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DEVELOPMENT OF QUALITY STANDARDS OF SUPRABHATAM CHURNA: A POLYHERBAL FORMULATION

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ABSTRACT
Suprabhatam Churna, an Ayurvedic formulation, currently used in all types of gastric disorders, rheumatic pain and insomnia. was standardized in order to assess the quality of drugs, based on the concentration of their active principles according to World Health Organization (W.H.O) guidelines. Marketed and in-house formulation were used for the study. The various parameters performed included organoleptic characteristics and physicochemical. The set parameters were found to be sufficient to standardize the ***Suprabhatam Churna*** *and can be used as reference standards for the quality control and quality assurance study mostly on plant drugs for their primary health care needs.* ***The results obtained may be considered as tools for assistance to the regulatory authorities, scientific organizations and manufacturers for developing standard formulation of great efficacy.***

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INTRODUCTION

Churna is a fine powder of a drug or drugs which is prepared by mixing clean, finely powdered and sieved drugs. Suprabhatam Churna shows its effects mainly on costipation which contains Hritaki (fruit), Gulab (flower), Senna (leaflet), Kutki (rhizome), Nagarmotha (root), Fennel (fruit) Celery (leaves), Indian Jalap (roots) and Rock salt. Practitioners usually do the identification of different herbs used in vatari churna according to Ayurvedic parameters.[1] The preparation of vatari churna is based on traditional methods in accordance with the procedures given in classical texts.[2] Due to lack of modern pharmacopoeial standards laid down and followed for processing of vatari churna, the medicine prepared using traditional methods may not have the desired quality and batch to batch consistency. Hence this formulation required standardization according to guidelines given by World Health Organization (WHO). [3]

MATERIALS AND METHODS

Plant material

Following herbal drugs were chosen: contains Hritaki (fruit), Gulab (flower), Senna (leaflet), Kutki

(rhizome), Nagarmotha (root), Fennel (fruit) Celery (leaves), Indian Jalap (roots) and Rock salt. All herbs were procured from local market of Dehradun and were authenticated by Department of botany F.R.I. Dehradun.

Preparation of Polyherbal formulation

All the procured and authenticated individual drugs were dried in shade and cleaned by hand sorting. The individual drugs were then crushed using willing grinder and passed through mesh no. 40. The individual drugs were then weighed as per the quantity required. The drugs were mixed geometrically using a double cone blender. The mixed formulation was unloaded, weighed, and packed in labeled plastic bags.[4]

Organoleptic Evaluation

Organoleptic evaluation refers to evaluation of formulation by color, odor, taste, texture etc. The organoleptic characters of the samples were carried out based on the method described by Siddique et. Al.[5]

Physicochemical Investigation

Determination of total ash

Total ash determination constitutes detecting the physiological ash (ash derived from plant (tissue) and nonphysiological ash (ash from extrageneous matter, especially sand and soil adhering to the surface of the drug). For its detection, 2g of powdered material of each formulation and the individual ingredients of the powers were placed separately in a suitable crucible of silica previously ignited and weighed. The powdered drugs were spread into an even layer and weighed accurately. The materials were incinerated by gradually increasing the heat, not exceeding 450°C until free from carbon, cooled in a desiccator, weighed and percentage ash was calculated by taking in account the difference of empty weight of crucible & that of crucible with total ash.[6]

Acid insoluble ash

The ash obtained as above was boiled for 5min with 25ml of dilute hydrochloric acid; the insoluble matter was collected on an ashless filter paper, washed with hot water and ignited to constant weight. The percentage of acid-insoluble ash with reference to the air-dried drug was calculated.

Water soluble ash

The ash was boiled for 5 minutes with 25 ml of water; collected insoluble matter in an ash less filter paper, washed with hot water, and ignited for 15 minutes at a temperature not exceeding 450C. Subtract the weight of the insoluble matter from the weight of the ash; the differenceinweight represents the water-soluble ash. The percentage of water-soluble ash with reference tothe air-dried drug was calculated.

Alcohol soluble extractive value

5g of coarsely powdered air-dried drug was macerated with 100ml of alcohol in a closed flaskfor twenty-four hours, shaking frequently during six hours and allowed to stand for eighteen hours. It was then filtered rapidly; taking precautions against loss of solvent. 25ml of the filtratewas evaporated to dryness in a tared flat-bottomed shallow dish at 105°C to constant weight andweighed. The percentage of alcohol-soluble extractive was calculated with reference to the airdried drug and is represented as% value.[6]

Water soluble extractive value

5g of coarsely powdered air-dried drug was macerated with 100ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowed to stand for eighteen hours. It was then filtered rapidly, taking precautions against loss of solvent. 25ml of the filtrate was evaporated to dryness in a tared flat bottomed shallow dish at 105°C to constant weight and weighed. The percentage of water-soluble extractive was calculated with reference tothe air-dried drug and is represented as % value.[6]

Loss on drying

Loss on dying is the loss of mass expressed as percent w/w. About 10g of dug samples of each formulation was accurately weighed in a dried and tared flat weighing bottle and dried at 105C for 5hrs. Percentage was calculated with reference to initial weight. [6]

Determination of pH

The pH of different formulations in 1% w/V and 10% w/V of water soluble portions was determined using standard glass electrode at 240 according to

the prescribed standard method in Indian Pharmacopoeia.

Bulk density and Tap density

The term bulk density refers to a measure used to describe a packing of particles or granules. The equation for determining bulk density (D) ,Db=M/Vb Where M is the mass of the particles and Vb is the total volume of the packing. The volume of the packing can be determined in an apparatus consisting of a graduated cylinder mounted on a mechanical tapping device that has a specially cut rotating can. 100gm of weighed formulation powder was taken and carefully added to the cylinder with the aid of a funnel. Typically the initial volume was noted and the sample was then tapped until no further reduction in volume was noted. The initial volume gave the Bulk density value and after tapping the volume reduced, giving the value of tapped density.[7,8]

Angle of repose

Angle of Repose has been used as an indirect method of quantifying powder flowability because of its relationship with interparticle cohesion. As a general guide, powders with angle of repose greater than 50 degree have unsatisfactory flow properties, whereas minimal angle close to 25 degrees correspond to very good flow properties. The fixed funnel and the free standing cone method employs a funnel that is secured with its tip at a given height, which was taken 2.5 cm (H), above the graph paper that is place on flat horizontal surface. Powder or granulation was carefully poured through the funnel until the apex of the conical pile just touched the tip of the funnel.[7,8]

Hausner ratio

It is related to interparticle friction and as such can be used to predict the powder flow properties. Powders with low interparticle friction such as coarse spheres have a ratio of approximately 1.2, whereas more cohesive, less flowable powders such as flakes have a Hausner ratio greater than 1.6. The equation for measuring the Hausner ratio is: Df / Do, where Df = Tapped density and Do = Bulk density.[9,10]

RESULTS AND DISCUSSION

In house formulation was prepared in accordance with the Ayurvedic Formulary of India. As part of standardization procedure, the finished product Suprabhatam Churna was tested for relevant physical and chemical parameters. Both the samples were whitish brown in color. The powders were moth, having fragrant odor, possessing slight bitter taste. The organoleptic properties of the marketed formulations and the in-house formulations were reported in table 1. Quality tests for Suprabhatam Churna and its individual ingredients were performed for moisture content, ash content, water soluble extractive, methanol soluble extractive, acid insoluble ash and water insoluble ash, and were found to be within standard ranges but differ from the standard formulation.[11,12] The results are expressed as mean (n=5) ±Standard deviation (SD).Variations were observed in most of the physicochemical parameters studied. The total ash value of MF was found to be higher than that for in house formulation (IHF). Acid insoluble ash value for IHF was found to be 8.31%±0.028 and in case of MF this was found to be 10.21%±0.031. The extractive values of formulations in water were found to be much lower than alcohol extractive values. The results of the market formulations and in house formulation were found to be comparable. The flowability of the formulation was found to be poor in both market formulation and in house formulation, which was further confirmed by high values of Hausner ratio.

Table: 1 Different Physiochemical Parameters:

S. No.	Parameters	Marketed formulation (Mean value, n=5)	In home formulation (Mean value, n=5)
1.	Water soluble extractive value	0.785%±0.023	0.905%±0.031
2.	Alcohol soluble extractive value	0.475%±0.041	1.3475%±0.033
3.	Ether soluble extractive	0.23%±0.011	0.31%±0.021
4.	Total Ash	4.9%±0.026	12%±0.021
5.	Acid insoluble Ash	10.21%±0.031	8.31%±0.028
6.	Water soluble Ash	2.9%±0.045	2.6%±0.051
7.	Carbonated Ash	4.1%±0.033	3%±0.029
8.	Sulfated Ash	12.13%±0.09	11.12%±0.12
9.	Nitrated Ash	2.3%±0.02	2.7%±0.019
10.	Bulk density	14 m/v±0.32	13 m/v±0.029
11.	Tapped density	07 m/v±0.11	09 m/v±0.16
12.	Carr's index	31.2%±0.021	28.1%±0.03
13.	Hausner Ratio	0.5±0.017	0.069±0.013

CONCLUSION

The result of the present study clearly indicates that there is no uniformity in preparation of formulations. It may be due to varied geographical location where there plant grow ,coupled with the problem of different vernacular name these plant known by, a great deal of adulteration or substitution is encountered in commercial market [13]. It might be a useful contribution to the selection of an appropriate formulation in the clinical practice and hence effective rational therapy, the overall theme of the health science. So further, it can be studied for comparative pharmacological evaluation.

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