



Journal of Medicinal Plants Studies

Pharmacopeial Standardization of Mahasudarshan Churna: A Polyherbal Formulation

Shivani Chauhan^{*1}, Vikrant Pundir², Ashish Kr Sharma²

1. Department of Pharmaceutical Technology, M.I.E.T., Meerut, U.P, India
[E-mail: shivanichauhan232@gmail.com, Ttel: 09758833730]
2. Adarsh Vijendra Institute of Pharmaceutical Sciences, Gangoh, Saharanpur, U.P, India

Standardization of herbal formulation is essential in order to assess the quality of drugs for therapeutic value. Mahasudarshan churna, an ayurvedic formulation currently used as diaphoretic and anti-malarial. It is also useful in dyspepsia and loss of appetite. It was standardized in order to assess the quality of drugs, based on the concentration of their active principles according to world health organization guidelines. The various parameters performed included organoleptic characteristics and physicochemical. The set parameters were found to be sufficient to standardize the Mahasudarshan churna and can be used as reference standards for the quality control/ 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 organization and manufacturers for developing standard formulation of great efficacy.

Keyword : Standardization, Mahasudarshan Churna, Traditional medicine, Physico-chemical parameters, Marketed formulation (MF), WHO.

1. Introduction:

In the last few decades, there has been an exponential growth in the field of ayurvedic medicine. There are great need of standardization and quality control of ayurvedic formulations. ^[1] 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. ^[2] WHO has also issued Guidelines for quality control methods for medicinal plant material in 1992 with a clear objective to provide general test methods for correct botanical evaluation and identification of medicinal plants widely used in traditional

and home remedies. ^[3] Maha Sudarshan churna is used traditionally as antipyretic, anti-malarial, antiviral and antidiabetic formulation. It is made of a mixture of herbs and edible salts. It is recommended for all type of fever and common cold. ^[4] Mahasudarshan churna (MSC) contains Swertia chirata (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, Indrayava,

Bharang, Sigru, Saurastri, Vaca, Tvak, Padmaka, Svetacandana, Ativisa, Bala, Salaparn, Prsniparni, Vidanga, Tagara, Citraka, Devadaru, Cavya, Patola, Lavanga, Vamsa, Kamala, Ashwagantha, Tejapatra, Jatiphala, Sthauneya, Vidarikand, kiratatikta^[5]. 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 preparation of mahasudarshana churna is based on traditional methods in accordance with the procedures given in classical texts. This may not have the desired quality and batch to batch consistency. Hence this formulation required standardization according to guidelines given by WHO.^[6]

2. Materials and Methods

Ingredients of mahasudarshana churna consists of Triphala, Trikatu, Chiraita, Bidang, Lavang, Kateri Kachur, Daruhaldi, Giloy and other 40 items. They were procured from local market of gangoh distt. Saharanpur (UP) and was authenticated by Department of botany F.R.I. Dehradun.

2.1 Preparation of Mahasudarshana Churna

In house formulation of mahasudarshana churna was prepared as per Ayurvedic Formulary of India. Each gm is prepared from: Triphala, Haridra, Daruharidra, Kantakari, Brhati, Karcura, Sunthi, Marica, Pippali, Murva, Guduchi, Dhanvayasa, Katuka, Parpata, Musta, Trayamanag, Hrivera, Nimba (chhal), Puskara, Yasti, Kutaja, Yavani, Indrayava, Bharang, Sigru, Saurastri, Vaca, Tvak, Padmaka, Svetacandana, Ativisa, Bala, Salaparn, Prsniparni, Vidanga, Tagara, Citraka, Devadaru, Cavya, Patola, Lavanga, Vamsa, Kamala, Ashwagantha, Tejapatra, Jatiphala, Sthauneya 0.013g each, Vidarikand 0.026g, kiratatikta 0.335g. These all ingredients

were dried in shade and cleaned by hand sorting. The individual drugs were then crushed using a willing grinder and pass through mess no. 80. Weigh separately each powdered ingredient and mix together. Pass the Churna through sieve number 44 to prepare a homogeneous blend. Pack it in tightly closed containers to protect from light and moisture.^[7]

2.2 Organoleptic Evaluation

Organoleptic evaluation refers to evaluation of formulation by colour, odour, taste etc. The organoleptic characters of the samples were carried out based on the method described by Siddique *et.al*^[8].

Table 1: Organoleptic Properties of two Formulations

Parameters	Marketed formulation	In house preparation
Appearance	Powder	Powder
Colour	Yellowish brown	Yellowish brown
Odour	Fragrant	Fragrant
Taste	Bitter	Bitter

2.3 Physicochemical Investigation

Determination of Total Ash

Total ash determination constitutes detecting the physiological ash (ash derived from plant (tissue) and nonphysiological ash (ash from extraneous 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 tared 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^[9].

2.4 Acid insoluble ash

The ash obtained as above was boiled for 5 min 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^[8].

2.5 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 difference in weight represents the water-soluble ash. The percentage of water-soluble ash with reference to the air-dried drug was calculated^[9].

2.6 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 tared 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^[9].

2.7 Water Soluble Extractive Value

5g of coarsely powdered air-dried drug was macerated with 100 ml 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 to the air-dried drug and is represented as % value^[9].

2.8 Loss on Drying

Loss on drying 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. The percentage was calculated with reference to initial weight.

Table 2: Physicochemical Parameters: Maha Sudarshan Churna

Quantitative standards	Result in % w/w (Marketed formulation)	Result in % w/w (In house preparation)
Total Ash Value	62.90%	61.20%
Acid insoluble ash	18.20%	17.20%
Aqueous soluble ash	8.40%	7.20%
Moisture content	20.10%	23.30%
Alcohol soluble extractives	22.00%	21.70%
Aqueous soluble extractives	31.20%	35.70%

2.9 Determination of Systemic Solvent Extractive Values

The air dried powder of Mahasudarshan churna were extracted by successive

Table 3: Mahasudarshan Churna Extractive values (Showing percentage yield of various extracts)

S. N.	Extracts	% Yield (Marketed formulation)	% Yield (In house preparation)
1.	Petroleum Ether Extract	2%	1.6%
2.	Chloroform Extract	4.5%	3.17%
3.	Ethanol Extract	21%	21.7%
4.	Aqueous Extract	34.8%	35.7%

2.10 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), $D_b = M/V_b$ Where, M is the mass of the particles and V 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 (Jolting Volumeter) that has a specially cut rotating can. 100gm of weighing 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 tapping density^[10, 11].

2.11 Angle of Repose

Angle of Repose has been used as an indirect method of quantifying powder flow ability because of its relationship with interparticle cohesion. As a general guide, powders with the angle of repose greater

extraction with various solvents of different polarity, concentrated by evaporation, dried and percentage yield was determined^[9].

than 50 degrees 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 placed on a 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]. $\tan = H/R$ or $= \arctan H/R$ Where is the angle of repose, R being the radius of the conical pile^[10, 11].

2.12 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 flow able powders such as flakes have a Hausner ratio greater than 1.6. The equation for measuring the Hausner ratio is: D_f / D_o , where, D_f = Tapped density and D_o = Bulk density^[11, 12].

Table 4: Physical characteristics of marketed formulation and in house formulation of Mahasudarshan churna

Parameters	Marketed formulation	In house formulation
Tap density	0.5 ± 0.04	0.62 ± 0.005
Bulk density	0.38 ± 0.2	0.41 ± 0.03
Angle of repose	22 ± 0.23	23.8 ± 0.2
Hausner ratio	1.88 ± 0.02	1.79 ± 0.4

3. Result and Discussion

In house formulation was prepared in accordance with the Ayurvedic Formulary of India. As part of standardization procedure, the finished product Mahasudarshan Churna was tested for relevant physical and chemical parameters along with marketed formulation for a comparative study. All the samples were yellowish brown in color. The powders were smooth, having fragrant odour, possessing bitter taste. The organoleptic properties of the marketed formulation and the in-house formulations were reported in table 1. Quality tests for Mahasudarshan 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. The extractive values and ash values of the in-house formulation and marketed formulation are given in table 2. The results are expressed as mean (n=6) \pm Standard deviation (SD). Variations were observed in most of the physicochemical parameters studied. The total ash value of marketing formulation was found to be higher than that for in house preparation. Acid insoluble ash value for in house formulation was found to be 17.20% and in case of marketed formulation this was found to be 18.20%. On the contrary, the water soluble ash percentage of marketing formulation is high 8.40% in comparable with in house preparation. The extractive values of formulations in water were found to be much higher than alcohol extractive values. Loss on drying at (105°C) is also presented in Table 2. The results of the market formulation and in house formulation were found to be comparable. The flow ability 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, presented in Table 3.

4. Conclusion

The result of the present study clearly indicates that there is no uniformity in preparations of formulation. It may 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. It might be a useful contribution to the selection of an appropriate formulation in a clinical practice and effective rational therapy, the overall theme of the health science. So further it can be studied for comparative pharmacological evaluation.

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