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Study of Shelf Life of Churna According To Modern Pharmaceutical Parameters

Research Article

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Abstract

Quality control of herbal formulations such as Churna especially for determination of its 'Shelf life' is essential in order to assess the quality of the drugs for therapeutic value. According to an estimate of World Health Organization (W.H.O) nearly 80% population of developing countries rely on traditional medicines. The World Health Organization (WHO) in 1999 has given a detail protocol for the standardization of herbal drugs comprising of a single as well as multiple quality control parameters. During the study, Evaluation of five selected churna was done by determination of various parameters like Ash value, moisture contents, extractive values and TLC profile. It was observed that, total Ash value approximately remains the same. Due to seasonal variation, moisture content increases, which badly affects the shelf life of churna. Water soluble extractive value decreases with time. By determining the TLC profile, it is also concluded that there is a significant loss of the chemical constituents of churna. Further it will be interesting to study the shelf life of churna with the help of advanced analytical techniques such as HPTLC, LC_MS etc.

Keywords: Shelf life, modern pharmaceutical parameters, quality control of churna

Introduction

Basic principles of *Bhaishajkalpana* includes first & most "*Panchavidhakashaykalpana*". The medicines, which we used to offer patient, is in different forms & those main forms in ayurvedic literature are called as "*Panchvidhakashaykalpana*". This principle mainly contains those 5 basic varieties of drugs which are most commonly used by *vaidya's* during their medical practice. On the basis of these *kalpanas* all the formulation in *Ayurveda* have been made (1).

It contains *Swaras, Kalka, Kwatha, Hima* & *Phanta*. These all varieties are considered as "*Panch vidha kashay kalpana*". These are the main or primary *kalpanas* of drugs which are further classified or divided into various "*Upkalpanas*" for proper fast absorption of medicine for more stability, increase shelf life of drug than *panchvidhakashaykalpana (2). Churna, Mantha, Paniya, Avleha, Asava-Arishta,*

etc are the different subtypes of *kalpanas* & hence these are termed as "*Upkalpanas*". *Churna's* subtype of *kalka kalpana (3)*. Amongst these *churna* are one of the main or daily usable *upkalpana*, even essential in preparation of other medicine. *Churna* preparations are widely & largely used in pharmacy as well as by practitioners *Ayurveda* for different ailments.

Ayurvedic Definition of Churna

Meaning – *Churna* is defined as totally dried raw material which is powdered very minutely to make their small size & again filtered through cloth's grid & obtained fine powder is called as "*Churna*".

Why to determine the Shelf life?

The nature of drug, their mode of administration, doses & the time duration specially its expiry date & expected effect, ultimately decides the success of medicinal drugs & treatment of that pathy. Hence it is very important to study the shelf life of dosage form according to pharmaceutical parameters. According to *Ayurvedic* pharmaceutical science, *churna* preparations remain potent up to two months (13th century A.D., *sharangdhara samhita*), after which they start degrading gradually thus losing their efficacy. The most important challenge faced by *Ayurvedic* formulations arises from lack of complete evaluation of its constituents, due to its complex nature.

Very little literature is available for the quality control of *churna* in terms of its Shelf life. And hence the present study was designed to study the Shelf life of *churna* by application of modern quality control parameters.

Objective

To evaluate the shelf-life of *Ayurvedic* formulation *churna* by means of modern pharmaceutical techniques.

Material and Methods

Five single drug *churna* formulations were selected for the study.

1) *Manjishtha – Rubia cordifolia*
2) *Guduchi – Tinospora cordifolia*
3) *Vidang- Embelia ribes*
4) *Sariva – Hemidesmus indicus*
5) *Pippali – Piper longum*

Different 5 Ayurvedic drug viz. *Manjishta*, *Guduchi*, *Vidang*, *Sariva*, *Pippli* selected for the study. The drugs were purchased from MANAKARNIKA AUSHADHALAYA, PUNE. The drugs were authenticated by using morphological and anatomical data department of *dravyaguna vigyan* at *Aryangla Vaidyak Mahavidyalaya, Satara*.

In order to check the quality & purity of all the *churnas*, following parameters were used. The study was carried out at Department of Pharmacognosy at "Satara College of Pharmacy, Satara". Regular record of assessment according to modern pharmaceutical methods was maintained, after every 2 months. The study was started on 1st March 2014 & it was denoted as batch I. The various modern evaluation parameters were applied for standardization of *churnas*.

Standardization was carried out by using different methods like,(4,5,6,7,8,9,10)

I. Total Ash values
II. Moisture content (Loss on Drying)
III. Water soluble extractive value
IV. Ethanol soluble extractive value
V. TLC profile (Thin layer chromatography)

Thin layer chromatography (TLC)-

1) *Rubia cordifolia*-

Test solution- 5 gm of dried powdered plant material was refluxed with 25 ml of methanol for 25 min consecutively three times on a water bath, cooled, filtered and removed the solvent under reduced pressure. The residue was dissolved in 10ml of methanol.

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Solvent system-Toluene: Ethyl acetate [85:15]
Procedure-Applied test solution on prepared silica gel 60 GF254 on TLC plate.
Visualisation-Viewed under the UV light at 254 nm

2) *Tinospora cordifolia*-
Test Solution-
5 gm of dried powdered drug was refluxed with 50ml methanol for 2hours. Filtered and evaporated the filtrate to dry. The residue was dissolved in 5 ml methanol.

Solvent system-
Toluene: Acetone: Water (5:15:1)

Procedure-
Applied standard solution on prepared silica gel 60 GF254 on TLC plate.
Visualisation-
viewed under the UV light at 254 nm.

3) *Embelia ribes*-
Test Solution-
5 gm of the powdered drug was refluxed with 50ml methanol for 1 hour. Filtered and evaporated the filtrate to dry. The residue was dissloved in 5ml methanol.

Solvent system-
Toluene: Acetone: Acetic acid (9:1:0.5)

Procedure-
Applied standard solution on prepared silica gel 60 GF254 on TLC plate.

Visualisation-
Viewed under the UV light at 254 nm.

4) *Hemidesmus Indicus*-
Test Solution-
5gm of finely powdered drug was taken with 25ml of ethanol and left it for complete extraction for 24 hours, process was repeated for three times. Filtered combined extract and concentrated the filtrate to dry. The ethanolic extract was dissolved in 10 ml of chloroform.

Solvent System-
Toluene: Ethyl acetate: Methanol (8:2:0.5)

Procedure-
Applied standard solution on prepared silica gel 60 GF254 on TLC plate.
Visualisation-
Viewed under the UV light at 254 nm.

5) *Piper longum*-
Test Solution-
1 gm of the powdered drug was refluxed with 10ml methanol for 30 mins. Filter and evaporate the filtrate to dry. The residue was dissolved in 5ml methanol.

Solvent System-
Toluene: Ethyl acetate [7:3]
Procedure-
Applied standard solution on prepared silica gel 60 GF254 on TLC plate.

Visualisation-
Viewed under the UV light at 254 nm.

Results-
The Total Ash Values, Extractive Values, Rf Values & Moisture content of every *churna* was determined. The morphological changes in the *churnas* were also studied. The detail results have been shown in the following tables.

TABLE – I – Result Showing Morphological Study of Churnas.

Batch no.	Name of churna	Taste	Odour	Colour
1st BATCH	*Manjishta*	Sweetish	Characteristically Pleasant	Reddish Brown
	Guduchi	Bitter	Odourless	Creamish Brown
	Vidang	Pungent	-	Light Reddish Brown
	Sariva	Acrid, Vanilin Like	Pleasant (Coffee Like)	Yellowish Brown
	Pippli	Bitter	*Tikshna Gandha*	Deep Moss Green
2nd BATCH	*Manjishta*	Sweetish	Characteristically Pleasant	Reddish Brown
	Guduchi	Bitter	Odourless	Creamish Brown
	Vidang	Pungent	-	Light Reddish Brown
	Sariva	Acrid, Vanilin Like	Pleasant (Coffee Like)	Yellowish Brown
	Pippli	Bitter	Tikshna Gandha	Deep Moss Green
3rd BATCH	*Manjishta*	Sweetish	Characteristically Pleasant	Reddish Brown
	Guduchi	Bitter	Odourless	Creamish Brown
	Vidang	Pungent	-	Light Reddish Brown
	Sariva	Acrid, Vanilin Like	Pleasant (Coffee Like)	Yellowish Brown
	Pippli	Bitter	*Tikshna Gandha*	Deep Moss Green

TABLE – II – Result Showing Percentage of Total Ash Value and Percentage Of Moisture Content Of *Churnas*.

Batch no.	Name of churna	Percentage of total ash value	Percentage of moisture content
1st BATCH	*Manjishta*	8.88 %	6.5 %
	Guduchi	8.16 %	6.5 %
	Vidang	7.38 %	7 %
	Sariva	13.0 %	6.9 %
	Pippli	7.42 %	6.3 %
2nd BATCH	*Manjishta*	6.79 %	7.6 %
	Guduchi	8.16 %	7.6 %
	Vidang	7.4 %	7 %
	Sariva	12.8 %	8.2 %
	Pippli	6.6 %	7 %
3rd BATCH	*Manjishta*	11.7 %	7.8 %
	Guduchi	9.2 %	7.9 %
	Vidang	8.14 %	7.7%
	Sariva	13.6 %	7.9 %
	Pippli	8.1%	8.1 %

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TABLE – III Result Showing Percentage of Water Soluble Extractive and Percentage of Ethanol Soluble Extractive of Churnas.

Batch no.	*Name of churna*	Percentage of water soluble extractive	Percentage of ethanol soluble extractive
1st BATCH	*Manjishta*	3.45 %	1.66 %
	Guduchi	5.40 %	1.56 %
	Vidang	3.25 %	4.41 %
	Sariva	5.16 %	2.98 %
	Pippli	11.12 %	4.76 %
2nd BATCH	*Manjishta*	4.14 %	1.51 %
	Guduchi	4.98 %	1.91 %
	Vidang	2.82 %	4.36 %
	Sariva	5.13 %	3.05 %
	Pippli	9.38 %	4.91 %
3rd BATCH	*Manjishta*	3.27 %	1.014 %
	Guduchi	4.9 %	1.8 %
	Vidang	2.7 %	4.5 %
	Sariva	4.3 %	2.3 %
	Pippli	8.7 %	4.34 %

TABLE – IV Result Showing Rf Values of *Churnas*.

Batch no.	*Name of churna*	Rf value
1st BATCH	*Manjishta*	0.08,0.17,0.24,0.28,0.37,0.48,0.74,0.86,0.93
	Guduchi	0.08,0.13,0.21,0.40,0.47,0.55,0.63,0.71,0.82,0.91,0.96,0.98
	Vidang	0.05,0.08,0.14,0.18,0.29,0.44,0.55,0.67,0.76,0.87
	Sariva	0.05,0.22,0.38,0.54,0.65,0.78,0.90,
	Pippli	0.17,0.31,0.60,0.66,0.72,0.80,0.85,0.90
2nd BATCH	*Manjishta*	0.08,0.10,0.16,0.20,0.24,0.27,0.36,0.48,0.57,0.75,0.87,0.91
	Guduchi	0.08,0.14,0.20,0.28,0.51,0.62,.075,0.88,0.96,0.98
	Vidang	0.09,0.15,0.18,0.22,0.24,0.30,0.37,0.42,0.52,0.70,0.84
	Sariva	0.27,0.38,0.45,0.56,0.72,0.82,0.92
	Pippli	0.11,0.20,0.35,0.62,0.70,0.78,0.90,0.92
3rd BATCH	*Manjishta*	0.08,0.11,0.19,0.35,0.39,0.48,0.51,0.57,0.91
	Guduchi	0.09,0.32,0.39,0.45,0.70,0.77,0.86,0.97
	Vidang	0.24,0.28,0.34,0.41,0.52,0.63,0.78,0.90
	Sariva	0.12,0.20,0.64,0.73,0.94
	Pippli	0.13,0.22,0.28,0.42,0.60,0.67,0.78,0.86,0.92

DISCUSSION

Total Ash value

Ash value is a direct measure of soil and sand particles present in the powdered drug. There is no modified or significant change in the percentage of Ash value. The results have shown that there is no significant rise in total Ash value of each churna. All the churnas were preserved well in air tight containers, so it could be the reason for no change in ash value of every churnas. There is little change in the value of batch II, the reason might be the practical error.

Moisture content

Moisture content of batch III of all the churnas have found to be increased significantly. The batch I moisture content is the lowest for all the 5 churnas & gradually it has been increased in batch II & III. The significant rise in moisture content leads to attack of atmospheric moisture on the formulation. It is also subjected to the atmospheric conditions since, batch I was carried out in summer & batch III carried out in rainy season.

The moisture attack on the *churna* formulation may lead to microbial growth & fungus attack. This could be prevented by keeping & storing the formulation in air tight containers. We have also preserved all the *churna* in closed container, but moisture attack was not prevented. So to ensure the life of *churna* it should be preserved in well closed air tight containers, so that shelf life of *churna* could be improved.

Water and ethanol soluble extractive value

Water soluble extractive value of IIIrd batch is found to be lower compared with batch I and II. On standing *churna* might have lost certain ingredients (phytochemicals) so that it will reduce the total extractive value.

Extractive value is the measure of different phytoconstituents present in powdered drug. Extractive value may vary with the preservation of drug/formulation. In our study, it has been noticed that water soluble extractive value is decreased as the time proceeds i.e. from batch I to III for all 5 *churnas*, water soluble extractive value decreased. It signifies that water soluble active principles might have lost on standing the formulation for a longer period. So it becomes very essential for *churna* to retain its chemical constituents for at least 1 year, so that it could produce desired therapeutic effect. In case of ethanol soluble extractive value only *Guduchi* & *Vidanga chruna* retained their ethanol soluble extractives during the course of the study (4 months) & rest of all the *churna* i.e. *Manjista*, Sariva & *Pippali* have lost chemicals on standing.

Thin Layer Chromatography (TLC)

Thin layer chromatography is used to separate the various phyto-constituents present in drug or formulations. In our study, we have carried out the TLC of all the *churnas* by setting their mobile phase separately. Once the mobile phase was optimized, the TLC was run for respective *churna*. In our study, we have not used any standard marker compound to compare the results but it was considered that the results (Rf values & colour intensity of spot) of batch I procedure will be standard & it will be compared with the results of next batches to come. The TLC profile study reveals that there is much more diversity in the results of batch II & III compared with batch I. In batch II & III, the spot intensity was lost & we got certain elevations in Rf value of every *churna*. Some spots were not visible or very poorly visible under UV light. Hence, There is a certain chemical loss or changes in chemical constituents occurred during storage of *churna* since every spot is representing a phytoconstituent, so, we can conclude that there is loss of certain chemicals from all the churnas so that elevations are produced in the Rf values.

Also this could be supported by results of extractive values.

Conclusion

The present study was carried out on 5 different *churna* reveals that all 5 *churna* have lost certain amount of chemical constituents on standing for 4 months. Also moisture attack on *churna* signifies the deterioration of formulation & also decomposition of active chemicals. So, one can conclude that *churnas* under study have lost their potency on standing for 4-6 months. The traditional claim about shelf life of *churna* is 2 months[4] and there on it starts to degrade, present study also support this claim. When modern parameters used to evaluate the *churna*, it seems that the shelf life may be up to 6 months. The surrounding temperature, packing of container are the aspects to be considered while thinking about the shelf life of a *churna* formulation.

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