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Pharmacopoeial constants as indication of stability of polyherbal formulations – a study on Hutabhugadi and Sitopaladi Curna of Ayurvedic Formulary of India

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Abstract

Nowadays herbal medicines are popular all over the world. Drawback is consistency in the quality of the product over a range of time. Any considerable changes in the quality of the product over a time must be detectable. So stability testing is needed to ensure the quality of herbal products which is an evidence for the quality of the finished product. Present study reports the deviation in Pharmacopoeial constants of Hutabhugadi curna (HC) and Sitopaladi curna (SC) when stored at a recommended storage conditions and examined for a period of time. The variation in the Pharmacopoeial physico-chemical constants of the curna (fine powder) was observed during 0 (initial), 3rd and 6th month. Average shelf life is proposed for HC and SC based on 10% variation in physico-chemical tests specified in pharmacopoeia while compared to initial value. It was found that HC showed average ±10% variation in the values at 11.41 months while SC showed it at 22.58 months. This method of shelf life assessment can be used as routine shelf life check for polyherbal herbal formulations though this method is not bioavailability based assay applicable for single herb formulations.

Keywords: Poly herbal formulation, Quality control, Real time stability, Shelf life.

Introduction

Though herbal products have become increasingly popular throughout the world, one of the impediments in its acceptance is the lack of standard quality control profile. However, due to the complex nature of the constituents of plant based drugs, it is difficult to establish quality control parameter through modern analytical techniques[1]. As herbal formulation contains few to many active ingredients; it is difficult to sustain the stability of the product. According to Ayurvedic pharmaceutical science, churna preparations remain potent up to two months, after which they start degrading gradually losing their efficacy[2]. Hence stability testing is essential to improve the quality of the herbal products.The purpose of the stability testing is to provide proof of how the quality of a finished product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light[3]. In the present study a real time stability study of Hutabhugadi (HC) and Sitopaladi curna (SC) was undertaken. HC is used in the treatment of Agnimandya (digestive impairment), pandu (anemia), sopha (oedema) and arsa (piles), while SC is used in the treatment of arocakatva (tastelessness), agnimandya (digestive impairment), svasahara (aniasthmatic), jvarahara (antipyretic), kasahara (cough), hasta pada daha (burning sensation in palms and soles), parsva sula |(intercostals neuralgia and pleurodynia), ksaya (pthisis), saptajihvatva, urdhvagata raktapitta (bleeding disorders)[4]. Pharmacopoeial parameters specified for curna (fine powder) type of formulations like organoleptic, moisture content, pH, water and alcohol soluble extractive, total ash, acid in soluble ash and water soluble ash were periodically checked using standard procedures[5].

Tracking the variation in the Pharmacopoeial constants at different interval of time the stability of the above products was validated based on standard methodology. Increase or decrease in the above constants was observed during 6 months of storage at normal storage conditions (real time). Number of months when 10 % degradation would occur was calculated using the formula; ([0 Month Assay value-{(0 Month Assay value x 10)/100}]-Intercept) / Slope[6].

Materials and Methods

Formulation and packing

HC was prepared with ingredients *viz*. Hutabhuga (*Plumbago zeylanica*) root - 1 part, Ajamoda (*Apium leptophyllum*) fruit - 1 part, Saindhava lavaṇa (Rock salt) - 1 part,Magadha (*Piper longum*) fruit - 1 part, Marica (*Piper nigrum*) fruit - 1 part and Pathya (*Terminalia chebula*) pericarp - 5 parts as per Ayurvedic Formulary of India (AFI)[4] (Table 1). SC was prepared with ingredients *viz*. Hutabhuga (*Plumbago zeylanica*) root - 1 part, Ajamoda (*Apium leptophyllum*) fruit - 1 part, Saindhava lavaṇa (Rock salt) - 1 part,Magadha (*Piper longum*) fruit - 1 part, Marica (*Piper nigrum*) fruit - 1 part and Pathya (*Terminalia chebula*) pericarp - 5 parts as per AFI[4] (Table 2). Formulation was prepared as per procedure detailed in Ayurvedic Pharmacopoeia of India (API)[7]. All the ingredients except Saindhava lavaṇa and Sharkara were washed properly to have no microbial load[8]. The washed and dried raw drugs werefinely powdered. Saindhava lavana was roasted in a stainless steel pan on low flame till free from moisture and then powdered. The individual raw drug powders were passed separately through sieve number 44 followed by 85. Each ingredient was weighed separately and mixed together in the proportion specified and passed the through sieve number 44 to obtain a homogenous blend and packed in an air-tight plastic container covered with aluminium foil. The formulation HC was compliant to quality standards reported earlier[10].

Table 1: Formulation composition of Hutabhugadi Curna

Hutabhuga (Citraka API)	***Plumbago zeylanica***	**Root**	**1 part**
Ajamoda (Ajamoda API)	*Apium leptophyllum*	Fruit	1 part
Saindhava lavana	Halite	Rock salt	1 part
Magadha (Pippali API)	*Piper longum*	Fruit	1 part
Marica API	*Piper nigrum*	Fruit	1 part
Pathya (Haritaki) API	*Terminalia chebula*	Pericarp	5 parts

Table 2: Formulation composition of Sitopaladi Curna

Sitopalā Sugar API	**Sucrose**	**Table sugar**	**192g**
Vamśarocanā API	*Bambusa arundinaceae*	Siliceous Secretion	96g
Māgadha (Pippalī API)	*Piper longum*	Fruit	48g
Elā (Sūkṣmailā API)	*Elettaria cardamomum*	Seed	24g
Tvak API	*Cinnamomum zeylanicum*	Stem Bark	12g

Storage

Six bottles containing 50 g each sample was kept for real time stability study at an interval of 0, 3 and 6 months. The studies were carried out at temperature: 25 °C ± 2, Relative Humidity (RH): 60% ± 5. Changes occur during an interval of 0, 3 and 6 months were studied by HPTLC.

Organoleptic examination, physico-chemical studies *viz.* total ash, water soluble ash, acid insoluble ash, water and alcohol soluble extract, loss on drying at 105°C and pH were carried out as per the standard procedure mentioned in the API[5].

Results and Discussion

Stability testing is necessary to ensure the quality of an herbal product. In the present investigation real time stability was calculated by performing Pharmacopoeial tests of HC and SC during 0 (initial), 3rd and 6th month. Changes observed in organoleptic and physico-chemical characteristics of HC and SC were noted under environmental conditions of Udupi in coastal Karnataka (real time stability). There was no change observed in colour, odour and taste upto six months (Table 3).

Table 3: Organoleptic characters of Hutabhugadi and Sitopaladi

	Hutabhugadi Curna			**Sitopaladi Curna**		
	Initial	3rd Month	6th Month	Initial	3rd Month	6th Month
Colour	Yellowish light brown	-do-	-do-	Beige	-do-	-do-
Odour	Characteristic	-do-	-do-	Aromatic	-do-	-do-
Taste	Salty, astringent and pungent	-do-	-do-	Sweet pungent	-do-	-do-

Loss on drying (LOD - moisture content); total ash (TA - total inorganic content); acid insoluble ash (AIA - acid insoluble part of total ash, mainly silica); water soluble ash (WSA - water soluble part of total ash, inorganic content without water insoluble inorganic salts like silica); water and ethanol soluble extractive (WSE and ESE - percentage active constituents soluble in water and ethanol) and pH (acidity) were the selected Pharmacopoeial constants for the analysis. Variation in LOD and ESE was not linear; it was found to increase from initial to 3rd month decreasing again during 6th month. TA and WSE showed a slight decrease from initial to 6th month in contrast to AIA and pH which tends to increase on storage. The therapeutically beneficial constant ESE has shown considerable reduction in percentage in comparison to and WSE.

Extrapolated results at 10 % degradation and months when 10 % degradation occurs was calculated using the reported formula by calculating the slope and intercept values for the above deviations[6] (Table 4). Every curna in the AFI may not have same shelf life as it will majorly depend on its ingredients; for example the drugs which contain lavana (salts) may have lesser shelf life because of its hygroscopic nature[2]. SC has sarkara (table sugar) as one of the ingredients which will have an effect on stability due to its hygroscopic nature as well as acting like a medium for microbial growth. The expiry dates are explained in detail in Ancient Ayurvedic text books. Taking that into consideration, the Government of India has established the shelf life period of the Ayurvedic medicines. According to that, shelf life of curna is 2 years (once opened, the Curna jar should be finished within 2 to 4 months)[11]. In present investigation, employing the variation inthe Pharmacopoeial constants, HC showed stability upto 11.41 months where as SC was found to be stable up to 22.58 months. As specified in Ayurvedic literature the curnas tested were not stable beyond 2 years. The method adopted is not based on bioavailability of phytochemicals, because there are practical difficulties in tracing active constituents from each ingredient, particularly when there are many ingredients in a formulation.

Methods employed in this report are found to be insensitive as do the HTPLC method. Employing variation in HPTLC fingerprinting during the course storage shown real time shelf life of HC to be 1.27 months[12]. The HPTLC method, being direct tracking of variation in phytochemical fingerprint by TLC pattern, may be more sensitive to detect deterioration in the quality of polyherbal formulations.

Table 4: Stability of Hutabhugadi and Sitopaladi Curna at different intervals and time for 10% degradation

(% w/w)	Hutabhugadi Curna							Sitopaladi Curna						
	Initial	3rd Month	6th Month	Slope	Intercept	At 10 % degradation	10 % degradation (in months)	Initial	3rd Month	6th Month	Slope	Intercept	Results at 10 % degradation	10 % degradation (months)
LOD	8.25	10.12	9.58	0.222	8.652	7.425	5.527	5.21	4.92	4.69	-0.0867	5.2	4.689	5.894
TA	12.88	12.87	12.34	-0.09	12.97	11.592	15.278	22.65	22.79	23	0.0583	22.638	20.385	38.645
AIA	0.25	0.7	1.2	0.158	0.242	0.225	0.108	21.71	21.49	21.47	0.04	21.677	19.539	53.45
WSA	11.39	10.39	9.26	-0.355	11.41	10.251	3.27	1.3	1.45	0.95	-0.0582	1.408	1.17	4.089
ESE	29.94	21.85	22.17	-1.295	0.719	26.946	20.253	3.08	2.87	2.03	-0.175	0.893	2.772	10.74
WSE	42.73	41.53	41.3	-0.238	42.57	38.457	17.273	46.27	51.63	52.23	0.9933	0.825	41.643	41.093
*p*H	3.25	3.93	3.96	0.118	0.782	2.925	18.161	7.22	6.77	6.12	-0.1833	7.2533	6.498	4.12
Average (Months)							11.41	Average (Months)						22.58

LOD – Loss on drying at 105º; TA – Total ash; AIA – Acid insoluble ash; WSA – Water soluble ash; ASE – Alcohol soluble extractive; WSE - Water soluble extractive

Conclusion

Stability study is necessary to each and every new formulation to ensure that the herbal product is safe and effective during its shelf life. Real time stability data of HC and SC showed stability up to 11.41 and 22.58 months respectively. The methodology can be employed as a useful tool for stability check of traditional polyherbal medicines. As phytomedicines are believed to act on synergistic effect of multiple components this method can be used as a rapid test to trace depletion in quality.

Conflicts of interest

Nil

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