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Original Article

ACCELERATED STABILITY STUDY OF CHITRAK HARITAKI AVALEHA

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ABSTRACT

Objective: Accelerated stability study of *Chitrak Haritaki avaleha* was done for six months to know the stability of formulation in reference of its phyto-constituents and microbial growth therein.

Methods: *Chitrak Haritaki avaleha* was made in laboratory following classical method [Sample lab (SL)] as per AFI part-1(The Ayurvedic formulary of India, part-1) and two samples were collected from local market [Market Sample-1(MK-1) & Market sample-2 (MK-2)] of reputed brand. These three samples were put in controlled condition following ICH (International Conference on Harmonization) guidelines for accelerated stability study for six months. The intermediate samplings were done at starting, after one, three and six month respectively. These samples were investigated for reducing sugar, phyto-constituents (Total tannins, piperine, vitamin C and total polyphenols contents), microbial load and their organoleptic characteristics.

Results: All the results were calculated and compared for variation during course of time. Variation in the result of samples was evaluated against Arrhenius equation which ensured that formulation was stable over two years and no significant variation was found over six month of accelerated stability condition.

Conclusion: Since it is traditional *avalehakalpana*, the shelf life period was about one year (Sharangdhar Samhita) and updated to three year in Drug and cosmetic rule 1945, 161B. The presented study reflect that *Chitrak Haritaki avaleha* was stable over two year (by taking inference from Arrhenious equation) and more sophisticated packing may improve the shelf life period.

Keywords: *Avaleha*, Shelf life, Accelerated stability, *Chitrak Haritaki avaleha.*

INTRODUCTION

Ayurveda, the world's most ancient yet unique futuristic system of medicine used for healing and maintaining the good health of mankind's. Several ayurvedic formulations are described in ayurvedic text viz. *avaleha* (Semi solid dosage form in Ayurveda), *asava-arista* (alcoholic preparation), *churna* (powder), *ghrita* (Medicated ghee), *taila* (Medicated oil), *vati*(tablet) etc. Among them, *avaleha* is the most potent formulation and widely used in the form of food supplement as well as for great medicinal values. *Chitrak Haritaki avaleha* is one of the most common *avaleha* preparation mentioned in AFI-I, indicated for *gulma* (Abdominal lump), *pratishyaya* (chronic rhinitis), *kasa* (cough), *swasa* (Respiratory problems), *agnimadhya* (digestive weakness) and *krimi* (helminthiasis) [1]. Major ingredients of *Chitrak Haritaki avaleha* are Chitrak (*Plumbago zeylanica* Linn.), Haritaki (*Terminalia chebula* Retz.), Amalaki (*Emblica officinalis* Gaertn.) and Guduchi (*Tinospora cordifolia* (Willd.) Miers ex Hook. f. & Thoms.), while minor ingredients are Twak (*Cinnamomum tamala* Nees & Eberm.), Ela (*Elettaria cardamomum Maton.),*Trikatu (mixture containing equal amount of rhizome of *Zingiberofficinale,* fruit of *Piper longum* and *Piper nigrum*) etc.(table 1) [2].

Table 1: Ingredients of Chitrak Haritaki avaleha

Ingredient	Botanical name	Part used	Quantity
Chitrak	*Plumbago zeylanica* Linn.	Root bark	2.5 kg
Amalaki	*Emblica officinalis* Gaertn.	Fruit	2.5 kg
Guduchi	*Tinosporacordifolia* (Willd.) Miers ex Hook. f. &Thoms.	Stem	2.5 kg
Haritaki	*Terminaliachebula* Retz.	Fruit	3.20 kg
Dashamoola		Root bark	2.5 kg
Bilva	Aegle marmelos Correa		
Agnimantha	Premna integrifolia Linn.		
Shyonaka	Oroxylumindicum Vent.		
Patala	Stereospermum suaveolens DC.		
Gambhari	Gmelinaarborea Roxb.		
Brihati	Solanumindicum Linn.		
Kantakari	Solanum xanthocarpum Linn.		
Shalaparni	Desmodium gangeticum DC.		
Prushniparni	Urariapicta Desv.		
Goksharu	Tribulusterrestris Linn.		
Tvak	*Cinnamomum zeylanicum* Blume.	Stem Bark	75 g
Ela	*Elettaria cardamomum Maton.*	Fruit	75 g
Patra	*Cinnamomum tamala* Nees & Eberm.	Leaf	75 g
Yavakshara	Potassium carbonate	Kshara	25 g
Trikatu	(Mixture containing equal amount of rhizome of *Zingiber officinale* Roscoe, fruit of *Piper longum* Linn. and *Piper nigrum* Linn.)	-	75 g
Madhu	Honey	-	200 g
Sharkara	Sugar	-	5 Kg

Shelf life of *avaleha* formulation was described as one year while it was updated in 20th century as three year of shelf life [3, 4]. Shelf life is main concern in the formulation as to fulfil the demand of population and continuous supply in the market over a definite period of time as well as to make cost effective product. In the era of globalization and increase global demand for *Ayurvedic*, herbal and herbo-mineral medicines, it is essential to ensure the quality and consistency of drugs to achieve their safety and maximal efficacy at the same time. In *Ayurveda*, whole medicinal action is due to synergistic effect of each agent in spite of single constituents [5]. Now day's analytical techniques like thin layer chromatography (TLC), high performance liquid chromatography (HPLC), high performance thin layer chromatography (HPTLC), X-rays diffraction (XRD), atomic absorption spectroscopy (AAS), infrared spectroscopy (IR), nuclear magnetic spectroscopy (NMR), UV-visible spectroscopy are available for more recent and advanced analysis. Accelerated stability study of the product was conducted to ensure shelf life and product stability of the product as per ICH guidelines measuring the above mentioned parameters. Time is now demanding the revalidation of the ayurvedic products on the edge of contemporary science to create more faith in ayurvedic medicines without compromising fundamentals of ayurvedic science. Since it is poly herbal formulation, so evaluating each phytoconstituents is not an easy task but at the same time it is mere necessary to estimate the major categories of phytoconstituents viz. total polyphenol, total tannins, piperine content, vitamin C content etc that may help in drawing the pharmacokinetics and pharmacodynamics of the formulation in compliance of contemporary science. So in presented work author had evaluated the variation in categories of phytoconstituents that was present in formulation over six month of accelerated stability condition along with the variation in the organoleptic characteristic and the microbial growth therein.

MATERIALS AND METHODS

Chitrak Haritaki avaleha was prepared in Ayurvedic Pharmaceutical Science laboratory, Banaras Hindu University as per the classical method by using authentic ingredients and symbolized as SL (Sample of Lab) [6]. Ingredients were procured from the local market in Varanasi and authenticated by Prof. A. K. Singh, Department of Dravyaguna, Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, and Varanasi. Two marketed samples [Market Sample-1(MK-1) & Market sample-2 (MK-2)] of reputed brands were purchased from local medicine market in Varanasi.

All the three samples was packed well and put in the accelerated stability condition (40 °C±2 °C &75% RH±5% RH) for six months [7]. Sample was then collected at time interval of three month i.e. at 0 mo, one month, 3 mo and 6 mo respectively. The samples were evaluated for their phytoconstituents, microbial content and organoleptic characteristic.

Sample was evaluated for Total polyphenol content[8], total tannin content [9], vitamin C content [10], piperine content [11] and reducing content in order to see the variation over six month. The microbial load was estimated for total bacterial count, fungal count and E. coli etc [12] and organoleptic properties were evaluated by sensory organ by authors.

RESULTS AND DISCUSSION

Chitrak Haritaki avaleha was evaluated for organoleptic characteristic (table 2), phyto-constituents, reducing sugar and microbial load (table 3) in the formulation during the accelerated stability study and the results (fig 1, 2, 3) were compared.

Accelerated stability study was done for *avaleha* over 6 mo of time and frequency of test is 0 mo, 1 mo, 3 mo and 6 mo as per ICH guideline. The laboratory sample of *Chitrak Haritaki avaleha* (SL) was dark brown colored, pleasant spicy odor, astringent and bitter in taste and thick semi solid mass. Dark brown color of the formulation was due to the pigments and color of ingredient drugs. Astringent taste in the formulation was due to the *Katu and Kashaya rasa* of the ingredients. Organoleptic properties did not show significant variation over time and it reflects that the physical properties of the sample were stable. Stability study was done to see change in phyto-chemical profile over a time period. There was no much variation found in reducing sugar content during 6 mo of storage at specific condition. Variation in tannin content was found little when stored on stability condition. Variation in vitamin C content was found little and insignificant when stored on stability condition and it reflects that product was stable over stability condition and performs normally. Gallic acid (high molecular weight phenols) and tannin play a protective role over degradation of vitamin C [13]. Variation in Piperine content and polyphenol content found little when stored over stability study condition of six month, piperine is the important constituent in the formulation that show their pharmacodynamics in *kasa* and *swasa* (respiratory disorder) disease [14]. Microbial content (Table-3) of the formulation is increasing over time but restrict within limit [15]. It also reflects that product packing was done in recommended way and it prevents contamination and thus product was stable over stability condition and performs normally. At last the accelerated stability condition was recalculated as normal condition by using Arrhenius equation through rate of reaction. When there is variation in temperature and humidity, the rate of reaction also altered and became faster in accelerated stability condition than real time. So after drawing reference, it was concluded that product that was stable for six months in accelerated stability condition (ICH/WHO), will be stable for two years (four times than accelerated condition as rate of reaction was four times in accelerated condition) [16]. After all the testing and evaluation *Chitrak Haritaki avaleha* was found to be stable (fig 1, 2, 3) for two years in presented study and this data will help in presenting the variation in quantitative data of phyto constituents during storage.

Table 2: Organoleptic characteristic over six months of accelerated stability condition

Organoleptic characters	Laboratory sample (SL)	Market sample-1 (MK-1)	Market sample-2 (MK-2)	At 0, 1, 3 and 6 mo [SL, MK-1 & MK-2]
Colour	Blackish Brown	Blackish Brown	Brown	No remarkable variation
Odour	Spicy, Pleasant odour	Spicy, Pleasant odour	Spicy, Pleasant odour	No remarkable variation
Taste	Bitter-astringent	Bitter-astringent	Bitter-astringent	No remarkable variation
Appearance	Thick Semi Solid Mass	Semi Solid	Semi Solid Mass with lesser consistency	No remarkable variation
Touch	Soft and viscous	Soft and viscous	Soft and viscous	No remarkable variation

Table 3: Microbial load over six months of accelerated stability condition

Sample	Period (Month)	Total bacterial count	Total fungal count	E. *coli*	*Salmonella* sp.	P. *aureus*
SL	0	10 CFU	61 CFU	Absent	Absent	Absent
	3	82 CFU	79 CFU	Absent	Absent	Absent
	6	136 CFU	118 CFU	Absent	Absent	Absent
MK-1	0	103 CFU	201 CFU	Absent	Absent	Absent
	3	156 CFU	306 CFU	Absent	Absent	Absent
	6	209 CFU	503 CFU	Absent	Absent	Absent
MK-2	0	188 CFU	655 CFU	Absent	Absent	Absent
	3	356 CFU	1022 CFU	Absent	Absent	Absent
	6	402 CFU	1652 CFU	Absent	Absent	Absent

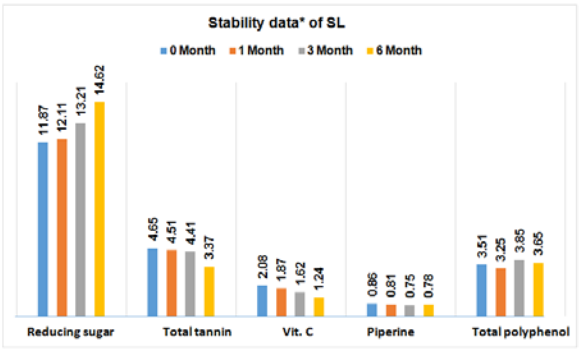

Fig. 1: Variation in SL over six months of accelerated stability condition, *mean of three reading (n=3)

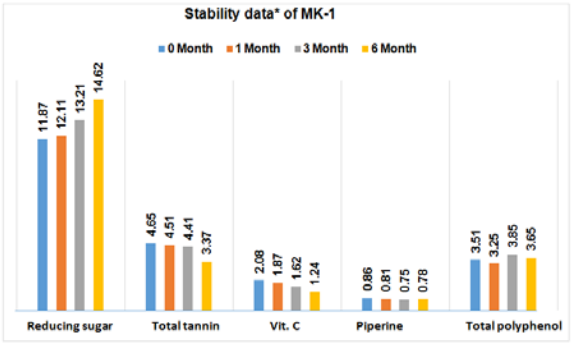

Fig. 2: Variation in MK-1 over six months of accelerated stability condition, *mean of three reading (n=3)

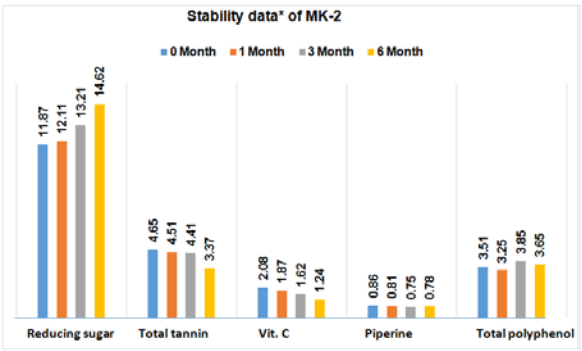

Fig. 3: Variation in MK-2 over six months of Accelerated stability condition, *mean of three reading (n=3)

CONCLUSION

Chitrak Haritaki avaleha is poly herbal *Ayurvedic* formulation under *avalehakalpana* meant for many respiratory disease, antioxidant activity etc. Saviryataavadhi (Shelf life period) was given six months in Sharangdhar Samhita while three years in The Drugs and Cosmetic Rule 1940. Stability period is directly related with packaging science.

ICH and WHO make guideline to know the period during which formulation give maximum potency i.e. shelf life. The laboratory sample and two marketed samples were put under accelerated stability condition for six month and the intermediate sampling was done at staring and after 1 mo, three month and six month of storage. Evaluation of phyto-constituents and microbial growth in these samples along with their organoleptic characteristic ensure the product stability for a period of two years in the light of Arrhenius equation as no significance variation was found.

CONFLICT OF INTERESTS

Declared none

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