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Review Article

A Systemic Review on Standardization of Poly-Herbal Churna

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ABSTRACT

Standardization is the need of the hour in Ayurvedic system of medicine. The traditional systems of medicine are really effective but the problem with them is they lack in quality assurance. This enables us to recognise the quality of the formulation. The Central Council of Research in Ayurveda and Siddha has prescribed the preliminary guidelines for testing the quality of these formulations. It is essential to derive a protocol or develop methods for evaluation of herbal formulation to maintain uniformity between batches during production. The present work aims to review to standardize a poly-herbal churnas available in the market.

KEYWORDS: Ayurvedic,churna, evaluation, poly-herbal formulation, standardization.

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INTRODUCTION

In the long struggle to overcome the powerful forces of nature, the human beings have always turned towards plants for food, shelter, clothing, and healing. Even today herbal medicine plays an important role in the management of diseases. Though we are in 21st century where modern technology and scientific discoveries are ushering remarkable changes in our lives, nevertheless, the story of plants as herbal medicines definitely continues to unfold, however, quietly and independently[1].Synthetic drugs are being prepared by keeping the natural drugs as standards but the efficacy of the herbal drugs cannot be imitated & hence 80% of the world population relay on natural drugs for treating their ailments. Ayurvedic science has got its rich heritage in India. People in India believe that natural products are safe compared to synthetic drugs. The development in these traditional systems of medicine leads to maintain proper quality of the product[2].

Advantages of Herbal Medicine

- They have large amount of use.
- They have better patient tolerance as well as acceptance.
- The medicinal plants have renewable source of cheaper medicines.
- Improvements in the quality, efficacy and safety of herbal medicines with the development of science and technology.
- Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.
- They are cheap in cost.
- They are not harmful.
- They are more effective than any synthetic drug.
- Throughout the world herbal medicines have provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form as well as a pure chemical upon which modern medicines are constructed[4,5] .

Need of standardization:

Standardisation is an essential parameter to be done. It is a vital step in formulation since it determines the quality of the product and is essential to develop a protocol on standardisation of every product available in the market to avoid variation arising between batch to batch.[3] Plant materials are not like synthetic drugs, they vary in many conditions even in their chemical content depending on the time and season of collection of plant material, the geographical location of the plant being grown etc.[6]

Eladichoorna was standardized by A. Thankamma *et,al,*.[7] It is a compound preparation of 6 ingredients along with sugar, nagakesara, maricham, twak, ela, sunti, pippali. Chromatographic technique was used for the detection of the ingredients. Different solvent systems were developed for each ingredients and spots were visualized in Iodine vapours. The results of the TLC indicates the presence of the single drugs in the finished product.

Mahasudarshan Churnawas standardized by Shivani Chauhan, *et.al.*, [8]Mahasudarshanchurna (MSC) contains Swertiachirata (50%) along with other 49 Ingredients (50%) Triphala, Haridra, Daruharidra, Kantakari, Brhati, Karcura, Sunthi, Marica, Pippali,Murva, Guduchi, Dhanvayasa, Katuka, Parpata, Musta, Trayamanag, Hrivera, Nimba (chhal), Puskara, Yasti, Kutaja, Yavani, IndrayavaBharang, Sigru, Saurastri, Vaca, Tvak, Padmaka, Svetacandana, Ativisa, Bala, Salaparn, Prsniparni, Vidanga, Tagara, Citraka, Devadaru, Cavya, Patola, Lavanga, Vamsa, Kamala, Ashwagantha, Tejapatra, JatiphalaSthauneya, Vidarikand, kiratatikta. All other ingredients have different therapeutic uses which support to treat the malaria and other fevers and are also useful in rejuvenating the body. The marketed product was standardized against in-house preparation by performing organoleptic evaluation, physico-chemical evaluation like Determination of Ash value, extractive value, loss on drying, bulk density, tap density, hausner's ratio, angle of repose and the results clearly indicates that there was no uniformity found in any of the results so we can conclude that may be the geographical factors affected the raw materials or may be due to adultration of the raw materials affected the formulation.

Nyagrodadichurna was standardized by K.R. Gopala Simha *et.al.*,[9] this churna is a poly herbal formulation contains 28 ingredients dhava, danti, priyala, adhaki, aragwadha, varuna, amalaki, pribhadra, jambu, kapittha, nyagrodha, udumbara,, aswattha, yashtimadhu, meshasringi, kutaja, madhuka, amra, shyonaka, chitraka, karanja, vijayasara, bhallataka, lodhra, arjuna, vibhitaki, haritaki, patola6 batches of the finished product was collected and the coparative studies was conducted by performing organoleptic evaluation, morphological evaluation, a detailed phytochemical screening for each and every individual ingradients for the presenceor absence of alkaloids, glycosides, tannins, resins, fixed oils, etc., and also TLC was carried out. By the results obtained we can conclude that there the difference was negligible and finished products of

all the batches are considered standard.

Trikatuchurna was standardized by ShailajanSunitha *et.al.*,[10] a poly herbal formulation was prepared by using mircha, pippali, shunti powders and studied against three marketed formulations by evaluating the raw materials by proximate analysis, preliminary phytochemical screening, qualitative and quantitative estimation of piperine by HPTLC method in the finished product and by seeing the results we can conclude that there was the considerable difference of quantity of piperine in the fresh sample and 4 months old marketed sample.

TriphalaChurna was standardized by YogendrBahuguna *et.al.*,[11] by taking one marketed product and analysing its total ash value after complete incineration and the acid insoluble ash value indicative of silicate impurities, which might have arisen due to improper washing of drug. The loss on drying value obtained is an indicative of amount of moisture content present in the drug. The extractive values names water soluble and alcohol soluble indicates the amount of active constituent in given amount of plant material when extracted with respective solvent, values obtained supports the fact that drug is unexhausted which is contrary to lower extractive value.The results of phytochemical tests indicate the presence glycosides, alkaloids, tannins, saponins and sugars. From the heavy metal test it is concluded that Dabur TriphalaChurna is free from heavy metals. From the all values, it can be concluded that the quality of marketedTriphalaChurnawas "GOOD".

AshwagandhaChurna was standardized by PallabDasgupta *et.al.*,[12] the marketed products were taken from dabur and sadhanaausadhalaya Dhaka and compared the parameters such as physicochemical standards like total ash, acid insoluble ash, water & alcohol soluble extractive values, loss on drying, phyto-chemical analysis, flow properties, TLC profile and safety evaluation were carried out, it can be concluded that the formulation of Ashwagandhachurna contains all good characters of an ideal churna and it was found to be harmless, more effective, and economic. The comparison between the two marketed samples have been done on the basis of the above mentioned parameters which shows satisfactory results, but the efficacy of the products can only be judged by doing the pharmacological studies of which is suggested as future scope of R & D.

SitopaladiChurna was standardized by SangramKeshari *et.al.*,[13]Ayurvedic medicine sitopaladichurna has been standardized by intervention of scientific quality control measures in the traditional preparation describe in classical texts.Pharmacognostic characters established for the raw material could be employed as Q.C, standards for evaluating its identity and can be used for routine analysis.of Purity and potency of the material and formulations following procedure given could be performed in QC\ QA laboratory of pharmaceutical house. The results of the parameters tested for the in-house and marketed products stats that all the formulations are standard.

Protocol for standardization

Determination of physico-chemical constants for individual ingredients of churna and for formulations

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.

Loss on drying (LOD)-About 2-5 g of the prepared air dried individual materials to be accurately weighed in a previously dried and tared flat weighing bottle. The samples to bedistributed evenly and to be placed in the drying chamber (Oven). Drying should be carried out by heating at 100-105°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.

Ash value-Ash content of the crude drug is generally taken to be the residue remaining after incineration. It represents the inorganic salts naturally occurring in the drug and adhering to it, but may also include inorganic matter added for the purpose of adulteration.

Total ash is the residue remaining after incineration. Acid insoluble ash is the part of the total ash, which is insoluble in dilute hydrochloric acid. Water-soluble ash is the part of total ash, which is soluble in hot water.

Total ash-About 2g of the individual powdered ingredients of churnato be accurately weighed in a tared silica crucible. The powdered drug should be spread as a fine layer at the bottom of the crucible. The crucible to be incinerated at a temperature not exceeding 450°C until free from carbon. Allow the crucible to cool and weighed. The procedure to be repeated till constant weight is observed. The percentage of the total ash calculated in triplicate with reference to the air dried drug.

Acid insoluble ash- The ash obtained as described in the determination of total ash to be boiled with 25 ml of hydrochloric acid for 5 min. The insoluble ash should be collected on an ashless filter paper by filtration and it should be washed with hot water. The insoluble ash is transferred into a tared silica crucible, ignited, cooled and weighed. The procedure has to be repeated till a constant weight was observed. The percentage of acid insoluble ash was calculated with reference to the air-dried drug.

Water-soluble ash- To the crucible containing the total ash, add 25 ml of water and boil for 5 minutes. Collect the insoluble matter in a sintered-glass crucible or on an ashless filter-paper. Wash with hot water and ignite in a crucible for 15 minutes at a temperature not exceeding 450°C. Subtract the weight of this residue in mg from the weight of total ash. Calculate the content of water-soluble ash in mg per g of air-dried material.

Extractive values-Extractive value is a measure of the content of the drug extracted by solvents. Extractive value can be water soluble, ethanol soluble and ether soluble extractives. Extractive value unless and otherwise prescribed, is carried out by maceration.

4.3.1 Water soluble extractive- 4 g of previously weighed air-dried powdered individual ingredients of churnato be taken in a glass stoppered flask and macerated with 100 ml of chloroform water (1:99). It was shaken frequently for 6 h and then allowed to stand for 18 h. It was filtered rapidly taking precautions against loss of the solvent. 25 ml of filtrate should be evaporated to dryness in a tared flat-bottomed petri dish, dried at 105°C, cooled in a dessicator and weighed. The percentage of water-soluble extractive should be calculated with reference to air-dried drug[14].

Note – Ether and alcohol soluble extractive, follow the same procedure of water soluble extractive excepting the solvent (water) which is replaced by ether and alcohol.

Fluorescence analysis- The powdered samples to be exposed to Ultraviolet light at wavelength of 254 nm and 366 nm. One mg of powdered drug to be placed on a micro slide and observed under UV 366, UV 254 and in day light to observe the fluorescent characteristics of powder, if any. One mg powdered drug to be placed on a micro slide and treated with one ml 1N HCl and observed under UV 366, UV 254 and in day light while wet. One mg powdered drug was placed on a micro slide and treated with one ml 1N NaOH and observed after a few minute in day light, under UV 366, UV 254. One mg powdered drug to be placed on a micro slide and treated with one ml 1N NaOH in one ml methanol and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug

to be placed on a micro slide and treated with one ml 50% KOH and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug to be placed on a micro slide and treated with one ml of 50% sulphuric acid and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug to be placed on a micro slide and treated with one ml of conc. sulphuric acid and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug to be placed on a micro slide and treated with one ml of 50% HNO_3 and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug to be placed on a micro slide and treated with one ml of Conc. HNO_3 and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug to be placed on a micro slide and treated with one ml of acetic and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug to be placed on a micro slide and treated with one ml of iodine and observed under UV 366, UV 254 and in day light while still wet[15].

Powder microscopy- The powder of Churnashould be examined for its microscopic characters. The powder passed through sieve no. 60 and boiled with chloral hydrate to remove colouring matter and viewed under microscope for fibers, starch and other characters. The clarified powder has to be later stained with phloroglucinol in the presence of hydrochloric acid for the lignified structures like stone cells to be viewed under microscope.[26]

Preparation of Churna: The In-house churna should be prepared as per the procedure given in Ayurvedic Formulary of India or any other standard books of ayurveda. All the ingredients to be powdered separately, passed through 80 # sieveand then mixed together in specified proportions to get uniformly blended churna.

Preparation of extracts

Alcoholic extract - The powdered churnashould be macerated with methanol for 2 days. After the completion of maceration residue should be removed by filtration followed by the evaporation of solvent and extract should be concentrated.

Phytochemical analysis of extract: Following chemical tests to be carried out for different extracts of Churna to identify the presence of various phytochemical constituents.

Detection of alkaloids

The small portions of fractions are stirred separately with a few drops of dil.HCl and filtered and then subjected to test for alkaloids.

Test for alkaloids

Mayer's test:- Few ml of extract should be treated with Mayer's reagent, Wagner's test, Dragendroff's test, Hager's test, Tannic acid test should be carried out

Test for triterpenes

Liberman-Burchard's test, Salkowski's Test, Tschugajew's test, Hirschorn testshould be carried out.

Test for steroids

Liberman-Burchard's test, Sulphur test, Salkowski's Testshould be carried out

Test for carbohydrates

Molisch's test, Barford's test, Benedict's test, Fehling's test, should be carried out

Test for glycosides

Chrysarobin test, Anthraquinone glycoside testshould be carried out

Test for flavonoids

$FeCl_3$ test, Shinoda test, NaOH test, Lead acetate test, Mineral acid test, Zn/Hcl testshould be carried out

Determination of physico-chemical parameters for finished products

Organoleptic evaluation - Organoleptic evaluation refers to evaluation of formulation by color, odour, taste, texture etc. The organoleptic characters of the samples to be carried out based on the official method.

Ash values and extractive values to be determined as described earlier.[16,17,18]

Determination of physical characteristics of formulations - Physical characteristics like bulk density, tap density, angle of repose, Haussner ratio and Carr's index to be determined for different formulations. The term bulk density refers to method used to indicate a packing of particles or granules. The equation for determining bulk density (D_b)is $D_b=M/V_b$ where M is the mass of particles and $V_b$is the total volume of packing. The volume of packing can be determined in an apparatus consisting of graduated cylinder mounted on mechanical tapping device that has a specially cut rotating can. 100gm of weighed formulation powder should be taken and carefully added to cylinder with the aid of a funnel. The initial volume should be noted and sample should be then tapped until no further reduction in volume should be noted. The initial volume gave the bulk density value and after tapping the volume reduced, giving the value of tapped density. Angle of repose has been used as an indirect method quantifying powder flowability, because of its relationship with interparticle cohesion. The fixed funnel and the free standing cone method employs a method that is secured with its tip at a given height (H), above the glass paper that is placed on a flat horizontal surface. Powder or granules to be carefully poured through the funnel until the apex of the conical pile just touched the tip of funnel. Thus, with R being the radius of the conical pile. Tan α = H/R or α = arc tan H/R, where α is the angle of repose refer Table no. I Relationship between angle of repose and type of flow.

Hausner's ratio is related to interparticle friction and as such can be used to predict the powder flow properties. The equation for measuring the Hausner's ratio is D_f/D_o. Where, D_f = Tapped density and D_0 = Bulk density. Relationship between Hausner's ratio and type of flow refer Table no. II Relationship between Hausner's ratio and type of flow.

Carr's compressibility index is another indirect method of measuring the powder flow from bulk density. The equation for measuring Carr's index is % Compressibility = $D_f - D_o/D_f$ x 100. Where D_f = tapped density, D_0 = Bulk density refer Table no. III Relationship between compressibility index and type of flow.

Thin layer chromatography

Thin layer chromatography is mainly used for qualitative screening of plant extract which serve as a very important tool in the overall phytochemical research studies.

Procedure:

Slurry of silica gel G should be prepared in distilled water and poured over a glass plate to form a thin film. The prepared plates to be allowed for setting (air-drying).After setting, the plates to be kept in an oven at 100 to 120^0 C (30 min) for activation.The fractions to be dissolved in respective solvent and spotted over an activated plate (1 cm above from the bottom). It should be then kept in previously saturated developing chamber containing mobile phase, and allowed to run 3/4th of the height of the plate. The developed plate should be removed, air dried and observed under ultraviolet light and florescent compound identified and sprayed with 5% ferric chloride then compared with standard drug spot and calculate the R_f value using following formula.

Table No.I: Relationship between angle of repose and type of flow

Flow property	Angle of repose (degree)
Excellent	25-30
Good	31-35
Fair	36-40
Passable	41-45
Poor	46-55
Very Poor	56-65
Very-very Poor	>66

Table no. II: Relationship between Hausner's ratio and type of flow

Flow property	Hausner's ratio
Excellent	1-1.11
Good	1.12-1.18
Fair	1.19-1.25
Passable	1.26-1.34
Poor	1.35-1.45
Very Poor	1.46-1.59
Very-very Poor	>1.6

Table no. III: Relationship between compressibility index and type of flow[18]

Flow property	Compressibility index (%)
Excellent	≤10
Good	11-15
Fair	16-20
Passable	21-25
Poor	26-31
Very Poor	32-37
Very-very Poor	>38

$$Rf^{20} = \frac{\text{Distance traveled by solute}}{\text{Distance traveled by the solvent}}$$

High-performance thin-layer chromatography (HPTLC)-Quantitative densitometric HPTLC analysis should be performed to develop the characteristic fingerprint profile for the methanolic extract of Churna.

CONCLUSION

By the above studies we can conclude that the parameters defined for the standardization of powder formulations (churna) are efficient enough to consider for quality control department for ensuring the consistency of the finished product from batch to batch is maintained.

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C. REFERENCE

1. Kumar T, Chatterjee TK. Herbal options. 2nd ed. Eastern Traders, Kolkata: 2004.p.1-7.
2. Jain S, Koka S, Gupta A, Barik R, Malavia N. Standardization of Chopchiniyadi Churna: An Ayurvedic Formulation. Journal of Pharmacognosy 2(5); 2010: 61.
3. Pattnayak P, Hardel D.K, Mahapatra P. Standardization of VaisvanaraChurna: A Polyherbal Formulation. Journal of Pharmacognosy 2010;2(5): 52.
4. Zhang. X. Traditional medicine, its importance and protection, In: Twarog. S., Kapoor. P. (eds). Protecting and promoting traditional knowledge: System, National experiences and International Dimensions. Part-I. The role of Traditional knowledge in Health care and Agriculture. New York; United nations, 48: p.3-6. 9.
5. Bhutani KK. Herbal medicines an enigma and challenge to science and directions for new initiatives. Indian J Natural Prod. 2003;19(1):3-8.
6. Meena AK, Mangal AK, Rao MM, Panda P, Simha GV, Shakya SK *et.al*. Evaluation of Standardization Parameters for SitopaladiChurna an Ayurvedic Formulation, Asian Journal of Research in Chemistry. 2011;4(12):1867 –71.
7. A. Thankamma, L.G. Radhika & C. Soudamini. Standardization of Eladichoorna Ancient Science of Life. 1998;18(1).
8. Shivani C, Vikrant P, Ashish Kumar S. Pharmacopeial Standardization of Mahasudarshan Churna: A Polyherbal Formulation, Journal of Medicinal Plants Studies. 2013; 1(2): 13-18.
9. Gopala Simha KR, Laxminarayana V, Standardization of a polyherbal formulation, nyagrodhadi Churna, Indian Journal of Traditional Knowledge. 2007;6(4):648-52.
10. Shailajan S, Sayed N, Joshi H, Tiwari B, Standardization of a Ayurvedic formulation, trikatu Churna using bioanalytical tools, International Journal of Research in Ayurveda & Pharmacy. 2011;2(6):1676-8.
11. Yogendr B, Suhaib Z, Neeraj K, and Kailash R, Standardization of Polyherbal Marketed Formulation Triphala Churna, Journal of pharmacognosy and phytochemistry.2014;2(3).
12. Pallab D and Amartya D, Comparative Standardization Study of Two Marketed Ashwagandha Churna Formulation, International Journal of Research in Pharmaceutical and Biomedical Sciences. 2012;3(2).
13. Sangram KP, Snehasis D, Manaswini B, Bichitra T and Debasis P, Standardization of Sitopaladi Churna: A Poly-Herbal Formulation. Scholars Research Library, 4 (1);2012:205-216
14. World Health Organization. Quality control methods for medicinal plant materials. WHO/PHARM/92.559/rev.1., Geneva; WHO, 1992.
15. http://www.phcogres.com/article.asp?issn=09748490;year 2010; volume 2; issue2;spage 98;epage101;au last Sriwastava
16. Kokate CK. Practical Pharmacognosy; 1991; 3rd ed. VPBN. New Delhi.
17. Ayurvedic Formulary of India, Part-I, 2nd revised edition, Government of India, Ministry of Health and family welfare. New Delhi: Department of ISM and H; 2003. p. 106.
18. Khandelwal KR. Practical Pharmacognosy Techniques and Experiments, 9thed; NiraliPrakashan: Pune; 2002: 41-4.
19. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy. 3 rd eds. Mumbai: Verghese Publishing House; 1987:183-316.
20. Wagner H, Bladt S. Plant drug analysis, A Thin Layer Chromatography. Atlas 2nd ed. Springer Verlag Berlin Heisenberg;1996.