



**PHARMACOGONSTICAL AND PHARMACEUTICAL ASSAY OF *HARIDRADI VATI* A
FORMULATION FOR PREDIABETES**

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ABSTRACT

Introduction: 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. Haridradi Vati is an Ayurvedic polyherbal preparation comprising of Haridra (*Curcuma longa* L.), Daruharidra (*Berberis aristata* D.C.), Kutaja (*Holarrhena antidysenterica* (L.) Wall.), Vacha (*Acorus calamus* Linn.), Musta (*Cyperus rotundus* Linn), Devadaru (*Cedrus deodara* Roxb), Shunthi (*Zingiber officinale* Rosc) and Haritaki (*Terminalia chebula* Retz.). The early stage of type-2 diabetes is known as prediabetes. Prameha Purvarupavastha can be correlated with earlier stage of diabetes i.e. prediabetes.^[1] Haridradi vati may help to reverse prameha purvarupavastha (prediabetes). In the present study, an attempt has been made to develop pharmacognostical and pharmaceutical standards for Haridradi vati. **Aims:** To evaluate pharmacognostical and physico-chemical characters of Haridradi vati **Materials and Methods:** The ingredients of Haridradi Vati were collected from the Pharmacy of Gujarat Ayurved University (GAU) Jamnagar district, Gujarat and pharmacognostical analysis of Haridradi Vati like organoleptic characteristics and micro pictographs were done. Pharmaceutical analysis of the drug included parameters like water and alcohol soluble extract, pH, total ash and loss on drying along with HPTLC **Results:** The pharmacognostical analysis of Haridradi Vati showed the presence of sclerides of Daruharidra, starch grain of Musta, fibers of Shunthi, starch grain of Kutaj, pitted stone of Haritaki, oleoresin of Haridra, oil globulin of Vacha. Physicochemical analysis of Haridradi Vati revealed weight variation of 28%, hardness 1.6 kg/cm², disintegration time > 1 hr. etc., In HPTLC Haridradi Vati revealed 5 spots at 254 nm and 4 spots 366 nm. **Discussion:** Pharmacognostical study helps in exact authentication of ingredients present in formulation through its organoleptic characters like taste, odor, color and touch along with microscopical characters and physico-chemical parameters. The presence of all contents of raw drugs in the final product shows the genuinity of the final product. All the pharmaceutical parameters analyzed showed values permissible for the Vati. **Conclusion:** As there are no reported study on the Haridradi Vati, the findings of the study will be useful in the standardization of the drug and study might help as reference guidance for future scientific evaluations of the drug.

KEY WORDS: *Haridradi Vati*, pharmacognosy, physicochemical analysis, prediabetes.

INTRODUCTION

The early stage of type-2 diabetes is known as prediabetes. It is the state in which blood glucose levels are higher than normal but not high enough to be called diabetes. Prediabetes has been shown to have harmful effects on the body in long run. Prediabetic state is

associated with a predisposition to abdominal obesity, insulin resistance, lipid disorder, high blood pressure i.e. the metabolic or insulin resistance syndrome. It raises short term absolute risk of type 2 diabetes five to six folds.^[2]

Presently over 387 million people have diabetes worldwide, with type 2 diabetes making up about 90% of the cases.^[3] From 2012 – 2014, diabetes is estimated to have resulted in 1.5 to 4.9 million deaths each year. The number of people with diabetes is expected to rise to 642 million by 2035. Global economic cost of diabetes in 2015 was estimated to be \$673 billion USD. Global prevalence impaired glucose tolerance in 2015 is 6.7% and number of people with impaired glucose tolerance is 318 million. There are estimated 77.2 million people in India who are suffering from prediabetes.

Considering this *Haridradi Vati* comprising of *Haridra* (*Curcuma longa* L.), *Daruharidra* (*Berberis aristata* D.C.), *Kutaja* (*Holarrhena antidysenterica* (L.) Wall.), *Vacha* (*Acorus calamus* Linn.), *Musta* (*Cyperus rotundus* Linn.), *Devdaru* (*Cedrus deodara* Roxb), *Shunthi* (*Zingiber officinale* Rosc) and *Haritaki* (*Terminalia chebula* Retz.) was formulated which belongs to either *Haridradi Gana* and *Vachadi Gana*.^[4] The state of prediabetes is similar to the early stage of *prameha* which is caused by *Santarpana Karaka Hetu* and has mainly involvement of vitiated *Kapha*, *Meda*, and *Kleda* along with disturbed *Agni*. Hence drugs which have *Tikta*, *Katu Rasa*, *Ushna Virya*, *Laghu*, *Ruksha Guna* and *Kapha Medohara* action can reverse the pathogenesis of *Apathyanimitaja Prameha*. Drug mention in *Haridradi Gana* and *Vachadi Gana* have *Tikta*, *Katu Rasa*, *Ushna Virya*, *Laghu*, *Ruksha Guna* and *Kapha Medohara* properties.^[5,6,7,8,9,10,11,12] As it is in *Vati* form its intake is easy and does not create any difficulty for the patient for its consumption. Keeping the current trend in mind, *Haridradi Vati* was subjected for standardization to ensure quality and also to authenticate the preparation. Pharmacognostical analysis of *Haridradi Vati* like organoleptic characteristics and micro pictographs were done. Pharmaceutical analysis of the drug included parameters like water and alcohol soluble extract, pH, total ash and loss on drying along with HPTLC.

MATERIALS AND METHODS

Collection of raw drugs

The ingredients of *Haridradi Vati* were collected from the Pharmacy of Gujarat Ayurved University (GAU) Jamnagar district, Gujarat and were authenticated at Pharmacognosy Laboratory of I.P.G.T & R.A, Jamnagar.

Method of preparation

Haridradi Vati was prepared in the Pharmacy of GAU as per classical text reference Fine powders of *Haridra*, *Daruharidra*, *Kutaja*, *Vacha*, *Musta*, *Devadaru* *Shunthi* and *Haritaki* was taken in same proportion. Out of total amount of drugs 10% of the crude drugs was used for the preparation of decoction. This decoction was added into the mixture of above drugs and then *vati* of with 500 mg each was prepared with the help of tablet preparing machine.

Pharmacognostical study

Pharmacognostical analysis of *Haridradi Vati* powder was based on organoleptic characters and microscopic studies. For this *Haridradi Vati* powder was dissolved in small quantity of distilled water, filtering through filter paper and the precipitate treated with or without stain to find out the characters and was later compared with the findings of individual ingredients of the *Haridradi Vati* powder. The micro photographs taken under Carl Zeiss Trinocular microscope attached with Camera.^[13]

Pharmaceutical study

Haridradi Vati powder was analyzed with appropriate protocols for standard physico-chemical parameters, such as aqueous soluble extract, alcohol soluble extract, pH, uniformity of weight, total ash, loss on drying as per CCRAS recommendations^[14] at the Pharmaceutical Chemistry Laboratory, IPGT & RA

HPTLC: Methanol extract of *Haridradi Vati* powder was spotted on pre coated silica gel GF 60₂₅₄ aluminum plates by means of Camang Linomate V sample applicator fitted with a 100 µL Hamilton syringe. The mobile phase consisted of Chloroform: Me OH in a ratio of 9:1 v/v. After development densitometry scan was performed with a Camag T. L. C. scanner III in reflectance absorbance mode at 254nm and 366nm under control of Win CATS Software (V 1.2.1. Camag). Then the plate was sprayed with vanillin sulphuric acid followed by heating and then visualized in day light.^[15]

Organoleptic evaluation: Organoleptic features like color, odour, taste and consistency of the *Haridradi Vati* were recorded and are placed in **Table no 1**.

Table 1: Organoleptic characters of *Haridradi Vati*.

Parameter	Result
Colour	Blackish Brown
Odour	Slightly light Aromatic
Taste	Astringent Bitter

Microscopic evaluation: Microscopic evaluation was conducted by dissolving powders of *Haridradi Vati* in the distilled water, then stained and studied under microscope for the presence of characteristics of ingredient drugs Powder microscopy of *Haridradi Vati* showed striking characters of all 8 individual constituents such as sclerides of *Daruharidra*, starch grain of *Musta*, silica deposition of *Musta*, fibers of *Shunthi*, stone cell of *Daruharidra*, starch grain of *Kutaj*, group of sclerides of *Daruharidra*, starch grain of *Shunthi*, pitted stone of *Haritaki*, rhomboidal crystal of *Kutaja*, fibers of *Daruharidra*, oleoresin of *Haridra*, oil globulin of *Vacha*, annular vessel of *Vacha*, stone cell of *Haritaki*, prismatic crystal of *Kutaja*, starch grain of *Haritaki*, pitted Stone cell of *Devadaru*, fragment of border pitted vessel of *Devadaru*, epicarp cell of *Haritaki*, cork cell of *Shunthi*, lignified stone cell of *Devadaru*, lignified fibers of *Devadaru* (Plate no 1Fig 1-23).

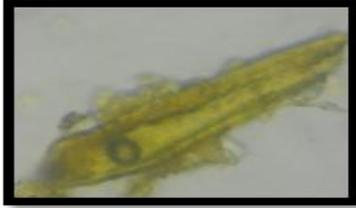
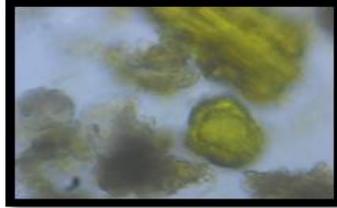
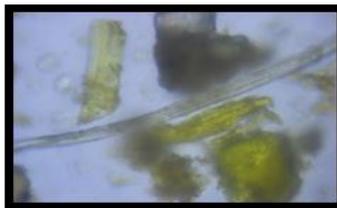
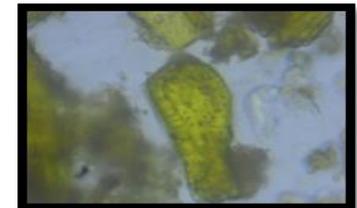
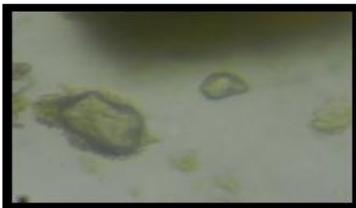
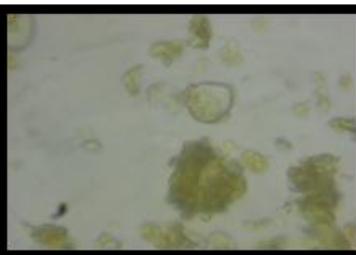
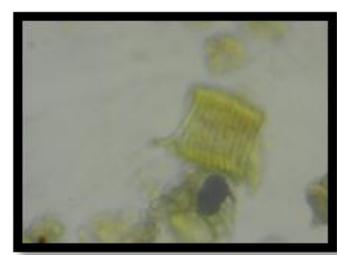
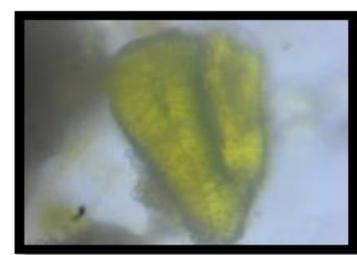
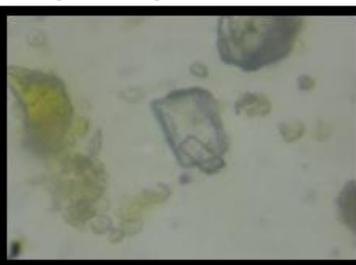
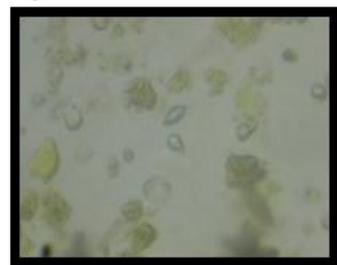
Plate 1. Photomicrographs of *Haridadi Vati* (Figure 1-23)Fig-1 Sclerides of *Daruharidra*Fig-2 Starch grain of *Musta*Fig-3 Silica deposition of *Musta*Fig-4. Fibers of *Shunthi*Fig-5 Stone cell of *Daruharidra*Fig-6 Starch grain of *Kutaj*Fig-7 Group of sclerides of *Daruharidra*Fig-8 Starch grain of *Shunthi*Fig-9 Pitted stone of *Haritaki*Fig-10 Rhomboidal crystal of *Kutaja*Fig-11 Fibers of *Daruharidra*Fig-12 Oleoresin of *Haridra*Fig-13 Oil globulin of *Vacha*Fig-14 Annular vessel of *Vacha*Fig-15 Stone cell of *Haritaki*Fig-16. Presmectric crystal of *Kutaja*Fig-17. Starch grain of *Haritaki*Fig-18 Pitted Stone cell of *Devadaru*



Fig-19 Fragment of border pitted vessel of *Devadaru*

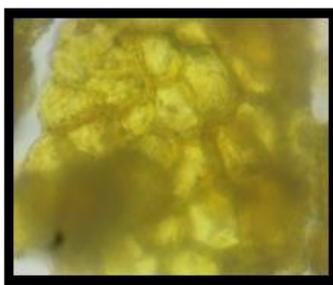


Fig-20.Epicarp cell of *Haritaki*

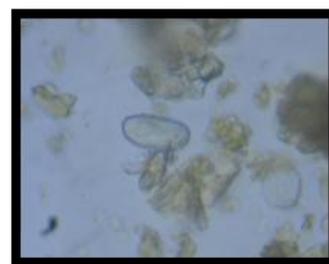


Fig-21. Cork cell of *Shunthi*

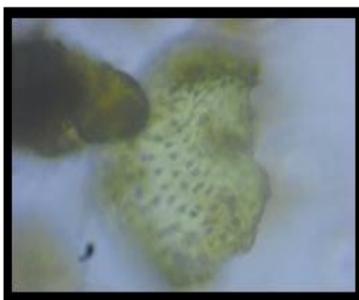


Fig-22. Lignified stone cell of *Devadaru*

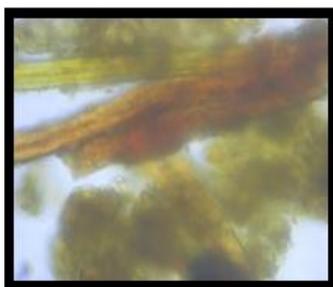


Fig-23. Lignified fibers of *Devadaru*

Pharmaceutical study of *Haridradi Vati*: Physico-chemical parameters like loss on drying, ash value, water and alcohol soluble extract etc. were carried out as per

the WHO guidelines^[16], Ayurvedic Pharmacopoeia^[17] and Indian Pharmacopoeia^[18] and the results are depicted in **Table no.2.**

Table 2: Physico-chemical parameters of *Haridradi Vati*.

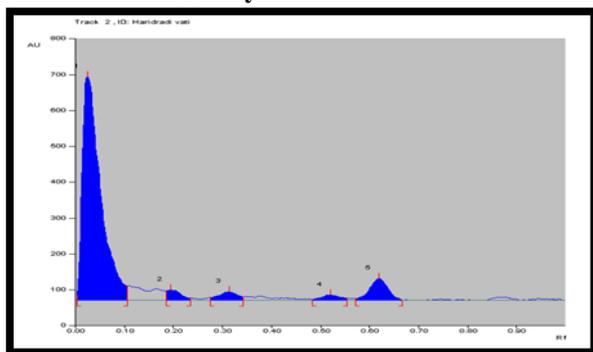
Analytical tests	Value of <i>Haridradi Vati</i> powder.
Ash value percentage	0.64% w/w
Loss on drying percentage	12.12% w/w
Water soluble extract percentage	13.7% w/w
Alcohol soluble extract percentage	7.32% w/w
Weight variation of <i>Vati</i>	Average wt. 0.545gm Highest wt. 0.600gm Lowest wt. 0.460gm
Hardness test (Kg/cm)	1.6
Disintegration time (Min)	29
Diameter (Cm)	0.7
pH value	6.5

High performance thin layer chromatography (HPTLC)

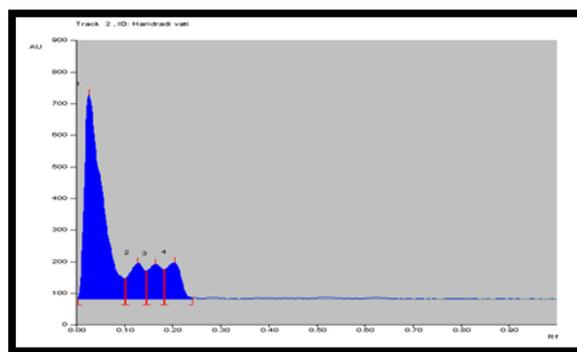
On performing HPTLC, the chromatogram of *Haridradi Vati* powder showed 5 peaks with maximum R_f values 0.02,0.19 and 0.31,0.52,0.62 at short wave UV 254nm; while at long wave UV 366 nm, the chromatogram showed 4 spots with maximum R_f values 0.03, 0.13,0.16,0.20 [Table 3 (Plate 2.Fig.1 - 2).]

Table 3: HPTLC results of *Haridradi Vati*.

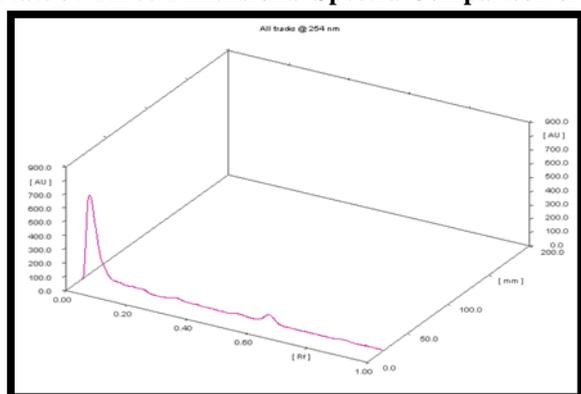
HPTLC	254 nm		366nm	
	No. of Spots	Rf Value	No. of Spots	Rf Value
	5	0.02,0.19,0.31,0.52,0.62	4	0.03,0.13,0.16,0.20

Plate 2. HPTLC Study of the *Haridradi Vati*.

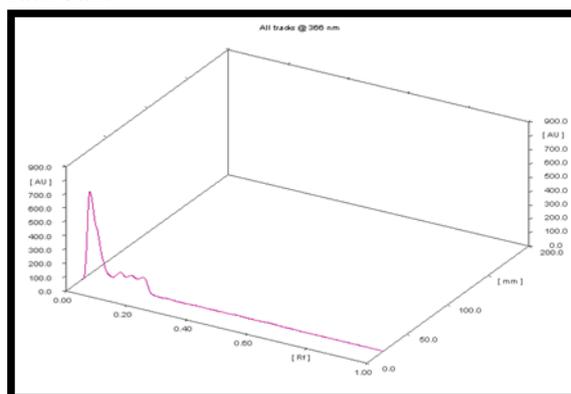
A



B

Plate 3: Three Dimensional Spectra Comparison of *Haridradi Vati*.

Spectra at 254nm



Spectra at 366nm

RESULTS AND DISCUSSION

Pharmacognostical study revealed presence of sclerides of *Daruhardra*, starch grain of *Musta*, fibers of *Shunthi*, starch grain of *Kutaj*, pitted stone of *Haritaki*, oleoresin of *Haridra*, oil globulin of *Vacha*. Standardization tests performed for *Haridradi Vati* were as per AYUSH testing protocol for *Vati* (Table 1, 4). *Haridradi Vati* is found to be blackish brown in color with aromatic odor and bitter taste. pH of *Haridradi Vati* was found to be 6.5 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 take place. As *Haridradi Vati* is slightly 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 was 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. In consistent 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/cm² which is also well within the normal limit. The testing of a tablet's 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 29 min 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. However, it is not a bioavailability indicator. Diameter of the tablet was found to be uniformly 0.7 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. The physicochemical parameters showed that percentage of water soluble extract was more than alcohol soluble extract. Ash value of the final product is 0.64% w/w shows the presence of inorganic material. HPTLC study showed 5 and 4 peaks for *Haridradi Vati* at 254nm & 366nm respectively. HPTLC is an important tool in standardization 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. These physico-chemical constants like pH, diameter, variation in weight, hardness, disintegration time, results of HPTLC photo documentation can be used as fingerprint to check quality of *Haridradi vati*.

CONCLUSION

The formulation *Haridradi Vati* which was subjected to pharmacognostical study, reveal genuineness as all the ingredient microscopic characters were observed. Physico-chemical and HPTLC studies inferred that the formulation meets the minimum quality standards as reported in the API at a preliminary level. Though the ground work requisites for the standardization of *Haridradi Vati* is covered in the current study, additional important analysis and investigations are required for the identification of all the active chemical constituents of the test drug to substantiate the clinical efficacy. The inference from this study may be used as reference standard in further quality control researches.

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