

Development of Quality Control Methods for Polyherbal Formulation of Mahasudarshan Churna

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In the present study, three batches of different marketed polyherbal formulation, Mahasudarshan churna were procured from the local market and they were evaluated as per Indian Pharmacopoeia and WHO guidelines on the following parameters *viz.*, organoleptic characteristics, extractive value, ash value, physical characteristics, moisture content, loss on drying, phytochemical evaluation, fluorescence analysis, pH value *etc.* The result of the present study revealed that all three batches of Mahasudarshan churna were found in close proximity. This study on Mahasudarshan churna was precise, reproducible and may be considered as a protocol for its evaluation.

Key Words: Mahasudarshan churna, Polyherbal formulation, Protocol, Quality control.

INTRODUCTION

The recent interest in Ayurvedic system of medicine is seen by large scale manufacturing of ayurvedic products. A quality ayurvedic formulation must conform to the test for identity, potency, purity, safety and efficacy. Majority of the ayurvedic formulations use whole plants either alone or in combination. It has been stated that combining herbs improves efficacy and reduces adverse effects due to the low concentration of active ingredients adequate to produce therapeutic effects but to reduce the toxicity. In spite of the large number of ayurvedic formulation available in the market, for many of them, standard for their quality are yet to be laid. Various marketed formulation shows dose variation, content variation and lack of standardization which affect its therapeutic activity, therefore it is imperative to develop fast, sensitive and accurate methods of analysis for ayurvedic formulations which will be in alignment with modern technology^{1,2}.

This paper includes the investigation of quality control methods for three different samples of Mahasudarshan churna designated as MSC1, MSC2 and MSC3. The formulation is official in the Ayurvedic literatures and therapeutically useful in the treatment of chronic fevers, peptic ulcers,

diaphoresis, malaria, loss of appetite *etc.* It is one of famous ayurvedic formulation containing more than 40 different ingredients. Different manufacturing companies used different active ingredient for their preparation, which are not claimed on the container due to which their efficacy can not be access accurately. Therefore, the present study was undertaken to evaluate Mahasudarshan churna as per Indian Pharmacopoeia and WHO guidelines.

EXPERIMENTAL

Three marketed formulation of Mahasudarshan churna from different manufactures (designated as MSC1, MSC2 and MSC3) were procured for the present study. Alcohol, acetone, methanol, *n*-hexane, chloroform, 1N hydrochloric acid, 1N sodium hydroxide (aqueous), ferric chloride, 1N nitric acid, ammonia, iodine, 1N sodium hydroxide (alcoholic), picric acid and 1N sulphuric acid *etc.*

Organoleptic properties of Mahasudarshan churna: Organoleptic properties of each of three batches of Mahasudarshan churna was done by using reported method^{3,4} (Table-1).

Extractive values: Mahasudarshan churna (5 g) from each batch for individual extraction was extracted with *n*-hexane, chloroform, methanol and distilled water separately by cold maceration method described below and their extractive values were determined as per the methods given in Indian Pharmacopoeia⁵ and WHO⁶ publication.

***n*-Hexane and chloroform soluble extractives:** *n*-Hexane and chloroform soluble extractives were determined by same procedure as described above and dried under reduced pressure.

Methanol soluble extractives: Mahasudarshan churna was dispersed in 100 mL of methanol and allowed to stand for 24 h with occasional shaking. Extract was filtered and evaporated.

Water soluble extractives: Mahasudarshan churna was dispersed in 100 mL of water and allowed to stand for 24 h with occasional shaking and filtered. The above procedure was performed for each batch and the dried water extractives of MSC1, MSC2 and MSC3 were weighed.

The extractive values of the all three batches of Mahasudarshan churna in above solvent are given in Table-2.

Ash values: Total ash, acid insoluble ash and water soluble ash values were determined using standard procedure^{5,6} (Table-3).

Physical characteristics: The physical characteristic of the Mahasudarshan churna were determined for MSC1, MSC2 and MSC3 in terms of the bulk density, true density, angle of repose, hausner's ratio and carr's index according to the standard procedure⁷ (Table-4).

Moisture content and loss on drying: Moisture content and loss on drying was determined for all three batches of Mahasudarshan churna as per standard procedure^{5,8} (Table-5).

Phytochemical evaluation: For this study, aqueous extract of Mahasudarshan churna has been employed, screening process of each batch of Mahasudarshan churna for phytochemical evaluation was done using reported methods^{9,10} (Table-6).

Fluorescence analysis: For fluorescence analysis, the drug powder was treated with different solvents in different test tubes. The solvents used were 1N HCl, 1N NaOH (aq.), ferric chloride, 1N HNO₃, NH₃, I₂, 1N NaOH (alcoholic), picric acid and 1N H₂SO₄. Then they were subjected to fluorescence analysis in daylight and in UV light as per standard procedure⁹ (Table-7).

pH determination: The pH values of 1 and 10 % (w/v) solution of different batches of Mahasudarshan churna were determined as per I.P.⁵ (Table-8).

Foreign matter, foaming index and swelling index: Foreign matter, foaming index and swelling index were determined for all three batches of Mahasudarshan churna as per standard procedure^{6,8,9}.

RESULTS AND DISCUSSION

Mahasudarshan churna (three batches, MSC1, MSC2 and MSC3) was evaluated in the laboratory according to standard procedures. They were evaluated by comparative analysis for their organoleptic properties, extractive values (*n*-hexane, chloroform, methanol and water), ash value (total ash, water soluble ash and acid insoluble ash), physical characteristics, moisture content, loss on drying, phytochemical evaluation, fluorescence analysis, pH value, foreign matter, foaming index and swelling index.

Organoleptic studies revealed that all the three batches (MSC1, MSC2 and MSC3) of Mahasudarshan churna were brown in colour, having pleasant odour and possessing pungent taste. More than 90 % of two samples (MSC1 and MSC2) passed through 60-mesh sieve except MSC3 passed 60 % only. It was also observed that more than 40 % of all samples passed through 85-mesh sieve.

Extractive values are reported in Table-1 and ash values are included in Table-2. The extractive values (% w/w) of Mahasudarshan churna (Mean \pm SD of MSC1, MSC2 and MSC3) in *n*-hexane and chloroform were found to be 4.39 ± 0.63 and 14.08 ± 1.70 , respectively and that in water and methanol were 12.96 ± 0.51 and 4.39 ± 0.63 , respectively, indicating the presence of polar and semipolar constituents in Mahasudarshan churna. The ash values for each batch of Mahasudarshan churna for total ash, water soluble and acid insoluble are found to be 70.38 ± 2.93 , 45.08 ± 3.73 and 51.31 ± 2.39 , respectively, which indicates the presence of inorganic matters as major components.

TABLE-1
EXTRACTIVE VALUES OF MAHASUDARSHAN CHURNA

Extractive	Values* % w/w (Mean \pm SD)		
	MSC1	MSC2	MSC3
Water soluble	13.40 \pm 0.26	12.40 \pm 0.40	13.08 \pm 0.03
Methanol soluble	8.06 \pm 0.05	7.62 \pm 0.03	9.20 \pm 0.34
<i>n</i> -Hexane	4.07 \pm 0.15	3.96 \pm 0.86	5.15 \pm 0.21
Chloroform	16.05 \pm 0.87	13.19 \pm 0.54	13.01 \pm 0.89

*Values of mean of three experiments.

TABLE-2
ASH VALUES OF MAHASUDARSHAN CHURNA

Samples	Ash values* % (Mean \pm SD)		
	MSC1	MSC2	MSC3
Total ash	73.30 \pm 4.00	67.43 \pm 2.68	70.43 \pm 2.00
Water soluble ash	49.66 \pm 2.66	45.43 \pm 1.02	41.16 \pm 1.06
Acid insoluble ash	52.56 \pm 1.55	52.83 \pm 1.48	48.56 \pm 1.48

*Values of mean of three experiments.

The physical characteristics of all the samples of Mahasudarshan were shown in Table-3. Low values of angle of repose show the poor flowability for all samples. The results of the three batches were found to be comparable. The % moisture content and loss on drying values of Mahasudarshan churana are reported in Table-4.

TABLE-3
PHYSICAL CHARACTERISTICS OF DIFFERENT FORMULATIONS
OF MAHASUDARSHAN CHURNA

Parameters	Values* % (Mean \pm SD)		
	MSC1	MSC2	MSC3
Bulk density (g/mL)	0.48 \pm 0.0004	0.48 \pm 0.0100	0.45 \pm 0.010
True density (g/mL)	0.10 \pm 0.0010	0.10 \pm 0.0008	0.10 \pm 0.003
Angle of repose (°)	25.14 \pm 0.0250	24.12 \pm 0.0320	23.07 \pm 0.360
Hausner ratio	1.24 \pm 0.0400	1.20 \pm 0.0060	1.19 \pm 1.000
Carr's Index	22.91 \pm 0.0100	21.16 \pm 0.0400	23.13 \pm 0.002

*Values of mean of three experiments.

The investigations of phytochemical evaluation are shown in Table-5, which shows the presence of different phytoconstituent. The fluorescence analysis (Table-6) revealed that each of the three batches of Mahasudarshan churana are not showed the major distinct fluorescing property.

TABLE-4
MOISTURE CONTENT AND FOREIGN MATTER OF
MAHASUDARSHAN CHURNA

Samples	Values* % (Mean \pm SD)	
	Moisture content	Loss on drying
MSC1	5.06 \pm 0.03	7.28 \pm 0.44
MSC2	4.00 \pm 0.10	7.29 \pm 0.04
MSC3	6.33 \pm 0.57	8.00 \pm 0.20

*Values of mean of three experiments.

TABLE-5
PHYTOCHEMICAL EVALUATION OF MAHASUDARSHAN CHURNA

Phytoconstituents	MSC1	MSC2	MSC3
Alkaloids	Present	Present	Present
Glycosides	Present	Present	Present
Phytosterols	Present	Present	Present
Essential oil	Absent	Absent	Absent
Tannins	Present	Present	Present
Saponins	Absent	Absent	Absent
Proteins	Present	Present	Present

TABLE-6
POWDER FLUORESCENCE ANALYSIS OF
MAHASUDARSHAN CHURNA

Material	MSC1		MSC2		MSC3	
	Day light	UV 254 nm	Day light	UV 254 nm	Day light	UV 254 nm
Powder as such	L.BR.	Y.BR.	L.BR.	Y.BR.	L.BR.	Y.BR.
P + 1N Hydrochloric acid	BR.	Y.BR.	L.BR.	Y.BR.	L.BR.	Y.BR.
P + 1N Sodium hydroxide (aqueous)	D.BR.	Y.BR.	BR.	Y.BR.	D.BR.	B.BR.
P + Ferric chloride	B.	B.	B.	B.	B.	B.
P + 1N Nitric acid	L.BR.	Y.BR.	L.BR.	Y.BR.	BR.	Y.BR.
P + Ammonia	L.BR.	B.	L.BR.	B.	D.BR.	B.BR.
P + Iodine	D.BR.	L.BR.	D.BR.	B.	L.BR.	D.BR.
P + Picric acid	Y.BR.	Y.	Y.	Y.	Y.	F.Y.
P+ 1N Sulphuric acid	L.BR.	Y.BR.	D.BR.	B.BR.	B.	D.BR.

BR = Brown, YBR = Yellowish brown, DBR = Dark brown, LBR = Light brown, BBR = Blackish brown, B = Black, Y = Yellow, FY = Fluorescent yellow.

The pH values of 1 and 10 % w/v solution of all the batches were included in Table-7, which showed that Mahasudarshan churna is acidic in nature. No foreign matter was found and the result of foaming and swelling index reveals the absence of saponin and mucilage in all three batches of Mahasudarshan churna. The data analysis reveals that all parameters remain in close proximity for each batch of Mahasudarshan churna.

TABLE-7
pH OF 1 AND 10 % w/v SOLUTION OF DIFFERENT
FORMULATIONS OF MAHASUDARSHAN CHURNA

Different formulations	1 % (w/v) concentration (Mean \pm SD), n = 3	10 % (w/v) concentration (Mean \pm SD), n = 3
MSC1	4.63 \pm 0.02	2.85 \pm 0.06
MSC2	4.14 \pm 0.06	3.80 \pm 0.05
MSC3	5.63 \pm 0.53	4.26 \pm 0.18

No attention has been paid to evaluate a polyherbal formulation by comparative analysis. The calculated parameters and the developed methods for their determination can be considered as the protocol for the evaluation of Mahasudarshan churna, which will assist the regulatory authorities, scientific organizations and manufacturers in developing standards. The method used for evaluation is found to be precise and reproducible and help to produce uniform standard products, which will restore faith in Ayurvedic system.

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