DEVELOPMENT OF QUALITY CONTROL METHODS FOR POLYHERBAL FORMULATION OF TRIPHLA CHURNA

Dikshit C. Modi[1], Biren N. Shah[1], Bhavesh S. Nayak[1], Rajvi Desai[2], Bhavik Patel[2], Kinara Maheshwari[2] and Amish Gandhi[3*]

[1]Department of Pharmacognosy, Vidybharti Trust College of Pharmacy, Umrakh, Gujarat, India.
[2]P.G. Students, Department of Pharmacognosy, Vidybharti Trust College of Pharmacy, Umrakh, Gujarat, India.
[3]P.G.Student,Department of Clinical pharmacy,R.C.Patel college of pharmacy, Shirpur,Maharashtra,India.

*** For Correspondence**
Mr. Bhavik G. Patel
Bhavikpharma29@yahoo.com
Mob: +919979698865.

Summary

In the present study, three batches of different marketed polyherbal formulation. Triphla 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 characteriristics, Moisture content, Loss on drying, Phytochemical evaluation, Fluorescence analysis, pH value etc. The result of Triphla Churna was found in close proximity. This study on Sitopaladi Churna was precise, reproducible and may be considered as a protocol for its evaluation.

Key Words: Triphla 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. Inspite 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 Triphla Churna designated as TC1,TC2 and TC3. 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 containg 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 access accurately. Therefore, the present study was undertaken to evaluate Triphla Churna as per Indian Pharmacopoeia and WHO guidelines.

Experimental

In the present study, three different marketed polyherbal formulation of Triphla churna (designated as TC1,TC2 and TC3) were produced. Triphla Churna were purchased from the local market of Bardoli and they were evaluated as per Indian Pharmacopoeia and WHO guidelines on the following parameters.

Organoleptic properties of Triphla Churna: Organoleptic properties of each of three batches of Triphla Churna were done by using reported methods.

Extractive values: 5 g of Triphla 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: Triphla Churna was dispersed in 100 ml of Methanol and allows it to stand for 24 hrs with occasional shaking. Extract was filtered and evaporated.

Water soluble extractives: Triphla Churna was dispersed in 100 ml of Water and allows 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 TC1,TC2 and TC3 were weighed.The extractive values of the all three batches of Triphla Churna in above solvent are given in Table-I.

TABLE-I: EXTRACTIVE VALUES OF TRIPHLA CHURNA

Extractive	Values (% w/v)		
	TC1	TC2	TC3
Water soluble	3.56 %	2.64 %	3.64 %
Methanol soluble	3.04 %	2.48 %	3.16 %
Petroleum Ether	0.08 %	0.08 %	0.02 %
Chloroform	0.12 %	0.12 %	0.04 %

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

TABLE-II: ASH VALUES OF TRIPHLA CHURNA

Samples	Ash values % (Mean ± SD)		
	TC1	TC2	TC3
Total ash	72.28 ± 3.00	66.42 ± 2.38	70.01 ± 2.12
Water soluble ash	48.66 ± 2.55	45.57 ± 1.07	39.92 ± 1.17
Acid insoluble ash	51.46 ± 1.44	52.00 ±1.44	48.56 ± 1.16

Physical characteristics: The physical characteristics of the Triphla Churna were determined for TC1,TC2 and TC3 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 TRIPHLA CHURNA

Parameters	Values % (Mean ± SD)		
	TC1	TC2	TC3
Bulk density (g/mL)	0.781 ± 0.004	0.595 ± 0.010	0.595 ± 0.010
Tap density (g/mL)	0.833 ± 0.001	0.657 ± 0.008	0.833 ± 0.003
Angle of repose (◦)	25.97 ± 0.025	21.33 ± 0.032	24.68 ± 0.360
Hausner's ratio	1.07 ± 0.040	1.05 ± 0.006	1.40 ± 1.000
Carr's index	6.25 ± 0.010	9.52 ± 0.040	8.65 ± 0.002

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

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

TABLE –IV: MOISTURE CONTENT AND LOSS ON DRYING OF TRIPHLA CHURNA

Samples	Values % (Mean ± SD)	
	Moisture content	Loss on drying
TC1	5.27 ± 0.04	7.57 ± 0.66
TC2	4.52 ± 0.35	7.72 ± 0.03
TC3	6.83 ± 1.01	8.09 ± 0.30

TABLE-V: PHYTOCHEMICAL EVALUATION OF TRIPHLA CHURNA

Phytoconstituents	TC1	TC2	TC3
Alkaloids	Absent	Absent	Absent
Glycosides (anthraquinone)	Present	Present	Present
Phytosterols	Absent	Absent	Absent
Essential oil	Present	Present	Present
Tannins	Present	Present	Present
Saponins	Present	Present	Present
Proteins	Present	Present	Present

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), $FeCl_3$, 1N HNO_3, NH_3, I_2, 1N NaOH (alcoholic), picric acid and 1N H_2SO_4. Then they were subjected to fluorescence analysis in daylight and in UV light as per standard procedure. (Table-VI)

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

TABLE-VI: POWDER FLUORESCENCE ANALYSIS OF TRIPHLA CHURNA

Material	TC1		TC2		TC3	
	Day Light	UV 254nm	Day Light	UV 254nm	Day Light	UV 254nm
Powder as such	L.B.	L.B.	L.O.	L.O.	Buff	Buff
P + 1N HCL	—	—	—	—	—	—
P + 1N NaOH	B.	G.B.	Y.B.	Y.B.	Y.B.	Y.B.
P + $FeCL_3$	G.B.	G.B.	G.	G.	G.	G.
P + 1N HNO_3	Y.O.	Y.O.	Y.O.	Y.O.	O.	O.
P + Ammonia	R.B.	Y.B.	R.B.	B.	R.B.	B.
P + Iodine	G.B.	G.B.	R.B.	R.B.	R.B.	R.B.
P + Picric acid	Y.	Y.	Y.	Y.	Y.	Y.
P + 1N H_2S0_4	B.R.	B.R.	R.	R.	R.	R.

R=Red, BR=Brown , LB=Light brown, B=Black, Y=Yellow YB=Yellowish brown, LB=Light blue, G=Green, G.B=Greenish brown, LO=Light orange, YO=Yellowish orange

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

Formulations	1%(w/v) (Mean ± SD)	10%(w/v) (Mean ± SD)
TC1	4.14 ± 0.02	3.26 ± 0.05
TC2	3.63 ± 0.06	2.94 ± 0.08
TC3	4.87 ± 0.50	3.77 ± 0.21

Results and Discussion

Triphla Churna (three batches, TC1,TC2 and TC3) 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 three batches (TC1,TC2 and TC3) of Triphla Churna were brown in colour, having pleasant odour and possessing pungent taste. More than 90% of these samples (TC1,TC2and TC3) passed through 60-mesh sieve.

As per table- I, the extractive values (%w/v) of Triphla Churna (Mean of TC1,TC2 and TC3) in water, Methanol,chloroform and petroleum ether were found.it shows that in the Triphla churna water soluble contents are more than others.

As per table- II, the ash value of each batch of Triphla Churna (Mean ± SD of TC1, TC2 and TC3) for total ash, acid insoluble ash and water soluble ash were found. which indicates the presence of inorganic matters as major components.acid insoluble ash indicate the silicates and heavy metals remain in the drug while water soluble ash indicate the metals which does not form oxide.

As per the table- III , Physical characteristics (%) of Triphla Churna (Mean ± SD of TC1, TC2 and TC3) like Bulk density (g/mL), True density (g/mL), Angle of repose (◦), Hausner's ratio, Carr's index is found.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 three batches of Triphla churna % (Mean ± SD of TC1,TC2 and TC3) was found. loss on drying indicates the amount of moisture and volatile matter present in the formulation.

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

As per table-VII , the pH values of 1 and 10 % w/v solutions of three batches were found. which showed that Triphla Churna is acidic in nature.

Conclusions

Standardization is considered as the heart soul for any formulation. Particularly for the herbal medicines, standardization is always been a tough task. Due to various probelms standardization of herbal medicines are an expensive and tedious job. So always been and afforts are made to find out suitable and less expensive methods for the standardization of herbal formulation.

Here some of the PHYSICO-CHEMICAL methods used to fix the standardization criteria for the herbal formulation.these physico-chemical criterias are going to be an important way to standardize any herbal formulation.

From the results it should be concluded that all the formulation which were used in the study was not found in the proximity standards. The deviation in the results may be due to the geographical variation of plant collected, metod of preparation, etc…

Still it is a preliminary study, lot of further research is needed to fix such criterias as to be the standard for standardization of any herbal formulation.

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