

DEVELOPMENT OF QUALITY CONTROL METHODS FOR POLYHERBAL FORMULATION OF KAYAM CHURNA

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Summary

In the present study, two batches of different marketed polyherbal formulation. Kayam Churna were purchased 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 Kayam Churna was found in close proximity. This study on Kayam Churna was precise, reproducible and may be considered as a protocol for its evaluation.

Key Words: Kayam Churna , Polyherbal formulation , Protocol and Quality Control

Introduction

The recent interest in Ayurvedic system of medicine is seen by large scale manufacturing of 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 therapeutics effects but to reduce the toxicity. In spite of the large number of ayurvedic formulation available in 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 affects 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.

This paper includes the investigation of Quality Control methods for three different samples of Kayam Churna designated as KC1 and KC2. The formulation is official in the ayurvedic literatures and therapeutically useful in the treatment of severe constipation, acidity and purgative etc.

It is one of famous ayurvedic formulation containing more than 18 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 accessed accurately. Therefore, the present study was undertaken to evaluate Kayam Churna as per Indian Pharmacopoeia and WHO guidelines.

Experimental

Two marketed formulations of Kayam Churna from different manufacturers (designated as KC1 and KC2) were produced for the present study.

Organoleptic properties of Kayam Churna: Organoleptic properties of each of two batches of Kayam Churna were done by using reported methods.

Extractive values: 5 g of Kayam Churna from each batch for individual extraction of 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 Pharmacopoeia and WHO 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: Kayam Churna was dispersed in 100 ml of Methanol and allowed it to stand for 24 hrs with occasional shaking. Extract was filtered and evaporated.

Water soluble extractives: Kayam Churna was dispersed in 100 ml of Water and allowed it to stand for 24 hrs with occasional shaking and filtered. The above procedure was performed for each batch and the dried water extractives of KC1 and KC2 were weighed. The extractive values of the all two batches of Kayam Churna in above solvent are given in Table-I.

TABLE-I: EXTRACTIVE VALUES OF KAYAM CHURNA

Extractive	Values (% w/v)	
	KC1	KC2
Water soluble	38.4%	36.7 %
Methanol soluble	33.6%	32.6%
n-hexane	4.0 %	2.0%
Chloroform	8.8%	6.0%

Ash values: Total ash, acid insoluble ash and water soluble ash values were determined using standard procedure. (Table-II)

TABLE-II: ASH VALUES OF KAYAM CHURNA

Samples	Ash values % (Mean \pm SD)	
	KC1	KC2
Total ash	28.0 \pm 0.4	21.0 \pm 0.3
Water soluble ash	71.43 \pm 0.5	85.18 \pm 0.8
Acid insoluble ash	78.25 \pm 0.3	78.82 \pm 0.5

Physical characteristics: The physical characteristics of the Kayam Churna were determined for KC1 and KC2 in terms of the bulk density, true density, angle of repose, hausner's ratio and Carr's index according to the standard procedure. (Table-III)

TABLE-III: PHYSICAL CHARACTERISTICS OF DIFFERENT FORMULATION OF KAYAM CHURNA

Parameters	Values % (Mean \pm SD)	
	KC1	KC2
Bulk density (g/mL)	0.66 \pm 0.5	0.78 \pm 0.7
Tap density (g/mL)	0.49 \pm 0.6	0.45 \pm 0.3
Angle of repose ($^{\circ}$)	49.25 \pm 0.3	48.56 \pm 0.6
Hausner's ratio	1.342 \pm 0.6	1.750 \pm 0.06
Carr's index	25.49 \pm 0.03	42.86 \pm 0.09

Moisture content and Loss on drying: Moisture content and Loss on drying was determined for all two batches of Kayam Churna as per standard procedure. (Table-IV)

TABLE -IV: MOISTURE CONTENT AND LOSS ON DRYING OF KAYAM CHURNA

Samples	Values % (Mean \pm SD)	
	Moisture content	Loss on drying
KC1	5.36 \pm 0.07	7.45 \pm 0.03
KC2	6.08 \pm 0.08	7.45 \pm 0.03

Phytochemical evaluation: For this study, aqueous extract of Kayam Churna has been employed, screening process of each batch of Kayam Churna for phytochemical evaluation was done using reported methods. (Table-V)

TABLE-V: PHYTOCHEMICAL EVALUATION OF KAYAM CHURNA

Phytoconstituents	KC1	KC2
Alkaloids	Absent	Absent
Glycosides (anthraquinone)	Present	Present
Steroids	Present	Present
Terpenoids	Present	Absent
Tannins	Present	Absent
Saponins	Present	Present
Volatile oil	Absent	Absent
Carbohydrates	Present	Present
Proteins	Absent	Absent

Fluorescence analysis: For fluorescence analysis, the drug powder was treated with different solvent in different test tubes. The solvents used were 1N HCL, 1N NaOH (aqueous), FeCl₃, 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 procedure. (Table-VI)

TABLE-VI: POWDER FLUORESCENCE ANALYSIS OF KAYAM CHURNA

Material	KC1		KC2	
	Day Light	UV 254nm	Day Light	UV 254nm
Powder as such	BR	—	BR	—
P + 1N HCL	DBR	—	DBR	—
P + 1N NaOH	BR	—	BR	—
P + FeCL ₃	LB	DB	LB	DB
P + 1N HNO ₃	BR	—	BR	—
P + Ammonia	—	—	—	—
P + Iodine	YBR	LBR	DBR	LBR
P + Picric acid	Y	FY	Y	FY
P + 1N H ₂ S0 ₄	—	LBR	—	LBR

BR=Brown, YBR=Yellowish brown, DBR=Dark brown LBR=Light brown, BBR=Blackish brown, B=Black, Y=Yellow FY=Flourescent yellow, LB=Light blue, DB=Dark blue

pH determination: The pH values of 1 and 10 % (w/v) solution of different batches of Kayam Churna were determined as per I.P. (Table-VII)

TABLE-VII: pH OF 1 AND 10 % w/v SOLUTION OF DIFERENT FORMULATION OF KAYAM CHURNA

Formulations	1%(w/v) (Mean ± SD)	10%(w/v) (Mean ± SD)
KC1	5.537 ± 0.6	5.594 ± 0.4
KC2	5.685 ± 0.9	5.660 ± 0.3

Results and Discussion

Kayam Churna (two batches, KC1 and KC2) 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 values (Total ash, acid insoluble ash and water soluble ash), Physical characteristics, Moisture content, Loss on drying, Phytochemical evaluation, Fluorescence analysis, pH value.

Organoleptic studies revealed that all the two batches (KC1 and KC2) of Kayam Churna were brown in colour, having pleasant odour and possessing pungent taste. More than 90% of these samples (KC1 and KC2) passed through 60-mesh sieve.

As per table- I, the extractive values (%w/v) of Kayam Churna (Mean of KC1, KC2) in water, Methanol, n-hexane and chloroform were found to be (38.4%, 36.7%); (33.6%, 32.6%); (4.0%, 2.0%); (8.8%, 6.0%) respectively, it shows that in the Kayam churna water soluble contents are more than others.

As per table- II, the ash value of each batch of Kayam Churna (Mean \pm SD of KC1, KC2) for total ash, acid insoluble ash and water soluble ash were found to be (28.0 ± 0.4 , 21.0 ± 0.3); (78.25 ± 0.3 , 78.82 ± 0.5); (71.43 ± 0.5 , 78.82 ± 0.5) respectively, which indicates the presence of inorganic matters as major components.

As per the table- III, Physical characteristics (%) of Kayam Churna (Mean \pm SD of KC1, KC2) like Bulk density (g/mL), Tap density (g/mL), Angle of repose ($^\circ$), Hausner's ratio, Carr's index is found to be (0.66 ± 0.5 , 0.78 ± 0.7); (0.49 ± 0.6 , 0.45 ± 0.3); (49.25 ± 0.3 , 48.56 ± 0.6); (1.342 ± 0.6 , 1.750 ± 0.06); (25.49 ± 0.03 , 42.86 ± 0.09) respectively. Low values of angle of repose show the poor flow ability for all samples.

As per the table-IV, moisture content and loss on drying of 2 batches of Kayam churna % (Mean \pm SD of KC1 and KC2) was found to be (5.36 ± 0.07 , 6.08 ± 0.08) and (7.45 ± 0.03 , 7.45 ± 0.03) respectively.

As per table-V, active constituents like glycosides, carbohydrates, steroids, tannins and saponins are present. Among this constituents anthraquinone glycosides are present in more amount than any other constituents.

As per table-VII, the pH values of 1 and 10 % w/v solutions of 2 batches were (5.537 ± 0.6 , 5.594 ± 0.4); (5.685 ± 0.9 , 5.660 ± 0.3) which showed that Kayam Churna is acidic in nature.

Conclusions

In the present study, two different marketed polyherbal formulation of Kayam churna was taken. Kayam Churna were purchased from the local market of Bardoli 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 extractive values (%w/v) of Kayam Churna (Mean of KC1, KC2) in water, Methanol, n-hexane and chloroform were found to be (38.4%, 36.7%); (33.6%, 32.6%); (4.0%, 2.0%); (8.8%, 6.0%) respectively, it shows that water soluble contents are more than others.

The ash value of each batch of Kayam Churna (Mean \pm SD of KC1, KC2) for total ash, acid insoluble ash and water soluble ash were found to be (28.0 ± 0.4 , 21.0 ± 0.3); (78.25 ± 0.3 , 78.82 ± 0.5); (71.43 ± 0.5 , 78.82 ± 0.5) respectively.

Physical characteristics (%) of Kayam Churna (Mean \pm SD of KC1, KC2) like Bulk density, Tap density, Angle of repose, Hausner's ratio, Carr's index is found to be (0.66 ± 0.5 , 0.78 ± 0.7); (0.49 ± 0.6 , 0.45 ± 0.3); (49.25 ± 0.3 , 48.56 ± 0.6); (1.342 ± 0.6 , 1.750 ± 0.06); (25.49 ± 0.03 , 42.86 ± 0.09) respectively. Low values of angle of repose show the poor flow ability for all samples.

Moisture content and loss on drying of 2 batches of Kayam churna % (Mean \pm SD of KC1 and KC2) was found to be (5.36 ± 0.07 , 6.08 ± 0.08) and (7.45 ± 0.03 , 7.45 ± 0.03) respectively.

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