gm of air dried material.

Ash Values

Total ash place 2gm of accurately weighed ground air-dried material was incinerated in a tared crucible to a temperature between 500ºC-600ºC until it is white, which indicating the absence of carbon. Cooled in a desiccator and weigh if carbon free ash can not be obtained then add 2ml of water dry on a water-bath then a hot plate and ignite to a constant weigh. Allowed the residue to cool in a desiccator for 30 minutes, then weigh without delay calculated the amount of total ash in mg/gm of air dried material.

Acid-insoluble ash

To the crucible containing total ash add 25ml of hydrochloric acid then cover with a watch glass and boil gently for 5 minutes, the watch glass rinse with 5ml of hot water and add the liquid to the crucible, the insoluble matter collected on ash less filter paper and wash with hot water until the filtrate is neutral, transfer the filter paper containing insoluble matter to the original crucible,

Then dry on a hot plate and ignite to constant weight. The residue allowed to cool in a desiccator for 30 minutes, then weigh without delay calculated the amount of acid-insoluble ash in mg/gm of air dried material.

Water-soluble ash

To the crucible containing total ash add 25ml of water and boil gently for 5 minutes, collected the insoluble matter on ash less filter paper and wash with hot water and ignite it in a crucible for 15 minutes at a temperature not exceeding 450ºC substrate the weight of the residue in mg from the weight of total ash calculated the amount of water-insoluble ash in mg/gm of air dried material [3].

Phytochemical screening of constituents

Table 3: Phytochemical screening

S. No.	Test	Result
1.	Alkaloids	+ve
2.	Proteins	+ve
3.	Carbohydrate	+ve
4.	Tannin	+ve
5.	Flavanoid	+ve

Physical characteristics of Bhringrajaadi Churna

Angle of repose, Bulk density, Tapped density, Hausner's ratio, Carr's index was determined for evaluating of physical characterstics of the churna.

Table 4: Physical characteristics

S. No.	Parameters	Values
1	Angle of Repose	38.04º
2	Bulk density	0.444 g/ml
3	Tapped density	0.645gm/ml
4	Hausner's Ratio	1.452
5	Carr's index	31.46 %

Angle of Repose

It is determined by funnel method. The powder was which is fix on a stand to a graph paper was kept below the heap and the height and radius oh heap give angle of repose.

$$\tan\theta = h/r,\ \theta = \tan^{-1} h/r$$

Where,

h- height of the heap, r- Radius of the heap

Bulk density
Bulk density is the mass of powder divided by the bulk volume. The powder about 20g is weighed accurately, and introduced into a 100 ml graduated measuring cylinder then the cylinder is dropped at 2-second interval on a hard surface three times from the 1 inch of height then the volume of powder is noted.

Bulk density = mass/volume = g/ml

Tapped density
The powder about 20g weighed accurately then transfer it into 100 ml graduted cylinder then tap it 1000 time and note the volume which is the tapped volume.

Tapped density = mass/tap vol.

Hausner's Ratio
Hausner's Ratio is related to interparticle friction and it can be use to predict the powder flow property.
Hausner's Ratio = tapped density/bulk density

Carr's index / %compressibility [5]
It show the relationship between flow and compressibility of a powder this index evaluate the flow of a powder by comparing the bulk density and tapped density
Compressibility is the property of a stable intact mass when pressure is applied.

Carr's index
= tapped density–bulk density /tapped density x100

Solubility of bhringrajaadi churna [6]
Solubility is the amount of solute that dissolve in a unit volume of solvent.

Table 5: Solubility of Bhringrajaadi Churna

S. No	Solvents	Solubility
1	Water	Springly soluble
2	Hydro chloric acid	Insoluble
3	Nitric acid	Springly soluble
4	Sodium hydroxide	Springly soluble
5	Sulphuric acid	Springly soluble
6	Potassium hydroxide	Sightly soluble
7	Methanol	Springly soluble

Fluorescence Analysis of Bhringrajaadi churna [7]
It is an analysis which is done under florescence light, for that a small amount of churna was macerated with a small quantity of solvents for 1 hour then filter the solution then analysis is done under day light and UV light. The solvents are 1N Nitric acid, 1N Sulphuric acid, 1N Hydrochloric acid, Potassium hydroxide and 1N Sodium hydroxide.

Table 6: Fluorescence Analysis of Bhringrajaadi churna

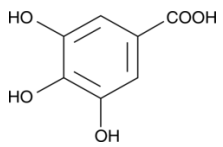
S. No	Solvents	Color under day light	Color under UV light
1	1N Nitric acid	Dark orange	Light orange
2	1N Sulphuric acid	Colourless	Colourless
3	1N Hydrochloric acid	Colourless	Colourless
4	1N Sodium hydroxide.	Colourless	Colourless
5	Potassium hydroxide	Dark yellow	Light yellow

Estimation of Gallic acid in Bhringrajaadi Churna by HPLC
In chromatography a small volume of a mixture of chemicals is passed through a column using a solvent and different molecules exit the column at different times – this is called separation. The separation of a compound involves its physical interaction with a stationary phase and a mobile phase. In chromatography a tube is filled with stationary phase (typically surface-modified silica particles or silica gel) and a mobile phase (solvent) is passed through the system. In HPLC the stationary phase is extremely small.

Table 7: Chromatographic condition of Gallic acid for HPLC

Mobile phase	Water: acetonitrile (80:20%v/v)
Stationary phase	C18 250x4.6 5umm
Wavelength	272nm
Run time	20 min
P^H of mobile phase	3 with or to phosphoric acid
Flow rate	1ml/min
Injection volume	20ul
Temperature	Ambient
Mode of operation	Isocratic elution

The gallic acid is a type of the phenolic and oraganic acid compound, chemical formula of gallic acid ia $C_7H_6O_5$ (trihydroxybenzoic acid) and the IUPAC name is 3,4,5-trihydroxybenzoic acid and the density of gallic acid is 1.70gm/cm gallic acid have antioxident properties its λ_{max} 272nm.



Gallic acid has the anticancerous property because it kills the formation of cancer cells it has also anti-fungal and anti-viral property without affecting the normal cells.

6.9.1 Preparation of standard stock solution
Firstly weight 10 mg of Gallic acid then transfer it in a 10ml volumetric flask, then diluted it up to mark with water : methanol in 9:1 ratio standard stock solution.

6.9.2 Preparation of dilution from the stock solution
Firstly take the three volumetric flask in that take 0.1, 0.3 and 0.5 all of separately diluted with the water : methanol (9:1) solution up to mark, which is the concentration is respectively 10ug/ml, 30ug/ml, and 50ug/ml. for further dilutions take 0.1, 0.2, 0.5, and 1ml and then transfer it separately in 10-10 ml volumetic flask and make up volume up to mark with the water : methanol (9:1) solution which is the dilution of 0.5ug/ml, 1ug/ml, 2.5ug/ml, and 5ug/ml solutions.

6.9.3 Preparation of sample solution from the bhringrajaadi churna
Accurately weight the 100mg powder of the bhringrajaadi churna in a 10ml volumetric flask and make up the volume up to mark with water : methanol (9:1) solution and then sonicate it for 10 minutes and filtered it with 0.22u filter paper it is the standard stock solution of the bhringrajaadi

churna. Further dilution make for that take 1ml of stock solution and diluted up to mark with water: methanol (9:1) the again filtered it with 0.22u filter paper, and same procedure for further two dilutions.

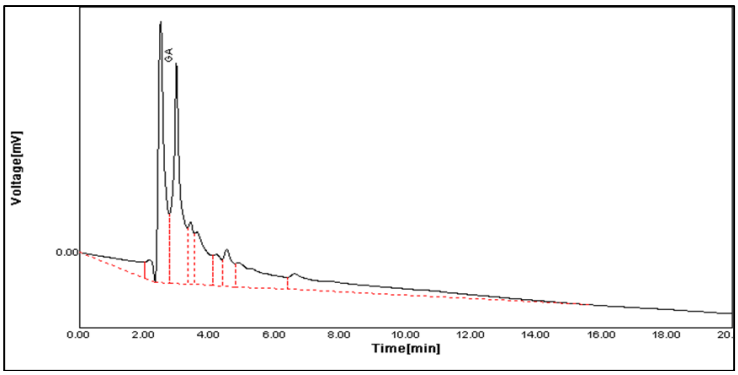


Fig 1: Chromatogram of Standared of (gallic acid)

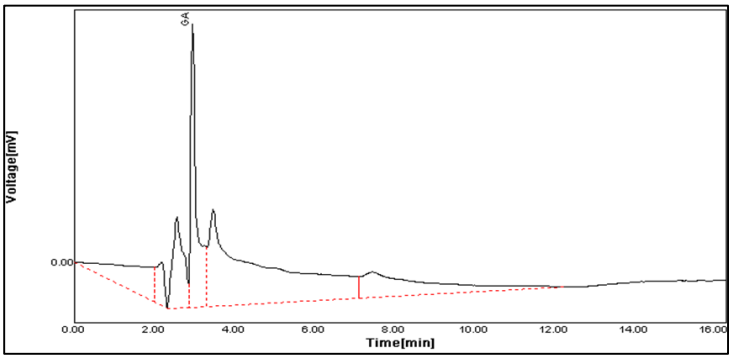


Fig 2: Chromatogram of Standared of (gallic acid)

- Red line indicate Standard
- Black line indicate Sample

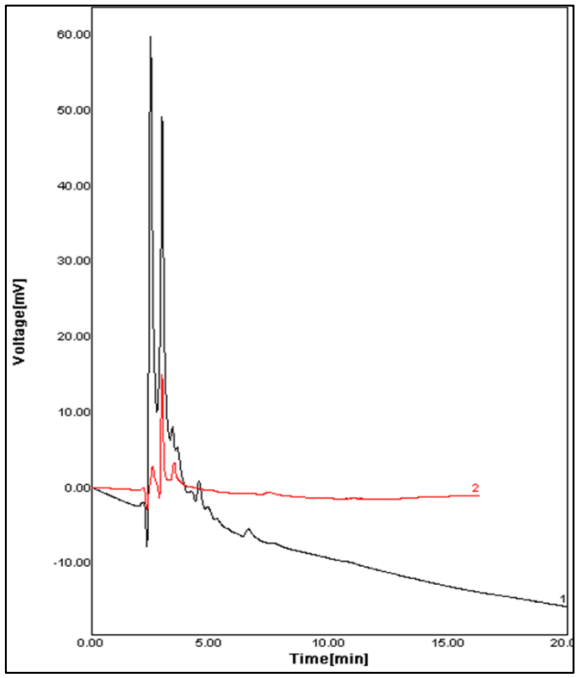


Fig 3: Over lay Chromatogram of Standared and sample (gallic acid)

Results and discussion

The churna was prepare and was evaluated for it's physical physicochemical organoleptic all the result is show in tabulated form.

Conclusion

The standardization of bhringrajaadi churna was based on the WHO parameters and the results obtained was found to be within the standard for crude drugs and if the crude drug evaluation is observe under the limit so the formulation can be prescribed as standard. The results obtained may be considered as tools for assistance to the regulatory authority's scientific organization & manufacturer for developing standard formulation & great efficacy.

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