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ORIGINAL RESEARCH ARTICLE

An Unique Concentrated & Fermented Dosage Form i.e. *Pravahi kwatha*

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ABSTRACT

Concentrated and fermented formulation is a new modified dosage form prepared by concentrating one of the basic formulations of Ayurveda, i.e. decoction. Due to its increased palatability & stability most of the pharmacies have started marketing these types of dosage form in place of decoction. Brihatpanchamoola was selected as basic raw materials for the preparation of same formulation. It includes roots of five trees i.e. *Aegle marmelos* Carr. (Rutaceae), *Clerodendrum phlomidis* Linn. (Verbenaceae), *Oroxylum indicum* Vent. (Bignoniaceae), *Gmelina arborea* Roxb. (Verbenaceae), *Stereospermum suaveolens* DC. (Bignoniaceae). Five batches were prepared to develop the SMP. Pravahi Kwatha (concentrated and fermented decoction) pH (4.63), viscosity (1.36 millipose), alcohol content (6.46) and total sugar (4.7). The decoction and its new dosage form were prepared from the same raw materials and compared analytically. . HPTLC profile shows that relatively more constituents are extracted in decoction from raw drug whereas they decrease when the concentrated dosage form is prepared from same decoction.

Key words: SMP, Pravahi Kwatha (concentrated and fermented Decoction), HPTLC profile.

INTRODUCTION

The most commonly used five basic formulations of Ayurveda has some drawbacks like less shelf life, higher chances of microbial growth, require high dose and are not palatable. Therefore, Acharya had developed secondary preparations like fermented preparation, confectionaries, medicated oil, pills etc., which have longer shelf life i.e. stability and palatability. The short shelf life is the major drawback of the decoctions for the large-scale production. Moreover, in today's chaotic life style, people find it difficult and tedious to prepare and administer decoctions. A strong competition from syrups and other flavoured medicaments has also led to decline in the use of decoctions. To overcome these problems, concentrated and fermented decoctions are prepared now days. In classical texts, direct references are not available regarding this formulation but Ayurveda Sara Samgraha mentioned it as a "Pravahi Kwatha", which is prepared by fermentation process. It can be said as secondary formulation of decoction prepared by adding sweetening and fermenting agent. In the present study, an attempt has been made to lay the SMP for preparation of this formulation as well as analytically compare it with decoction prepared from same source. Here, Brihatpanchamoola has been selected for the preparation of decoction and Pravahi decoction.

MATERIALS AND METHODS

Preparation of concentrated and fermented decoction was achieved under following headings:

i) Preparation of decoction:

Raw drugs were collected from the Dang forest (Dang District, Gujarat) after obtaining due permission from the concerned authorities. The raw drug samples were collected separately, packed in polythene bags and labelled with name, part, place and date of collection. Samples of the raw drugs were shade dried and subjected to pharmacognostical study and after the conformation of the genuineness; they were undertaken for the pharmaceutical study. Decoction and its dosage form were prepared in the department.

Raw drugs were coarsely powdered individually in disintegrator and passed through mesh no. 8 size. Then required amount of potable drinking water was mixed in w/v ratio with coarse

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powder in a stainless steel vessel and kept for overnight soaking (12 h). The ratio of ingredients has been shown in **Table 1**. Next day, decoction was prepared by applying constant mild heat until the volume reduced up to 1/8th of the initial quantity. After desirable reduction of volume, the decoction was filtered through double folded cotton cloth and collected in a separate vessel for further processing. The residue remained above cloth was discarded. The results obtained during the preparation of decoction have been tabulated in **Table 2.** Total 5 batches were prepared to maintain the SMP.

Table 1: Showing formulation composition of decoction

S. No.	Ingredients	Part used	Qty. (*g*)
1.	*Aegle marmelos* (Linn.)	Root	100
2.	*Clerodendrum phlomidis* (Linn.)	Root	100
3.	*Oroxylum indicum* (L.) Vent.	Root	100
4.	*Stereospermum suaveolens* (Roxb.)	Root	100
5.	*Gmelina arborea* Roxb.)	Root	100
6.	Water		81

Table 2: Sho wing observations an d r esults obtained during preparation of decoction;

Parameters	Batches					Avg.
	I	II	III	IV	V	
Initial qty. of raw material (g)	500	500	500	500	500	500
Size of the raw material (mesh no.)	08	08	08	08	08	08
Total qty. of water (*l*)	8	8	8	8	8	8
Total time for soaking (*h*)	12	12	12	12	12	12
Max.temp. during preparation of decoction, after 1 h (^{0}C)	88	90	90	92	90	90
Total time taken for 1/8threduction (*min.*)	240	225	210	215	235	225
Total qty. of decoction obtained (*ml*)	1080	1090	1075	1073	1088	1091

ii) Preparation of concentrated an d fermented decoction:

Thus, prepared decoction was used for preparation of new dosage form. **Table 3** shows the composition of formulation. Prior to preparation of formulation, fermenting vessel subjected to fumigation with drugs like *Commiphora wightii* Arn., *Piper nigrum Linn.*, *Acorus calamus* Linn., *Nardostachys jatamansi* DC and *Curcuma longa* Linn. After self-cooling up to 40^{o}C of decoction, Jaggery was added, mixed well by stirring and then filtered through a double folded cotton cloth. After filtration, solution prepared by flowers of *Woodfordia fruticosa* Linn. was added and mixed well. This mixture was transferred to vessel (Porcelain vessel) and kept at a dark place. After determination of initiation of fermentation, porcelain vessel was tightly sealed by mud smeared cloth, and placed in clean and dry chamber. After completion of the fermentation process, the supernatant fluid was decanted in another clean glass jar by filtering through a double folded cotton cloth. The marc remained at the bottom of the vessel was discarded. Observations and results are enumerated as in **Table N o. 4 , 5 & 6 .** Similar 4 another batches were prepared to ensure the SMP.

Table 3: Ra tio o f i ngredients u sed i n pr eparation o f fermented decoction;

S. No.	Ingredients	Ratio (%)
1.	Decoction of Brihatpanchamoola	100
2.	Jaggery	35
3.	Dhataki Pushpa	2

Table 4: Showing unit operative process during preparation of fermented decoction;

S. No.	Parameters	Batch					Avg.
		I	II	III	IV	V	
1.	Decoction (m*l*)	1000	1000	1000	1000	1000	1000
2.	Jaggery (*g*)	350	350	350	350	350	350
3.	Solution of *Woodfordia fruticosa* Linn. (*ml*)	80	80	80	80	80	80
4.	Temperature of decoction during addition of jaggery (ºC)	43	41	44	43	41	42.4
5.	Initial vol. of solution of fermentation (*ml*)	1350	1350	1350	1350	1350	1350
6.	Atmospheric temperature (ºC)	24	25	27	24	25	25
7.	Total duration (days)	30	30	30	30	30	30
	Final yield (*ml*)	**1060**	**1100**	**1070**	**1060**	**1100**	**1078**

Table 5: Tests performed during preparation of fermented decoction;

Observation		Batch					
		I	II	III	IV	V	Avg.
Effervescence	Present	5th day	3rd day	2nd day	2nd day	3rd day	3rd day
Burning match test	Absent	6th day	5th day	4th day	5th day	5th day	25th day
	Present	32nd day	31st day	30th day	31st day	31st day	31st day
Fermentation completion		Successful	Successful	Successful	Successful	Successful	Successful

Table 6: Observations and results obtained during preparation of fermented decoction;

S. No.	Parameters	Root
1.	Decoction (*l*)	1.000
2.	Jaggery (*g*)	350
3.	Solution of *Woodfordia fruticosa* Linn. (*ml*)	80
4.	Temperature of decoction during addition of Guda (ºC)	40-45
5.	Initial vol. of solution of fermentation (*ml*)	1350
6.	Atmospheric temperature(ºC)	24-27
7.	Total duration (days)	32
	Final yield (*ml*)	**1056.66**

Raw drug i.e. coarse powder of Brihatpanchamoola, in process formulation Brihatpanchamoola decoction and finished product were analysed by adopting various related analytical parameters, like

A. Organoleptic characteristics: Colour, odour, taste, form were observed.

B. Physico-chemical analysis: Loss on drying at 110°C, ash value, acid insoluble ash, pH value, specific gravity at 40^0C, total solid content, water soluble extractives, methanol soluble extractives was carried out.

C. Qualitative test for various functional groups was done and observation and results of the experiment are asserted in **Table 7 to 11.**

Table 7: Average result of Physico-chemical analysis of raw drugs;

S. No.	Parameters	Raw material
1.	Foreign mater (% w/w)	Nil
2.	Loss on drying (% w/w)	7.136
3.	Total ash (% w/w)	2.77
4.	Acid insoluble ash (% w/w)	0.01
5.	Water Soluble extractive (% w/w)	20.4
6.	Alcohol soluble extractive (% w/w)	14.3
7.	pH	5.85

Table 8: Qualitative analysis of raw drugs, decoction and fermented decoction;

S. No.	Chemical constituents	Raw	Decoction	Fermented decoction
1.	Alkaloids	+ ve	+ve	- ve
2.	Tannins	+ ve	+ ve	+ ve
3.	Saponins	- ve	- ve	- ve
4.	Cyongenic glycosides	+ ve	+ ve	+ ve
5.	Flavanoids	+ve	+ve	+ ve
6.	Phenols	+ve	+ve	+ ve

+ve = Present, -ve = Absent

Table 9: Organoleptic characters of decoction and its dosage form;

S. No.	Organoleptic characters	Decoction	Fermented decoction
1.	Colour	Brown	Dull brown
2.	Odour	Characteristic	Alcoholic
3.	Appearance	Dull	Viscous liquid
4.	Taste	Bitter	Astringent

Table 10: Average results of physico-chemical parameters of decoction and fermented decoction;

S. No.	Parameters	Batch										Avg.	
		A_1	B_1	A_2	B_2	A_3	B_3	A_4	B_4	A_5	B_5	A	B
1.	Total Solid Content (% w/v)	5.38	6.98	5.05	6.86	5.04	6.93	4.75	6.7	4.9	6.65	5.02	6.82
2.	pH	5.66	4.69	5.71	4.57	5.80	4.65	5.66	4.84	5.82	4.87	5.73	4.72
3.	Specific Gravity	1.02	1.01	1.02	1.02	1.02	1.02	1.02	1.01	1.02	1.01	1.02	1.01
4.	Viscosity (millipoise)	9.35	10.97	9.41	11.23	9.38	10.73	9.73	11.65	9.87	11.33	9.55	11.18
5.	Refractive Index	1.35	1.36	1.35	1.36	1.35	1.36	1.34	1.36	1.34	1.36	1.346	1.36

***A:** Decoction, **B:** Fermented decoction*

Table 11: Result of specific physicochemical parameters of fermented decoction;

S. No.	Parameters	Batch					Avg.
		I	II	III	IV	V	
1.	Alcohol content (%)	6.72	6.49	6.18	6.57	6.34	6.46
2.	Total sugar (%)	4.9	4.5	4.7	3.4	4.1	4.3
3.	Reducing sugar (%)	4.15	3.97	4.28	1.62	2.31	3.27
4.	Non-reducing sugar (%)	0.75	0.53	0.42	1.78	1.79	1.05

D. HPTLC profile:

Test solution: Methanolic extracts of coarse powder of Brihatpanchamoola, decoction of Brihat Panchmoola and Brihatpanchamoola Pravahi Kwatha. Chloroform : Acetone (4.6 : 0.37 v/v) was selected as solvent system after multiple trials and error method. The developed plate was visualised under visible day light, short UV (254 nm), long UV (366 nm) and after spraying with anisaldehyde-sulphuric acid reagent and again observed in daylight. The R_f values are recorded in **Table 12.**

Table 12: Maximum R_f values of methanolic extract of raw drug, decoction and fermented decoction observed at 254 nm and 366nm;

Tracks	Wavelength	No. of Spots	Max. R_f
Raw drug	254 nm	5	0.04, 0.24, 0.28, 0.34, 0.59
	366 nm	2	0.04, 0.88
Decoction	254 nm	13	0.05, 0.14, 0.21, 0.27, 0.34, 0.41, 0.45, 0.48, 0.50, 0.55, 0.60, 0.66, 0.71
	366 nm	4	0.05, 0.34, 0.41, 0.55
Fermented decoction	254 nm	6	0.05, 0.07, 0.16, 0.45, 0.56, 0.68
	366 nm	2	0.07, 0.95

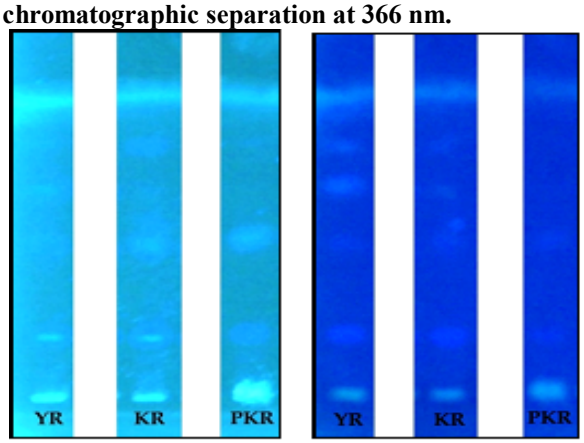
DISCUSSION

Decoction is an aqueous solution containing the properties of substance or substances that have been processed in it. The purpose of herbal decoction is to extract the water-soluble constituents of herbs by boiling. Quantum of heat and duration of heating are prime concern for preparation of decoction. Soaking of raw material results in the softening of drug due to diffusion of liquid into the raw material because of the osmosis. Due to the presence of hydroxyl group, the raw material swell, which results in the increased diffusion pressure inside the cells, there by ultimately bursting of the cell wall. Continuous heating and agitation during the preparation of decoction enhances the extraction process by weakening the bonds and there by separating the hydrophobic substances from hydrophilic substances. The water diffuses into the raw material, dissolves the water soluble constituents and discharges it to the liquid media due to collapse of the cell wall. Thus, transfer of water soluble principle into the solvent (Water) is achieved. Temperature is an important factor because there are chances that it can decompose some of the thermo labile active constituents. Therefore, during the preparation of decoction, temperature was maintained between 85 - 90^0C. Fresh raw drug samples were shade dried and made in to coarse powder by processing in hammer mill separately, and sieving through 8 no. mesh. The material was soaked overnight and then subjected to heat. Stirring was done during the preparation of decoction to get uniform concentration throughout the solvent and also to protect the drug from burning. Vapours were seen rising from the surface of the decoction around 70^{o}C. Decoction started boiling at around 95^{o}C. It takes about an average of 4 hours of boiling to prepare the decoction. After the preparation of decoction, it was filtered to remove the unwanted material. Jaggery and solution prepared by flowers of *Woodfordia fruticosa* Linn. were added to the filtrate in a definite proportion. The temperature during the addition of Jaggery was recorded around 40- 45^{o}C. It was mixed well and filtered through a double folded clean cloth. Solution prepared by flowers of *Woodfordia fruticosa* Linn. was added and stirred well uniformly. The mixture placed in a fumigated porcelain container and subjected to the fermentation for making free from pathogens. Proper space was left in fermenting vessel for the circulation of liberated gas i.e. CO_2 during the process of fermentation. The fermenting vessels were kept away from direct sunlight, air, temperature variations and to provide suitable condition for fermentation. At an average, it took 3-5 days for the commencement of fermentation. After confirmatory tests, the mouth of porcelain container was sealed with a lid and mud smeared cloth. It took nearly 25-30 days for the completion of the process. Here, solution prepared by flowers of *Woodfordia fruticosa* Linn. was used instead of solution flowers of *Woodfordia fruticosa* Linn. itself. During the pilot study it was observed that the new dosage form of decoction prepared by solution of *Woodfordia fruticosa* Linn. readily caught fungal growth although the onset of fermentation was rapid. Hence, in the consecutive batches solution of flowers was used instead of flower[6]. First batch took considerably more time for onset and completion of fermentation in comparison to other two batches. The probable reason for this may be that, this batch was prepared in cold season (oct. – nov.). As the temperature during this season is relatively low, this hinders the onset of fermentation. Therefore, artificial heating system by application of a 40W bulb in a closed chamber was devised to maintain the appropriate temperature (27-35^{o}C). The other reason may be the peak temperature of the decoction, which was observed to be around 95^{o}C in the first batch. As most of the microbes that facilitate the fermentation, die at this temperature, making fermentation impossible. Hence, the average peak temperature during the consecutive batches was maintained around 85-90^{o}C.

Physicochemical values of analysis of raw drug samples were in compliance with those mentioned in API. Qualitative analysis of raw drug sample revealed the presence of alkaloids, tannins, cyogenic glycosides, flavanoids and phenols whereas absence of saponins in raw material as well as decoction. Whereas, fermented decoction was devoid of alkaloids and saponins. The reason behind this may be lack of extraction of alkaloids in alcohol media (Pravahi Kwatha). Decoction was brown in colour and turned to dull brown in fermented decoction. Consistency changed from watery to viscous and taste from bitter to astringent. pH was changed from 5.27 to 4.63. Alcohol percentage was found to be 6.46 % on an average. This can be considered as standard parameter while assessing the quality of fermented decoction. Reducing as well as non-reducing sugars were found to 3.27% and 1.05% respectively. This may change according to the

percentage of sugar added in formulation. Preliminary HPTLC profile of fermented decoction was generated and compared with raw material and decoction samples (**Fig. 1, 2, 3, 4**). HPTLC profile shows that relatively more constituents are extracted in decoction from raw drug whereas they decrease when fermented decoction is prepared from same decoction.

Fig. 1: Chromatographic separation at 254 nm and Fig. 2: chromatographic separation at 366 nm.



YR : Raw material (Red)
KR : Decoction (Blue)
PKR : Fermented decoction (Light green)

Fig. 3: C hromatographic c omparison of al l tr acks i n HPTLC at 254 nm.

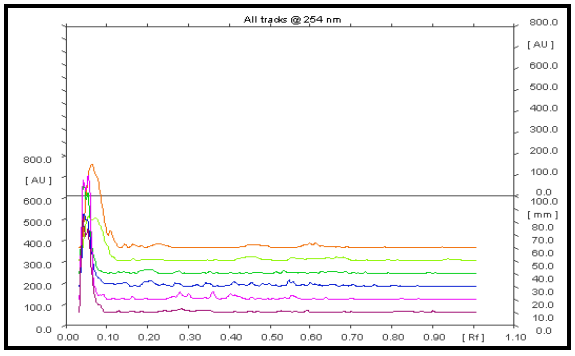
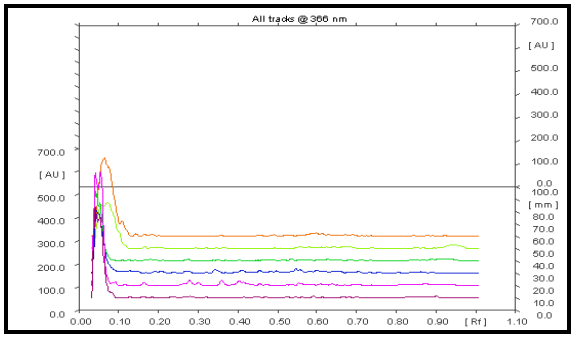


Fig. 4: C hromatographic c omparison of al l tr acks i n HPTLC at 366 nm.



Red : Raw material
Blue : Decoction
Light Green : Fermented decoction

CONCLUSION

Fermented decoction is very much in vogue in today's scenario. Hence, it is the need of hour to lay specific parameters for their quality control. Mass acceptance can be assured only by maintaining stringent quality control measures. pH, viscosity, alcohol percentage and HPTLC profiles can be considered as pilot tools for developing SMPs of these novel formulations.

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