ISBN 978-93-5137-179-3 ISSN 2320-7329

ayurlog

National Journal of Reseach in Ayurved Science

Title of Article

Review on Standardization Parameters of Churna

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ABSTRACT: Ayurved has a long and strong heritage use of Polyherbal drugs and formulations to treat various diseases. 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. It is a burning topic in Ayurvedic drug industry nowadays. Tremendous work is going on for standardization of Ayurvedic drugs to prove its reproducibility, compatibility and safety on modern parameters.

Concept of churna is well established in Ayurvedic pharmaceutics for therapeutic purposes as well as for production of other formulations. There is sound description of its various method of preparation along with shelf life period in Ayurveda. Implication of latest analytical techniques is the demand of time to standardize different churna. Plant material may vary in physiochemical content and therefore in its therapeutic effect; according to different places of collection, with different times in a year for collection, with collection at the same time and places but in different years and with a particular medicinal plant. Adding to this variability is the fact that in herbal medicine several plants may be used together in the same preparation. It is very important that a system of standardization is established for every medicine in the market because the scope for variation in different batches of medicine is enormous. This means that there should be a quality control test for the entire preparation to ensure quality of the product.

Methodology-

Reviewing the modern and ayurvedic scientific literature ; in this article there is an attempt to analyze the probable analytical parameters which may prove useful for the standardization of Churna.

KEYWORD: Churna, Polyherbal, Standardization, Formulations

Cite this article:

Ayurlog: National Journal of Research in Ayurved Science-2017 ;(5)(5):

INTRODUTION:

Churna is one of the drug dosage forms. Different part of plant shows different active constituents. These active principles get remains as such if parts of plant dried properly. There will not be any further change will occur in it. On its opposite if it remains wet it may expose to constant changeand its potency against disease may vary. Some of drugs like pippali, vacha, adrakshow different actions at their dry and wet conditions.[1]

Churna is fine powder of completely dry drug filtered through clean cloth. The fine powder obtained after pounding and filtering the complete dry drug. Pounding is done either manually in khalwayantra or mechanically in pulverising machines. Filtering is also done either manually using a clean cloth or a selected sieve or mechanically through sieve shakers. Depending on particle size powder is divided as coarse, fine or very fine.

Concept of churna is well established in Ayurvedic pharmaceutics for therapeutic purposes as well as for production of other formulations.[2]In the last few decades, there has been an exponential growth in the field of Ayurvedic medicine. It is used as drug so thereis great need of standardization and quality control of Ayurvedic formulations.[3]

Quality assurance is integral part and basic requirement for all type of system of medicine to ensure their quality of formulation.Standardization of Ayurvedic formulations is an important step for the establishment of a consistentbiological activity, a consistent chemical profile, or simply a quality assurance program for production andmanufacturing of herbal drugs.Standardization is a system to ensure that every packet of medicine that is being sold has the correct amount and will induce its therapeutic effect. [4]

Aims and objectives

1-To study churnakalpana

2-To study standardization parameters of churnakalpana

Types of Churna [2]

1-Sthula churna i.e. coarse powder

2-Sukshma churna i.e. fine powder

3-Atyanta sukshmachurna i.e. very fine powder

Classification of churna[5]

Marathi Name	English Name	Useful for dose form preparation	Fineness
Sthul	Coarse	Churna, Dhum,Kashaya	10 to 44
Pruthu	Moderate coarse	Fant	20 to 60
Pat	Moderate fine	Kalka, Him ,Lepa	44 to 85
Sukshmatar	Finer	Parpati, Gutika, Vati ,Pottali, Anjan	85
Sukshmtam	Finest	Bhasma-Pishti, Bhasma	120

Churnaprakshepaka and their ratio[2]

Prakshepakadravya	Ratio with that of churna dosage
Guda(Jaggery)	Equal
Sita(sugar)	Double
Ghritabhartij (ghee fried) hingu	Quantity that doesn't causes nausea
When licked with ghrita, madhu, taila, etc	Double
When drank with any other liquid (toya, kshira,madya, gomutra)	Four times

Quantity of anupana depending on disease conditions[2]

Diseases	The quantity of anupana
Vatajroga	3 pala (150ml)
Pittajroga	2 pala (100ml)
Kaphajroga	1 pala (50ml)

Materials and Methods

Reviewing the modern and ayurvedic scientific literatures to study standardization parameters of churna.

Descriptive term

Coarse (2000/355) All the particles will pass through a No. 2000 sieve, not more than 40% through a No. 355 sieve

Moderately coarse (710/250)All the particles will pass through a No. 710 sieve, and not more than 40% through a No. 250 sieve

Standardization Parameters

Ayurvedic parameters[5]

1 -Vastragalit (very fine)

2- Akarhin (amorphous)

3- Shusk (dry)

Modern Parameters [6]

Organoleptic

1-Colour

2- Odour

3- Taste

These are examination which can be done by the sense organs. Any deviation from the normal colour, any unpleasant smell or any change in normal taste in the sample signify that due to some chemical reaction sample is changing its normal phenomenon.

Powders[7]

The coarseness or fineness of a powder is classed according to the nominal aperture size expressed in hum of the mesh of the sieve through which the powder will pass, and is indicated as follow

Particle size

Moderately fine (355/180) All the particles will pass **through a No. 355 sieve** and not more than 40% through a No. 180 sieve

Fine (180) All the particles will pass through a No. 180 sieve

Very fine (125 All the particles will pass through a No 125 sieve

Sieves[2]

The numbered sieves indicate the number of meshes (opening) in a length of 1 inch (2.54) in each transverse direction parallel to the wires. So a sieve numbered 10 will have 10 meshes in specified length.

	All particles pass through sieve no	Not more than 40 pass through
Coarse powder	10	44
Moderately coarse powder	22	60
Moderately fine powder	44	85
Fine powder	All pass through 85 numbered sieve	
Very fine powder	All pass through 120 numbered silk sieve	

A suitable quantity of sample is weighed and transferred to the set of sieves from number 10 to 85. The sieves are shaken in sieve shakers for about 30 minutes and residue on each sieve is weighted separately.

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 Vis 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 (Jolting Volumeter) 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.[8,9]

Angle of repose

Angle of Repose has been used as indirect methods of quantifying powder flow ability because of its relationship with inter particle 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.[10,11]Tan = H/ R or = Ɵ tan H/R Where is the angle of repose, R being the radius of the conical pile.[11,9]

Foreign organic matter

250 g or the quantity specified in the individual monograph, of the original sample to be weighed accurately and spread out in a thin layer. The samples to be inspected with the unaided eye or with the use of a magnifying lens (6X or 10X) and the foreign organic matter has to be separated manually as completely as possible and weighed. The percentage of foreign organic matter should be weighed and determined with reference to the weight of the drug taken.[7]

pH

pH of churna was determined using pH meter by dispersing 1□ w/v and 10□ w/v churna in distilled water.

Loss on drying (LOD)

About 2-5 g of the prepared air dried individual materials to be accurately weighed in a previously dried and tarred flat weighing bottle. The samples to bedistributed evenly and to be placed in the drying chamber (Oven). Drying should be carried out by heating at100-105°C, the bottle to be removed from the oven and the bottle has to be closed promptly and allowed to cool to room temperature and then weighed. The experiment should be repeated till two consecutive weighing did not differ by more than 5 mg, unless otherwise stated in the test procedure. The loss in weight on drying to be then calculated.[7]

Determination of ash value

The ash remaining following ignition of medicinal plant materials is determined by three different methods which measure total ash, acid-insoluble ash and water-soluble ash.

The total ash method is designed to measure the total amount of material remaining after ignition. This includes both "physiological ash", which is derived from the plant tissue itself, and "non-physiological" ash, which is the residue of the extraneous matter (e.g. sand and soil) adhering to the plant surface.

Acid-insoluble ash is the residue obtained after boiling the total ash with dilute hydrochloric acid, and igniting the remaining insoluble matter. This measures the amount of silica present, especially as sand and siliceous earth.

Water-soluble ash is the difference in weight between the total ash and the residue after treatment of the total ash with water. [7]

Are helpful in determination of the quality and purity of crude drug specially in powder form. The objective of ashing vegetable drug is to remove all the traces of organic matter which may otherwise interfere in an analytical determination on incineration crude drug normally consisting of carbonate, potassium, calcium, magnesium.[12]

Total ash

For its detection, 2g of powdered material of each formulation and the individual ingredients of the powers were placed separately in a suitable tarred 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 desiccators, weighed and percentage ash was calculated by taking in account the difference of empty weight of crucible & that of crucible with total ash.[8]

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 ash less 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. [11]

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 450 ^{0}C. Subtract the weight of the insoluble matter from the weight of the ash; the difference in weight represents the water-soluble ash. The percentage of water-soluble ash with reference to the air-dried drug was calculated.[10]

Alcohol soluble extractive value

5g of coarsely powdered air-dried drug was macerated with 100ml of alcohol 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 tarred flat-bottomed shallow dish at 105°C to constant weight and weighed. The percentage of alcohol-soluble extractive was calculated with reference to the air dried drug and is represented as% value.[8]

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 tarred 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.[8]

Thin Layer Chromatography

TLC is a simple, quick, and inexpensive procedure that gives a quick answer as to how many components are in a mixture. TLC is also used to support the identity of a compound in a mixture when the Rf of a compound is compared with the Rf of a known compound (preferably both run on the same TLC plate). The Rf value is the retention factor, or how far up a plate the compound travels. [13]

High Performance Thin Layer Chromatography

This is an invaluable quality assessment tool for the evaluation of drugs based on herbal origin. It is a form of column chromatography used frequently in biochemistry and analytical chemistry to separate, identify, and quantify compounds. It allows for the analysis of a broad number of compounds both efficiently and cost effectively. HPTLC utilizes a column that holds chromatographic packing material (stationary phase), a pump that moves the mobile phase(s) through the column, and a detector that shows the retention times of the molecules. Retention time varies depending upon the interactions between the stationary phase, the molecules being analyzed, and the solvent(s) used.[13]

Discussion:

The preparations used in Ayurveda have to be standardized in order to get the optimal concentration of known active constituents and in preserving their activities on various physicochemical parameters discussed in the paper. Angle of Repose has been used for quantifying powder flow ability.Analysis of these parameters gives knowledge regarding various aspects of churna. Analysis of Loss on drying

signifies the amount of residual water in the finished product as water content in the formulations degraded its quality. Any deviation from the normal colour and odour in the sample signify that due to some chemical reaction sample is changing its normal phenomenon. TLC and HPTLC give the knowledge regarding the components of formulations. Bulkdensity of a powder that provide a guide to its flowcharacteristics. Coarseness or fineness of powder can be defined by the no on size of sieves through they pass.

Conclusion:

Standardization is the process of establishing a technical standard, which could be a standard specification, standard test method, standard definition, standard procedure (or practice), etc. The need for the quality control methods for theAyurvedic drugs is must due to commercialization of the Ayurvedic pharmacies during the current century and also due to the inclusion of the Ayurvedic drugs under the Drugs and Cosmetic Act.

Result:

Data obtained from the above parameters may be used to fix the standards for the formulations of churna. This fixation of different standards will be ultimately helpful to standardize churnakalpana.

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