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Research Article

PHARMACEUTICAL STANDARDIZATION AND PHYSICOCHEMICAL ANALYSIS OF AROGYAVARDHINI VATI

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ABSTRACT

It is very crucial to know the physicochemical properties of drugs during the development of pharmaceutical products. Drugs are on compulsion to assess their compatibility of active substances, excipients and medicinal products with established standards by the pharmaceutical laws. Characterization of these active pharmaceutical ingredients (APIs) helps in improving the quality parameters of all raw materials used during the manufacturing process of pharmaceuticals and also in the final products. Maintaining quality standards of the drugs is the need of the hour in this era of increasing demand for indigenous medicines. Due to the absence of reference standards, standardization of many of compound formulations is lagging behind. Ayurveda is one of the oldest medical sciences that has been serving the community since centuries. Arogyavardhini vati is one of the most important Avurvedic formulation that is advised by the Avurvedic scholars for liver disorders since centuries. Although, being administered by a vast community of Ayurvedic practitioners and from a very long period with multiple benefits, there were no many studies that are available on the physicochemical analysis and standardization of Arogyavardhini vati. Present study evaluated the physicochemical properties of Arogyavardhini vati and standardized. Arogyavardhini vati prepared by the Ayurvedic classical method complies with the standard parameters as mentioned in Ayurvedic Pharmacopeia of India. Present study observed that the analytical parameters and the pharmaceutical parameters for Arogyavardhini Vati were validated by HPTLC method and can be considered as the standard drug.

INTRODUCTION

Pharmaceutical research and development is viewed as one of the world's most sophisticated industries. The goal of a pharma company is to produce quality drugs and make them accessible, all the while cutting costs and minimizing production time. These goals are met by introducing certain changes to the industry's operations.

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Thus, in the last several years, focus has been shifted toward increasing the quality of products and reducing production plant sizes and resource utilization.[1]

Guided by pharmacology and clinical sciences, and driven by chemistry, pharmaceutical research in the past has played, the process of drug development starts with the innovation of a drug molecule that has showed therapeutic value to battle, control, check or cure diseases. The synthesis and characterization of such molecules which are also called pharmaceutical ingredients (APIs) and their analysis to create preliminary safety and therapeutic efficacy data are prerequisites to identification of drug candidates for further detailed investigations. [2]

Ayurveda, the traditional Indian medicinal system remains the most ancient yet living traditions with sound philosophical and experimental basis. It is a science of life with a holistic approach to health and personalized medicine. It is known to be a complete medical system that comprised physical, psychological, philosophical, ethical, and spiritual health. [3] According to the World Health Organization, about 70–80% of the world populations rely on non-conventional medicines mainly of herbal sources in their healthcare. [4]

Ayurveda, 5000yrs old considered as one of the complementary medicine by the modern community has proved its authenticity even during the Covid-19 through its effective therapies and drugs. Multiple benefits of these drugs have made the people increase their immunity along with the reduction of the symptoms. Though Ayurvedic treatment medicines are highly effective, their proper mode of action. pharmacology, pharmacokinetics, pharmacovigilance of many important Ayurvedic drugs are still not fully explored, whereas the Western medicinal system has reached almost at the top because of validated research and advanced techniques. [5] There is an urgent need to validate basic principles, therapies and the drugs used in the Ayurvedic system of medicine with the help of advanced research methodologies and techniques that play a very important role in the promotion of Ayurvedic science. Arogyavardhni Vati is one such medicinal drug and a very effective formulation that has advised by Ayurveda Acharyas since centuries for various disorders. The present study attempts in

evaluating the physicochemical analysis and standardization of the same.

Arogyavardhini Vati

Arogyavardhini vati is a formulation that improves Arogya or the health and comprises of two words Arogya which means health and Vardhini that improves. This formulation has been quoted by Rasaratnasamucchava in the context of Kustha (skin disorder) and in [6] Bhaishyajyaratnavali in the context of liver disorder Yakritvikara (liver disorder). [7] This drug is said to balance all the Tridoshas, cure the diseases and promote good health. It is said as *Sarvarogaprashamani*, the one which cures all types of disorders by Rasaratnasamucchaya.[8] Traditionally this formulation is used in treating jaundice and other liver disorders. [9] Apart from the liver disorders, it has also shown its efficacy in successful management of leprosy, fever, oedema, obesity, indigestion and irregular bowels, lack of appetite, skin diseases and carminative stomachic etc. [10]

Preparation of Arogyavardhini Vati

With the juice of *Nimba* leaves, all the ingredients such as *Triphala*, *Tamra bhasma*, *Shilajatu*, *Chitraka* and *Nimba swarasa* are taken, grounded for two days and made into the paste and pills are prepared. These pills should be the size of *Rajakola* like the fruit of Indian jujube. According to Acharya Hariprasanna Sharma, the size of the pills should be like *Kshudrakola*. These pills once prepared will be bitter in taste and black in colour and dose mentioned by the scholar approximately as 500mg- 1gm per day. [7.8.11,12]

Table 1: Showing ingredients of Arogyavardhini Vati

S.No	Ingredients	Quantity
1.	Triphala	2 parts
	a. Haritaki- Chebulic Myrobalan fruit rind	
	b. Bibhitaki– Belliric Myrobalan fruit rind	
	c. Amalaki – Indian gooseberry fruit	
2.	Shilajatu (Mineral pitch)	3 parts
3.	Pura – Guggulu – Indian bedelium (gum resin)	4 parts
4.	Chitramool- root of Indian led word.	4 parts
5.	Tikta – Katuki	4 parts
6.	Shuddha Parada (Herbal purified mercury)	1 part
7.	Shuddha Gandhaka (Herbal purified sulphur)	1 part
8.	Loha Bhasma (Ash prepared from iron)	1 part
9.	Abhraka Bhasma (Purified and processed mica)	1 part
10.	Tamra Bhasma (Ash prepared from copper)	1 part
11.	Juice extract of <i>Nimba</i> leaf – Neem	Sufficient quantity

Indications of Arogyavardhini vati

Arogyavardhini vati is indicated in all types of Kustha and said to be Kusthanashaka as per Rasaratnasamucchaya, Bhaisajyaratnavali and Bharatbhaisajyaratnakar, specifically indicated in Mandala kushtha for 14 days. It is also said as Tridosha Jvara nashaka and is administered for 5 days and is Sarvaroga prashamani, the one which alleviate all types of Vyadhis.

This formulation has an umbrella of properties like- *Hridya* (cardio protective), *Medonasaka* (can alleviate the diseases arising from hyperlipidemia), *Dipani* (appetizer), *Spachani* (digestive), *Pathya* (wholesome for channel), *Malashuddhikari* (cleaning of waste materials from body), increase *Kshudha* (appetizer) etc.^[9]

Anupana (Adjuvant)

Arogyavardhani vati is administered with various types of adjuvants based on the disease treated such as ghee, jaggery, buttermilk, curds, milk, sugarcane juice, Dashamoola Kwatha, Punarnavai kwatha, moong dal, Urad dal and barley etc. [13]

Adverse Effects

None of the studies have reported the adverse effects of *Arogyavardhini vati* till date. But precautions necessarily have to be taken regarding the *Shodhana* or the purification as the formulation contains various metals and minerals as these may lead to dangerous effects. Needs to be avoided in pregnant, lactating women and children and it's over dosage might also cause severe poisonous effects.

Preparation of *Arogyavardhani Vati* Place of Preparation

The ingredients were procured from the local market of Vijayawada, Andhra Pradesh, India and all the herbal and mineral material were thoroughly screened by experts of P.G. Dept. of Rasashastra, Dr.N.R.S. Govt. Ayurvedic College, Vijayawada, AP., based on the *Grahya lakshanas* (to be taken or accepted characters) mentioned in the classics.

Ingredients

Ingredients include one part of each Shuddha Gandhaka (purified sulhpur), Shuddha Parada (purified mercury), Lauha Bhasma (iron), Abhrak Bhasma (calcined biotite mica) and Tamra Bhasma (copper), 6 parts of Triphala including Haritaki, vibhitaki and Amalaki (combination of Terminalia chebula Retz., Terminalia bellirica (Gaertn.) Roxb. and Phyllanthus emblica L.), 3 parts of Shuddha Shilajatu (purified asphaltum), 4 parts of Shuddha Guggulu (purified exudate of Commiphora wightii (Arn.), 4 parts of powder of root of Chitraka (Plumbago zeylanica L.), 22 parts of powder of rhizome of Katuki (Picrorhiza kurroa Royle ex Benth.) and sufficient quantity of Nimba patra swarasa (juice of Azadirachta indica A.

Juss. leaf) for proper levigation in the preparation of *Vati*.

Method of Preparation

Step 1

Preparation of Kajjali

Equal quantities of mercury obtained from cinnabar known as *Hingulotha Parada* and purified sulphur, the *Shuddha Gandhaka* were taken in a *Khalva yantra* and was given *Bhavana* (trituration) thoroughly until a soft, black color, fine powder like collyrium or *Kajiali* which is lusterless is obtained.

Step 2

Preparation of Bhasmas

Equal quantities of *Sthali pakva Lauha* and *Triphala Kashaya* were taken in equal quantity. *Triphala kwatha* was mixed with *Lauha churna* that is washed and processed with *Sthali paka* and levigated well. By this, thin flat *Chakrikas* (pellets) were prepared, dried and placed in *Sharava samputa* (Earthen plates). The junction of both these *Sharavas* (earthen saucer) were properly sealed, dried and subjected to *Gaja puta*. The same method was repeated for 60 times to obtain *Lauha bhasma* and this was preserved in the air tight glass jar or porcelain containers.

Preparation of Abhraka Bhasma

ksheera was triturated with Dhanyabhraka for one day and Chakrikas (thin, flat cakes) were made, and dried in sun rays. Once the Chakrikas were ready, they were placed in a Sharava samputa or the earthen plates and their junctions were properly sealed and were subjected to Gaja puta. Thus, obtained material at the end of the Puta, was processed for six more times in the similar way and at the end of 7th Puta, Abhraka was again given Bhavana with Nyagrodha-mula kwatha and subjected to three Gaja putas after drying. As a next step, Abhraka was triturated with Kadali swarasa and 7 Gaja putas were given. After the completion of all *Putas, Abhraka* was collected, grounded and was preserved in air tight glass jar or porcelain containers for future.

Preparation of Tamra Bhasma

Thin plates or the *Patras* of *Shodhita Tamra* were taken and boiled in *Nimbu swarasa* for 3 days. Next, to this *Tamra patra*, one fourth quantity of *Shuddha parada* and *Nimbu swarasa* were mixed and triturated for 3 hours. Later *Shuddha gandhaka* was added to this and levigated by adding *Nimbu swarasa* and finally it is made into a bolus or a *Golaka*. Once the bolus is ready, it is covered carefully with the paste of *Punarnava moola* and dried completely. As done in other *Bhasmas*, even in this, the dried bolus was placed in *Sharava* and covered by another *Sharava* and junction was sealed carefully with clay smeared cloth. The *Sharava* was then placed in a heating device and

heated by gradually increasing heat for 12 hours. On cooling, the *Sharava* was removed from the pot and the product thus obtained was given *Bhavana* with the juice of *Surana kanda* for a day. By adding half part of *Gandhaka* and a little quantity of cow ghee, a bolus of was prepared and this was again placed in the *Sharava* joints sealed and given *Gajaputa* by repeating the procedure twice.

Step 3

Amrutikarana of Tamra bhasma

In this method, *Shuddha gandhaka* with *Tamra bhasma* and *Nimbu swarasa* was pulverized well for 3 hours and made into a bolus. This bolus was placed inside the *Surana kanda* and was wrapped with clay smeared with cloth and dried. After subjecting to *Gaja puta*, it was cooled, ashes were removed and the *Tamra* that was obtained was powdered, collected and stored.

Step 4

Shodhana (Purification) of Guggulu

This was done by mixing *Guggulu* with *Triphala kashaya* in the ratio of 1:2 and continuously stirred while subjecting to moderate heat. The contents were filtered to remove insoluble impurities after the complete dissolution of *Guggulu*. The filtrate obtained was again reheated with continuous stirring until the contents became semi solid. This semi solid content was transferred into *Ghrita* smeared steel trays and were dried. The final dried content of *Shuddha Guggulu* was taken out from the trays and stored.

Step 5

Shilajatu Shodhana (purification of asphaltum)

Shilajatu was added to Triphala kashaya with the ratio of 1:10 and this was kept undisturbed for 24 hours. The solution was heated after 24hrs and it resulted in a black cream like appearance upon the surface of the solution. After decanting the top most layer of solution, it was collected in another pot and Analytical Study

stored. Until the whole of the dirt was separated from the pure substance and collected in the bottom of the first container, the process was continued.

Step 6

Chitraka Shodhana (purification of Plumbago zeylanica L.)

Moola of Chitraka was cut into small pieces and placed in a clean container. To this Chitraka moola lime water was added and stirred, soaked for some time and thereafter washed, taken out and dried under the sun.

Step 7

Preparation of Nimba patra swarasa

The fresh leaves of *Nimba* or the *Nimba patras* were crushed after washing it in the tap water and made into a coarse paste. Thus *Swarasa* is obtained by subjecting the paste in to hydraulic pressure.

Step 8

Preparation of finished product - Vati

After making the fine powder of purified *Chitraka Mula, Triphala* and *Katuki* separately, next *Kajjali* was added and gradually with *Nimba swarasa* and this was well triturated till the material completely got dried. Thereafter the process was repeated 6 more times and the dried material was transferred to tablet section and thus the granules were prepared. With the addition of 2% talcum powder to the granules, *Vati* was prepared.

Once the *Vati* was ready, its chemical analysis, physicochemical analysis, estimation of loss on drying, ash content, acid insoluble ash, water/alcohol soluble extractive, ph, etc., qualitative/ quantitative elemental testing, residual pesticide, microbiological examination and tablet parameters viz. hardness, friability, average wt., dissolution time, etc. were executed out by as per the standard methods as per Ayurvedic Pharmacopoeia of India (API) 16-21 guidelines.

Test Report

Test Report							
Name and Address of	Customer	Report Number	Report Date				
		CARISM/CHEM/18-10-N-4052	22.10.18				
		ULRTC569218000000026/P					
		Sample Received on Sample Analys					
		12.10.18	15.10.18				
		Comple Not Dygram Dy Conic	Batch Number				
		Sample Not Drawn By Caris	NA NA				
Sample Name	Arogyavardini vati						
Sample Description	Black coloured round sha	ped tablet with beveled edges					
Test(s) Requested		weight, uniformity of weight, di n drying, WSE, ASE, hardness	sintegration time, total ash,				
Original Manufacture	r's Name (if applicable)	Manufacturing License No.	Reference No.				
NA		NA	NA				

Quantity (with units)	Date of Manufacturing	Date of Expiry	
1X50 tablets	NA	NA	

Test Results

S No	Parameters	Results	Reference of test methods
1	Appearance	Black coloured round shaped tablet with beveled edges	IP Vol-I, 2014, p1
2	Average net weight	0.2736g	-
3	Uniformity of weight	96.63% to 104.7%	IP Vol-I, 2014, p256
4	Disintegration time	11min 48sec	IP Vol-I, 2014, p251
5	Total ash	15.73%w/w	IP Vol-I, 2014, p98
6	Acid insoluble ash	5.197%w/w	IP Vol-I, 2014, p98
7	Loss on drying at 105°C	10.32%w/w	IP Vol-I, 2014, p162
8	Water Soluble Extractive(WSE)	34.78%w/w	IP Vol I, 2014, P-277
9	Alcohol Soluble Extractive(ASE)	37.55%w/w	IP Vol I, 2014, P-277
10	Hardness	2.4kg/cm ²	

Centre for Advanced Research in Indian System of Medicine (CARISM)

Test Report

Name and Address of	Customer	Report Nu	mber	Report Date			
		CARISM/C	HEM/18-10-N-4053	26.10.18			
		ULRTC569	ULRTC569218000000027/F				
		Sample Re	eceived on	Sample Analysed on			
		12.10.18	A VW VEG				
		Si Cama	La Nat Day Carriana	Batch Number			
		Samp	l <mark>e N</mark> ot D <mark>rawn</mark> By Carism	-			
Sample Name	Arogyavardini v	ati 💮 🥻	me				
Sample Description	Black coloured	rou <mark>nd s</mark> hape	ed tablet with beveled edges				
Test(s) Requested	Related to Glyce	oside	D.Har				
Original Manufacture	r's Name (if app	licable)	Manufacturing License No.	Reference No.			
-			NA	NA			
Quantity (with units)			Date of Manufacturing	Date of Expiry			
1X50 tablets			-	-			

Test Results

S.No.	Parameters Results Reference for Test Methods				
1	Appearance	Black coloured round shaped tablet with beveled edges	IP Vol-I, 2014, p1		
2	Identification	Related to Glycoside	Indian Herbal Pharmacopoeia, Vol-II, p109-110		

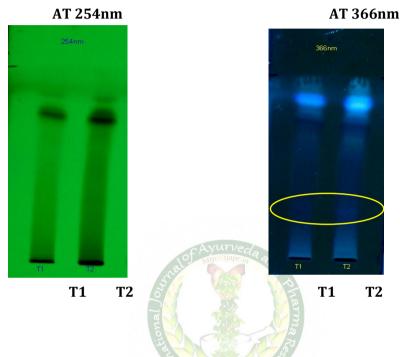
HPTLC method

High Performance Thin Layer Chromatography (HPTLC) is an enhanced form of Thin Layer Chromatography (TLC). A number of enhancements can be made to the basic method of thin layer chromatography to automate the different steps, to increase the resolution achieved and to allow more accurate quantitative measurements. Automation is useful to overcome the uncertainty in droplet size and position when the sample is applied to the TLC plate by hand. One recent approach to automation has been the use of piezoelectric devices and inkjet printers for applying the sample. The assay combines the separation and quantification of the analyses on silica gel HPTLC plates with visualization under UV and scanning. Using this technique, the alkaloid content of different parts of the drug *Arogyavardhini vati* finger print profile has been determined for the 3 experiments in the different times. HPTLC of *Arogyavardhini vati* is the preliminary quantitative analysis which shows the number of components present in the sample accurately and precisely on the basis of mild variations in Rf values, that can acceptable in this drug and it indicates the purity of drugs.

High Performance Thin Layer Chromatography was performed on TLC plates pre-coated with $0.25\mu m$ thin layers of silica gel 60 F254 (E. Merck). $10\mu L$ methanolic solution of formulation (three batches) were applied on the plates as bands 8.0 mm wide by use of a Linomat-V applicator (CAMAG, Switzerland) fitted with a $100\mu L$ syringe (Hamilton, Switzerland). The application positions X and Y were both 10 mm to avoid edge effects. Linear ascending development to a distance of 80 mm with Toluene: Ethyl acetate: formic acid 10:3:1 (v/v) as mobile phase for methanol extract was performed in a twin-trough glass chamber previously saturated with vapours of mobile phase for 20 min. The plates were dried in air and visualized under 254 nm and 366 nm for ultra violet detection and taken the fingerprints as evident. The results of HPTLC analysis are follows in Table 2 & Figs. 1 & 2.

HPTLC Fingerprinting Profile of Arogyavaradhini vati

Photo Documentation Under UV



TLC Details T1 (5 μl), T2-(10μl)

Identity Test

Test solution: About 1g of powdered drug was macerated with ethanol for 24 hours. Then it was filtered and evaporated to dryness. The dried residue dissolved in ethanol used for TLC analysis.

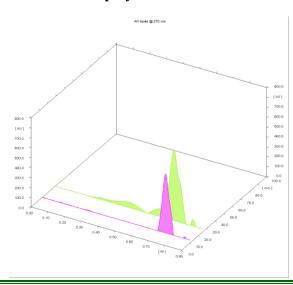
Stationary phase: Silica Gel 60 F₂₅₄

Mobile phase: Ethyl acetate: Methanol: Glacial acetic acid (18:5:0.2)

Procedure: Applied 5, 10μ l of test solutions (T1 & T2) spotted on a precoated silica gel 60 F₂₅₄ HPTLC plate (E.Merck) of uniform thickness 0.2mm using Linomat5 sample applicator. Developed the plate in the solvent system to a distance of 8cm. Observed the plate under UV light at 254nm & 366nm using CAMAG REPROSTAR3.

Evaluation: A band at R_f value of 0.45 corresponding to Kutkoside was visible in test solution track (T2)

3D Display @ 270nm



Peak Display (5µl of Test solution-T1)

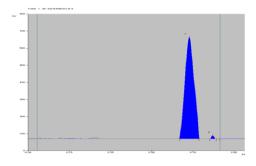


FIG-I

	Start	Start	Max	Max	Height	End	End		Area	
Peak	Rf	Height	Rf	Height	%	Rf	Height	Area	%	Assigned substance
1	0.69	3.6	0.74	592.9	97.13	0.79	2.9	19738.8	99.25	unknown *
2	0.84	0.0	0.85	17.5	2.87	0.87	0.0	149.9	0.75	unknown *

Peak Display (10µl of Test solution-T2)

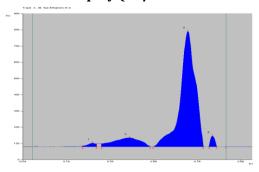


FIG-II

	Start	Start	Max	Max	Height	End	End		Area	
Peak	Rf	Height	Rf	Height	%	Rf	Height	Area	%	Assigned substance
1	0.23	4.7	0.28	22.8	2.66	0.30	18.0	662.9	1.49	unknown *
2	0.32	19.0	0.45	56.3	6.58	0.54	0.7	5345.7	12.05	unknown *
3	0.55	0.1	0.71	709.9	83.00	0.78	5.9	37335.8	84.19	unknown *
4	0.81	21	0.83	66.4	7.76	0.85	27	1004 5	2 27	unknown *

DISCUSSION

The aim of medical sciences including the ancient sciences too in general is to improve and maintain the good health of the individual and the society in total. The drug one which we are discussing in this study portrays by the name itself as the one which improves the health and is called the Arogyavardhini vati. This formulation is being advised and administered by the Ayurveda acharyas since centuries due to its multiple comprehensive benefits it is named so. Though not mentioned by Bruhatrayees, in Rasaratna samucchaya it is highly indicated in Kustha and liver disorders by Bhaisajya rathnakara. Apart from this, many scholars have witnessed its effectiveness through their studies. Present study focused on standardization of Arogyavardhni vati by studying its properties and hence physicochemical analysis was studied with the involvement of new technologies.

Analysis of Action

According to Ayurvedic science, balance of the *Tridoshas* namely *Vata, Pitta* and *Kapha* leads to the normal health and its maintenance. Any imbalances in these are the causes for illness or the diseases. Hepatic or the liver disorders are the commonest disorders among the middle aged people and *Arogyavardhini vati* is said to be very effective in these disorders which has been acknowledged by the clinical studies.

The formulation *Arogyavardhini vati* contains ingredients such as *Amalaki* which is an astringent, hypoglycaemic, stomachic, hypotensive antibacterial and carminative. It also has anti hepatotoxic, antioxidative, and immune modulator properties. *Haritaki*, an astringent and laxative, is effective in fatty liver and cirrhosis of liver etc liver disorders. *Bibhitaki* is a laxative and the most effective in digestive disorders and an anthelmintic. Additionally, it has a styptic property that can arrest the bleeding. *Guggulu*,

a gum resin, is very effective in reduction of cholesterol. A mineral named *Shuddh shilajit* is like a nectar and renews vitality by its antioxidant property. It has showed its effectiveness in liver diseases, digestive disorders, kidney diseases and psychological disorders too. *Katuki* (*Picrorrhiza kurroa*) an important drug for liver disorders helps in prevention of liver damage that is caused due to alcohol, paracetamol etc chemicals. Last, but not the least, *Chitraka* is very effective in gastrointestinal disorders where *Agni* has got impaired in conditions such as indigestion, piles, loss of appetite worms, various liver diseases and colitis. [9]

Pharmacological action of Arogyavardhani Vati

The combo of ingredients in Aroavavardhini vati confers multiple benefits for the patients. Studies show that Tamra Bhasma plays an important role in carbohydrate metabolism by stimulating hexose transport, insulin binding and lipogenesis. [14] Katuki improves glycemic control and provides better glucose uptake by skeletal muscles by increasing the insulin-mediated translocation of glucose transporter type 4 from the cytosol to the plasma membrane.[15] While Triphala inhibits lipid peroxide formation and scavenge hydroxyl and superoxide radicals and thereby lowers fasting blood sugar. [16] Shilajatu inturn helps in reduction of lipid and sugar from the gut. [17] A double-blind trial of Antarkar et al. (1980) conducted on acute viral hepatitis with *Arogyavardhini* had showed significant hepatoprotective effects by reducing inflammation of spleen, liver, bladder, kidneys, uterus and intestine. [18]

In the present study *Arogyavardhini vati* was prepared according to the Ayurvedic classics and was subjected to physicochemical analysis and standardization as per the Ayurvedic Formulary of India.

CONCLUSION

Arogyavardhini vati is one of the most important Ayurvedic formulations that is advised by the Ayurvedic scholars for liver disorders since centuries. Although, being administered by a vast community of Ayurvedic practitioners and from a very long period with multiple benefits, there were no many studies that are available on the physicochemical analysis and standardization of Arogyavardhini vati. In the present study, Arogyavardhini vati prepared by the Ayurvedic classical method complies with the standard parameters as mentioned in Ayurvedic Pharmacopeia of India. Hence we may conclude that pharmaceutical and analytical parameters for Arogyavardhini Vati are validated by HPTLC method and can be considered as the standard drug.

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