Research Article

www.ijrap.net

STANDARDIZATION OF *HARIDRADI VATI* OF AYURVEDIC FORMULARY OF INDIA (AFI)

Arun K [1]*, Tapas BT [2], Shivakumar [3], Sunil Kumar KN [4], Arun Raj GR [5]

[1]Research Scholar, Department of Swasthavritta, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

[2]Professor, Department of Swasthavritta, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

[3]Professor and Head, Department of Swasthavritta, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

[4]Senior Research Officer, SDM Centre for Research in Ayurveda and Allied Sciences, Lakshmi Narayana Nagar, Kuthpady, Udupi, India

[5]Assistant Professor, Department of Kaumarabhritya (Ayurveda Pediatrics), SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

Received on: 15/06/15 Revised on: 27/07/15 Accepted on: 02/08/15

***Corresponding author**

Dr. Arun K, Research Scholar, Department of Swasthavritta, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

E-mail: arun041984@gmail.com

DOI: 10.7897/2277-4343.066128

ABSTRACT

Standardization of Ayurvedic formulations is an important step for establishment of biological activity, consistent chemical profile, or quality assurance for production and manufacturing of herbal drugs. Most of the pharmaceutical industries are using substitute drugs instead of authentic drugs. Haridradi vati is an Ayurvedic polyherbal preparation comprising of Haridra (*Curcuma longa* L.), Daruharidra (*Berberis aristata* D.C.), Yastimadhu (*Glycyrrhiza glabra* L.), Prisniparni (*Uraria picta* Desv.) and Kutaja (*Holarrhena antidysenterica* (L.) Wall.). Haridradi vati help to reduce Kapha, which is the basis of fat accumulation, and it improves fat metabolism, hindering further fat deposition. These medicinal herbs can correct Kapha imbalance and help in weight loss. Keeping above facts in mind it is aimed to standardize Haridradi vati (HV), employing standard testing protocol for AYUSH drugs. Physico-chemical studies like pH, diameter, and variation in weight, hardness test, disintegration time and HPTLC were performed as per standard methodology. Quality indicating physical and chemical tests were done and standard values for HV were recorded. Standardization tests done on HV helped in authenticating the polyherbal preparation and also in ensuring the quality of the same.

Keywords: Ayurvedic Formulary of India (AFI), Daruharidra, Haridradi vati, Kutaja, Prisniparni, Yastimadhu, Quality control

INTRODUCTION

World Health Organization (WHO) encourages, recommends and promotes herbal remedies in natural health care.[1] The specific guidelines put forth by WHO serves as a prerequisite for global harmonization by assessing the safety, efficacy and quality of herbal medicines. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicine.[2] Standardization of Ayurvedic formulations is very important for assuring the quality of herbal drugs. According to an estimate of WHO an approximately 85 to 90% of the world's population consumes herbal medicines. The reason for this seems to be their negligible adverse drug reactions and better tolerance. WHO has also evolved guidelines for the validation of plant based drugs for developing countries like India.[3] It is also the need of the hour to develop economic, easily available as well as efficacious medicine.

Haridradi vati (HV) is an Ayurvedic polyherbal preparation comprising of Haridra (*Curcuma longa* L.), Daruharidra (*Berberis aristata* D.C.), Yastimadhu (*Glycyrrhiza glabra* L.), Prisniparni (*Uraria picta* Desv.), and Kutaja (*Holarrhena antidysenterica* (L.) Wall.).[4] The drugs like Haridra, Daru-haridra, Prisniparni, Kutaja (Indrayava) and Madhuyasti present in the vati has kapha-medhohara properties along with Lekhaniya and dipaneeya action. They work by the principle of Guru Cha Atarpana (heavy and non-nourishing diet) which regulates the hunger and satiety centre there by regulates the energy intake of a person. This aids in the proper utilization of stored fat to fulfill the energy needs. As it is in vati form its intake is very easy and does not create any difficulty for the subjects for its consumption. Keeping the current trend in mind, HV was subjected for standardization to ensure quality and also to authenticate the preparation.

MATERIALS AND METHODS

Physico-chemical studies like determination of pH, diameter, variation in weight, hardness test, disintegration time and HPTLC were carried out as per the WHO guidelines,[5] Ayurvedic Pharmacopoeia[6] and Indian Pharmacopoeia.[7] The studies were done at SDM Centre for Research in Ayurveda and Allied Sciences, Kuthpady, Udupi, Karnataka state, India as per standard procedure (Sample code: 14092001).

Plant material

The ingredients of HV were collected from the local market of Ernakulam district, Kerala state, India. The collected drugs were identified and authenticated at the teaching pharmacy of Department of Dravyaguna, SDM College of Ayurveda and Hospital, Hassan, Karnataka state, India.

High Performance Thin Layer Chromatography: One gram of powder of HV were soaked in 10 ml ethanol for 24 h and filtered. Four, 8 and 12 µl of the above samples of

were applied on a pre-coated silica gel F_{254} on aluminum plates to a band width of 7 mm using CAMAG Linomat 5 TLC applicator. The plate was developed in toluene: ethyl acetate (8.0:2.0). The developed plates were visualized in 254 and 366 nm, and then derivatised with vanillin sulphuric acid reagent after scanning the plates under 254 and 366 nm in CAMAG HPTLC Scanner 4. R_f, colour of the spots and densitometric scan were recorded[8].

RESULTS AND DISCUSSION

Standardization tests performed for HV were as per AYUSH testing protocol for Vati (Table 1, Figure 1). HV is found to be yellow in color with characteristic odour and bitter taste. pH of HV was found to be 4.07, that is in the acidic range. Most drugs are either weak acids or weak bases. Weak electrolytes, in addition to lipid solubility, depend upon its degree of ionization which is influenced by pH of the area. Weak acids become less ionized (charged) in an acidic medium and weak bases become less ionized in an alkaline medium. Basic drug will absorb more from intestine because it becomes unionized in basic medium. In acidic medium basic drug will become more ionized and thus no absorption will takes place. As HV is lightly acidic it will be absorbed properly. Variation in the weight was found to be within normal limit, as the tablets were prepared using punching machine no variation in weight were observed. Tablet weight is mainly affected by factors such as tooling of the compression machine, head pressure, machine speed and flow properties of the powder. Inconsistent powder or granulate density and particle size distribution are common sources of weight variation during compression. Variation between tablet with respect to dose and weight must be reduced to a minimum. Uniformity of weight is an in process test parameter which ensures consistency of dosage units during compression. The tablet is found to be hard until 1 kg/cm^2 which is also well within the normal limit. The testing of a tablets hardness (or more correctly breaking force) plays a vital role in both product development and subsequent quality control. High hardness values may indicate increased disintegration times and reduced dissolution values. On the other hand, if hardness is too low then friability and hence % defective may well be too high. By exploiting the correlation between hardness, disintegration, dissolution, friability, percentage defective and weight variation, the various parameters can be manipulated to produce a dosage form with optimum characteristics. The tablet disintegrated within 45 sec which is also a good property of a tablet for easy dissemination of active constituents. An orally administered drug must disintegrate to attain good absorption of its active substance. The first step toward dissolution is usually the break-up of the tablet**;** a process described as disintegration. The disintegration test results in a time necessary to disintegrate a group of tablets into small particles under standard conditions. The disintegration test is a valuable tool in quality control environments. The test is used for batch release and trending of lot-to-lot variations during manufacturing of tablets. However, it is not a bioavailability indicator. Diameter of the tablet was found to be uniformly 1.3 cm. The uniformity of diameter and weight may increase the patient compliance due to their uniform size of appearance. The uniformity of active ingredient and content will make sure the dosage supplied to the patients is correct and preventing from overdose cases and so on. Photo documentation of ethanolic extract of HV showed 8, 9 and 11 spots under 254, 366 and white light (after derivatisation) respectively (Table 2, Figure 2). Densitometric scan at 254 nm revealed 8 peaks corresponding to 8 different compounds in the ethanol extract, compounds with R_f 0.03 (48.00%), 0.23 (11.04% - probably Curcumin) and 0.31 (32.70%) were the major peaks (Figure 3). At 366 nm there were 6 peaks, one with R_f 0.03 (25.82%), 0.25 (31.43%) and 0.31 (28.98%) being the major peaks detected (Figure 4). HPTLC is an important tool in standardisation and quality control of polyherbal formulations. As there are more than one ingredient qualitative HPTLC fingerprinting can be used for development of quality standards for polyherbal formulations[9,10].

These physico-chemical constants like pH, diameter, variation in weight, hardness, disintegration time, results of TLC photo documentation, the unique R_f values and densitogram obtained at different wavelengths can be used as fingerprint to check quality of Haridradi vati.

Table 1: Results of standardization tests for Haridradi vati

Parameters	Results n=3 %w/w
Color	Yellow
Odour	Characteristic
Taste	Bitter
pH	4.07
Variation in weight (%)	Within normal limit
Hardness test (kg/cm)	1
Disintegration time (min)	45 sec
Diameter (cm)	1.3 cm

Table 2: R_f values of all the samples

At 254 nm	At 366 nm	Post derivatisation
-	0.07 (FL. green)	0.07 (L. purple)
0.12 (L. green)	0.12 (FL. blue)	-
0.19 (L. green)	-	0.19 (L. yellow)
-	-	0.22 (L. pink)
-	0.25 (FL. yellow)	0.25 (D. pink)
0.26 (D. green)	-	0.26 (D. yellow)
-	-	0.29 (L. purple)
0.36 (L. green)	0.36 (FL. yellow)	-
0.40 (L. green)	-	-
-	0.42 (FL. blue)	-
-	0.50 (FL. blue)	0.50 (D. purple)
0.56 (L. green)	0.56 (FL. blue)	0.56 (L. purple)
0.62 (L. green)	-	-
-	0.66 (FD. blue)	0.66 (D. purple)
0.71 (L. green)	-	-
-	-	0.74 (L. purple)
-	0.90 (FD. blue)	0.90 (L. purple)

Figure 1: Haridradi Vati

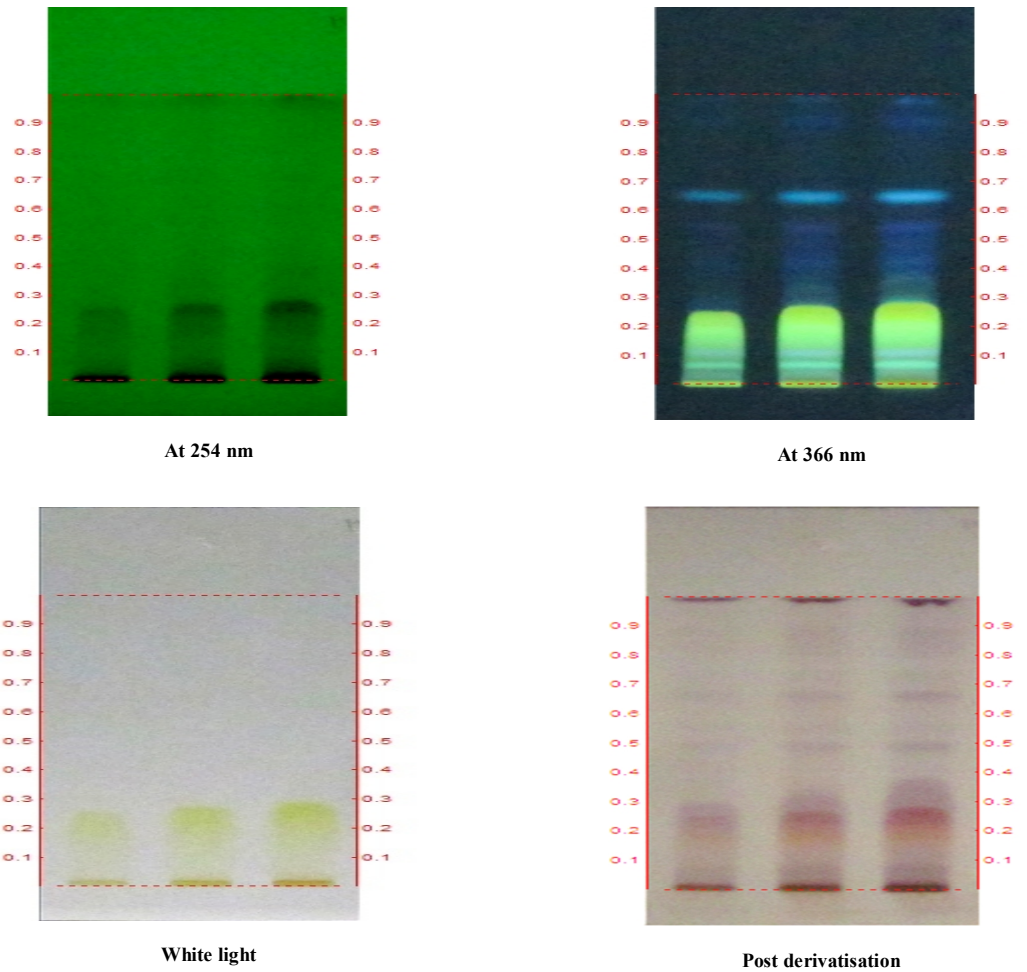
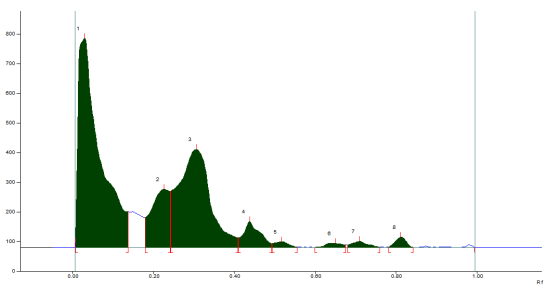
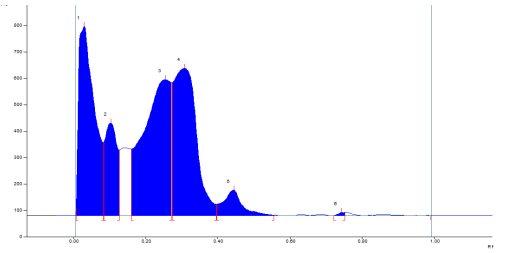


Figure 2: HPTLC photo documentation of Alcohol extract of Haridradi vati
Track 1-Haridradu vati– 4µl, Track 2- Haridradu vati – 8µl, Track 3- Haridradi vati – 12µl
Solvent system: Toluene: Ethyl acetate (8.0:2.0)



Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01 Rf	31.7 AU	0.03 Rf	704.3 AU	50.05 %	0.14 Rf	20.1 AU	27342.2 AU	48.00 %
2	0.18 Rf	101.7 AU	0.23 Rf	196.5 AU	13.96 %	0.24 Rf	89.4 AU	6290.0 AU	11.04 %
3	0.24 Rf	189.7 AU	0.31 Rf	330.1 AU	23.46 %	0.41 Rf	32.7 AU	18628.3 AU	32.70 %
4	0.41 Rf	32.7 AU	0.44 Rf	87.0 AU	6.18 %	0.49 Rf	13.1 AU	2541.7 AU	4.46 %
5	0.50 Rf	13.2 AU	0.52 Rf	19.1 AU	1.36 %	0.56 Rf	0.9 AU	480.9 AU	0.84 %
6	0.60 Rf	0.1 AU	0.65 Rf	14.0 AU	0.99 %	0.68 Rf	9.0 AU	421.5 AU	0.74 %
7	0.68 Rf	8.0 AU	0.71 Rf	20.7 AU	1.47 %	0.76 Rf	0.8 AU	578.5 AU	1.02 %
8	0.78 Rf	1.8 AU	0.81 Rf	35.5 AU	2.52 %	0.84 Rf	0.3 AU	680.1 AU	1.19 %

Figure 3: Densitometric scan at 254 nm



Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01 Rf	29.6 AU	0.03 Rf	715.1 AU	31.86 %	0.08 Rf	76.1 AU	22770.5 AU	25.82 %
2	0.09 Rf	278.5 AU	0.10 Rf	349.7 AU	15.58 %	0.13 Rf	48.3 AU	8334.3 AU	9.45 %
3	0.16 Rf	251.5 AU	0.25 Rf	514.0 AU	22.90 %	0.27 Rf	02.7 AU	27718.7 AU	31.43 %
4	0.27 Rf	503.1 AU	0.31 Rf	556.3 AU	24.78 %	0.40 Rf	42.9 AU	25559.3 AU	28.98 %
5	0.40 Rf	43.4 AU	0.45 Rf	96.7 AU	4.31 %	0.56 Rf	2.1 AU	3652.1 AU	4.14 %
6	0.72 Rf	0.6 AU	0.74 Rf	13.0 AU	0.58 %	0.75 Rf	11.8 AU	152.2 AU	0.17 %

Figure 4: Densitometric scan at 366 nm

CONCLUSION

The purpose of standardization of medicinal plants is to ensure therapeutic efficacy since the active constituents may vary according to geographical source of the drug. Thus it may not be easy to standardize drug chemically and hence maintaining the quality of these plant products is an essential factor. The constituents of Haridradi vati such as Haridra (*Curcuma longa* L.), Daruharidra (*Berberis aristata* D.C.), Yastimadhu (*Glycyrrhiza glabra* L.), Prisniparni (*Uraria picta* Desv.) and Kutaja (*Holarrhena antidysenterica* (L.) Wall.) are endowed with various biological properties and hence the polyherbal preparation HV prepared from these ingredients will have combined goodness of all the individual herbs. The quality indicating tests for HV reported from this study can be used as routine quality check parameter for this polyherbal preparation.

ACKNOWLEDGEMENT

Authors are highly grateful to the constant support of Dr. Girish K J, Research Coordinator, SDM College of Ayurveda and Hospital, Hassan. The Authors thank Dr. B. Ravishankar, Director, SDM Centre for Research in Ayurveda and Allied Sciences for providing the facilities for their guidance. The authors also like to thank the department of Swasthavritta, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India.

REFERENCES

1. Arun Rasheed, Sravya RB, Roja C. A review on standardisation of herbal formulation. Inter. J. of Phytotherapy, 2012; 2(2): 74-88.
2. Satheesh Madhavi NN, Kumud Upadhya, Asha Bishti. Phytochemical screening and standardization of poly herbal formulation for Dyslipidemia. Indian Journal of Physiology and Pharmacology, 2011; 3(3): 235-8.
3. N Kimmatkar, V Thawani, L Hingorani, R Khiyani. Efficacy and tolerability of *Boswellia serrata* extract in treatment of osteoarthritis of knee--a randomized double blind placebo controlled trial. Phytomed. 2003; 10: 3-7. http://dx.doi.org/10.1078/094471103321648593
4. Sreekumar T. Aashtanga Hridaya, vol.1. 3rd ed. Kerala; Publication Department Harishree Hospital; 2011 p-365.
5. WHO. Quality Control Methods for Medicinal Plant Materials. Geneva: AITBS Publishers and Distributors, Delhi; 2002, 65-67.
6. The Ayurvedic Pharmacopeia of India, Govt. of India, Min. of Health and Family Welfare, Department of Ayurveda, Yoga and Homoeopathy (AYUSH), New Delhi, 2001; Part-1; Vol.1-5; 1 edition.
7. Indian Pharmacopoeia, (Ministry of Health and Family Welfare, Government of India, New Delhi); 2010; Vol I:10-146.
8. Sethi PD. High Performance Thin Layer Chromatography. CBS Publishers and Distributors, New Delhi; 1996.
9. Kulkarni Reena, Abhimanyu Kumar, KN Sunil Kumar. Formulation and standardisation of Medhya Rasayana – A novel Ayurvedic compound nootropic drug. Pharmacognosy Journal, 2013: 5; 72-6. http://dx.doi.org/10.1016/j.phcgj.2013.03.004
10. Pushpendra, Koppala Narayana Sunil Kumar, Priyadarshini, Bantwal Shivarama Holla, Basaviah Ravishankar, Betkeri Yashovarma. Quality standards for Hutabhugadi curṇa (Ayurvedic Formulary of India). Journal of Traditional and Complementary Medicine, In press since January 2015 http://dx.doi.org/10.1016/j.jtcme.2014.11.019

Cite this article as:

Arun K, Tapas BT, Shivakumar, Sunil Kumar KN, Arun Raj GR. Standardization of haridradi vati of Ayurvedic formulary of India (AFI). Int. J. Res. Ayurveda Pharm. 2015;6(6):688-691 http://dx.doi.org/10.7897/2277-4343.066128

Source of support: Nil, Conflict of interest: None Declared