

PHARMACEUTICO-ANALYTICAL STANDARDIZATION OF VACHALASHUNADI TAILAM

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Published online: July, 2019

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ABSTRACT

Vachalashunadi taila is a compound *ayurvedic* preparation comes under *sneha kalpana*, prepared by using *Murchchita tila taila*, *Vacha*, *Lashuna*, and *Haridra*. It is indicated in *Karnaroga* as an external application. Different manufacturing techniques can be utilized to increase the potency or efficacy of a drug. Best effects are implied to fulfill the criteria of product standardization by tracing the guidelines in the classics. For the present study we are using *Murchchita tila taila* and the preparation will be based on *Samanya* (basic) *sneha* preparation as mentioned in *Sharangadhara samhitha*. After preparation the sample will be analyzed by using different chemical parameters. The present study will attempt on pharmaceutical and analytical standardization of *Vachalashunadi taila*.

Keywords: *Murchchana*, *Tila taila* (sesame oil), Analytical parameters

INTRODUCTION

'*Ayurveda*' is one of the most ancient systems of life, health and cure whose antiquity goes back to *Vedas*. This system of knowledge flourished through over 5000 years and has had an unbroken tradition of practice down the ages update. *Ayurveda* is a highly evolved and codified system of life and health science based on its unique and original concepts and fundamental principles.

Bhaishajya Kalpana is a broad subject including more relevant topics than modern pharmaceutical science. Only the method of preparation, ingredients

and some other related portions are included in modern pharmacy as it is a separate well developed wing. But *Bhaishajya Kalpana* includes medicinal preparations, food preparations, collections, preservation, dosage, purification methods, prescription writing etc. The basic processing techniques of *Bhaishajya Kalpana* are elaborately explained in *Samhitas*. The *Ayurvedic* system of medicine is on the way to regain its past glory because of its preventive as well as curative nature and holistic approach with legal application of Good Agricultural and Collection Pro-

cess (GACP), Good Manufacturing process (GMP), Good Laboratory practice (GLP) in *Ayurveda* pharmacy. This submission give standardization of ayurvedic medicines which results in validation of evidence best clinical effect as described in *ayurvedic* texts. However efficient be the physician and accurate in its diagnosis and prescribe correct medicine it may not help the patient if the medicines of good qualities are not available. Thus standardization of ayurvedic medicines has become quite inevitable.

Vachalashunadi taila is prepared with *Murchchita tila* taila was carried out for standardization purpose as there was carried out as there was no previous work done hence an attempt is made to standardize the *Vachalashunadi taila* mentioned in *Sahasrayogam*.

Materials And Methods

The raw materials *Vacha*, *Lashuna*, *Haridra*, *Bilva patra*, *Tila taila* were procured from Anamaya drugs, Udupi. Raw material analysis like Loss on drying, Ash value, Extractive and purity test like Mineral oil, Argemone oil etc. were performed. *Vachalashunadi taila* was prepared as per *Sahasrayogam* reference (*Kalka: Sneha: Drava dravya* in 1:4:16 ratio) the process of *Taila paka* and the assessment of *Trividhapaka* were done as per the reference of *Sharangadhara Samhita*. The preparation was done in PG Department of *Rasashastra and Bhaishajya kalpana* MIAMS Manipal.

Procedure

The drug *Bilva patra* was collected washed well and grinded to obtain swarasa. 4 part of *Moorchchita tila* taila was taken in a stainless steel vessel, heated on *Mandagni* (Medium fire), add 1 part of (*Vacha*, *Lasuna*, *Haridra*) *Kalka* (paste) later 16 parts of *Bilva patra swarasa* (juice) was added and mixed well. This mixture was heated on *Mandagni* with continuous slow stirring for proper mixing, after all siddha lakshanas were obtained the heating was discontinued and the taila was filtered through a clean cloth.

Temperature 70-90.3°C

Total time duration 4 hour 30 minutes

Obtained quantity 260ml

Time of preparation September month

ANALYTICAL STUDY

To assess the quality of prepared *Vachalashunadi taila* was subjected to both classical and modern parameters

A. Classical parameters

The parameters like *Varna*, *Gandha* etc. were carried out for *Vachalashunadi taila* in *Rasashastra* and *Bhaishajya kalpana* Department MIAMS Manipal.

B. Physico-chemical parameters

Physical test like Organoleptic, Acid value, Specific gravity etc. were conducted in QC lab of MIAMS Manipal, Peroxide value conducted in MCOPS MAHE Manipal, HPTLC and GC-MS were conducted in CArE Keralam, Koratty, Kerala.

1) Loss on drying (LOD)⁴

Petri dish was cleaned in distilled water and dried in oven at 105°C for 2 hours. 5g of taila was taken in Petri dish. It was kept in the oven for drying at 105°C for 5 hrs. After cooling the weight was recorded. It was again subjected to drying for an hour and then weight was noted. This procedure was repeated till two consequent weights which are same were obtained. The weight loss is calculated and expressed as %w/w.

2) Specific gravity⁵

A 25 ml capacity Pycnometer was taken and its weight was noted. It was then filled with the taila, weight was taken at 40°C. Then it was rinsed and filled with distilled water, weight was noted at 40°C. The weight of taila and distilled water was calculated. Then the Specific gravity was determined by dividing the weight of the taila by weight of the water.

3) Refractive Index⁶

Make refractometer in proper calibration by means of suitable standard. Place a few drops of taila on the lower prism of refractometer. Close prism tightly and allow a short time for the taila come to the temperature of the instrument and then read the refractive index. The taila should be removed after each examination with a small swab of cotton saturated with a suitable solution such as toluene etc.

4) Viscosity⁷

Clean the viscometer with water, rinse with acetone and dry it. Using a clean pipette, transfer a known

volume of water in to the wider limb. Allow the viscometer to stand for some time so that the liquid attains the temperature of the bath. Suck the water above the upper mark of the viscometer. Allow it to flow freely through the capillary tube. When the level of water just crosses upper mark, start a stop clock when the water just crosses the lower mark. Note the time of flow in seconds (tl). Repeat the experiment with exactly the same volume of the taila.

5) Acid value⁸

1gm of taila was weighed and placed in a conical flask, to it add 50ml of mixture of equal volumes of alcohol and solvent ether, to that add 1ml of solution of phenolphthalein indicator. Afterward titrate with 0.1N potassium hydroxide, shaking constantly until a pink colour persists. Note the number of ml required. Calculate the value using formula.

6) Iodine value⁹

Place accurately weighed taila in a dry iodine flask. Add 10ml of carbon tetrachloride & dissolve to it add 20 ml of Wij's solution shake & keep it in a dark place for 30 min in a temperature between 15°C to 25°C afterwards add 15 ml of potassium iodide and 100 ml of distilled water. Shake and titrate with 0.1N sodium thiosulphate using solution of starch as indicator. Note the no. of ml of 0.1N sodium thiosulphate required.

7) Saponification value¹⁰

Weighed 2g of taila into a 250 ml round bottom flask fitted with a reflux condenser. Add 25ml of 0.5M Alcoholic Potash. Keep on a water bath for 1 hour. After cooling add 1ml of Phenolphthalein solution and titrate immediately with 0.5M Hydrochloric acid. Note the value.

8) Peroxide value¹¹

1g of taila was weighed and placed in a clean conical flask, add 3 volume of glacial acetic acid and 2 volume of chloroform and 0.5ml volume of potassium iodide solution to it. Allow to stand for exactly 1 minute, with occasional shaking, add 30ml of water and titrate gradually with continuous and vigorous shaking with 0.01M sodium thiosulphate until yellow colour almost disappears. Add 0.5ml of starch solution and continue titration, shaking vigorously until the

blue colour just disappears. Calculate the value by using formula.

9) Rancidity test (Krei's test)¹²

Mix 1 ml of melted taila with 1 ml of conc. hydrochloric acid in a test tube. Add 1 ml of one percent solution of phloroglucinol in diethyl ether and mix thoroughly with the taila and acid mixture. A pink colour formation indicates that the taila is slightly oxidized while a red colour indicates that the taila is definitely oxidized.

HPTLC (High performance thin layer chromatography)¹³

Sample preparation:

10 ml of sample was partitioned with 20 ml of methanol and methanol soluble portion was used for HPTLC 3, 6 and 9µl of the sample was applied on a precoated silica gel F254 on an aluminum plate to a band width of 8mm using Linomat 5TLC applicator. The plate was developed in Toluene-Ethyl acetate (9:1) and the developed plates were visualized under UV 254 and 366nm. R_f colour of the spots and densitometer scan were recorded.

GCMS (gas chromatography mass spectrometer)¹⁴

Gas chromatography is an analytical technique used for separation of thermally stable and volatile substances. A sample of the analyte is introduced by syringe injection into the heated injector tube, where it is vaporized and mixed with carrier gas. As the sample vapour is carried through the column by the carrier gas, the analyte portions between the gas and liquid phase according to the analyte components solubility in the liquid at the column operating temperature. This equilibrium partitioning continues as the sample is moved through the column by the carrier gas. The rate at which the sample travels through the column is determined by the sample solubility in the stationary phase.

RESULTS**Table 1** Showing organoleptic characters of *Vachalashunadi Taila*

Sl.No	Parameters	<i>Vachalashunadi Taila</i>
1	Colour	Brownish with reddish yellow tinge
2	Odour	Characteristic smell
3	Taste	<i>Katu, Tikta</i>
4	Consistency	Liquid, Oily

Table 2: Purity test for *Tila taila*

Test	Observation	Inference
Argemone oil	Orange colour seen in acid layer	Very slightly present
Mineral oil	No turbidity	Absence
Castor oil	No turbidity	Absence

Specific gravity	-0.9182g/ml
Refractive index	-1.468
Acid value	-3.5
Iodine value	-70.69
Saponification value	-182.3

Table 3: Raw drug analysis

	Total Ash	Water soluble Extractive	Alcohol soluble Extractive	Acid insoluble Ash
Normal Values	Not more than 7%	Not less than 16%	Not less than 9%	Not more than 1%
<i>Vacha</i>	3.54%	37.36%	22.48%	0.44%

Preliminary phyto-chemical screening of Drugs

Table 4: *Vacha*-Methanol Extract

Sr No	Test	Result	
1	Alkaloids	Mayer's test	-ve
		Hager's test	-ve
2	Sugar	Fehling's solution test	-ve
3	Glycosides	Keller-Kiliani test	+ve
4	Phenolic compound		-ve
5	Flavonoids	<i>Shinoda</i> test	-ve
6	Amino acids	Ninhydrin test	-ve
7	Proteins	Biuret test	-ve
8	Saponins	Foam test	-ve
9	Sterols	Salkowski test	+ve
10	Tanins	Ferric-Chloride test	-ve

Table 5: showing physico-chemical parameters

Parameters	<i>Vachalashunadi Taila</i>
Loss on drying	0.196
Specific gravity	0.89
Refractive Index	1.486
Acid value	0.44
Iodine value	111.81
Saponification value	187.09
Viscosity	64.7cp
Ester value	186.65
Peroxide Value	2.8908
Rancidity	Not oxidized

HPTLC

HPTLC Finger print – 0.044%

Figure 1: Showing highest peak value of *Vachalashunadi taila*

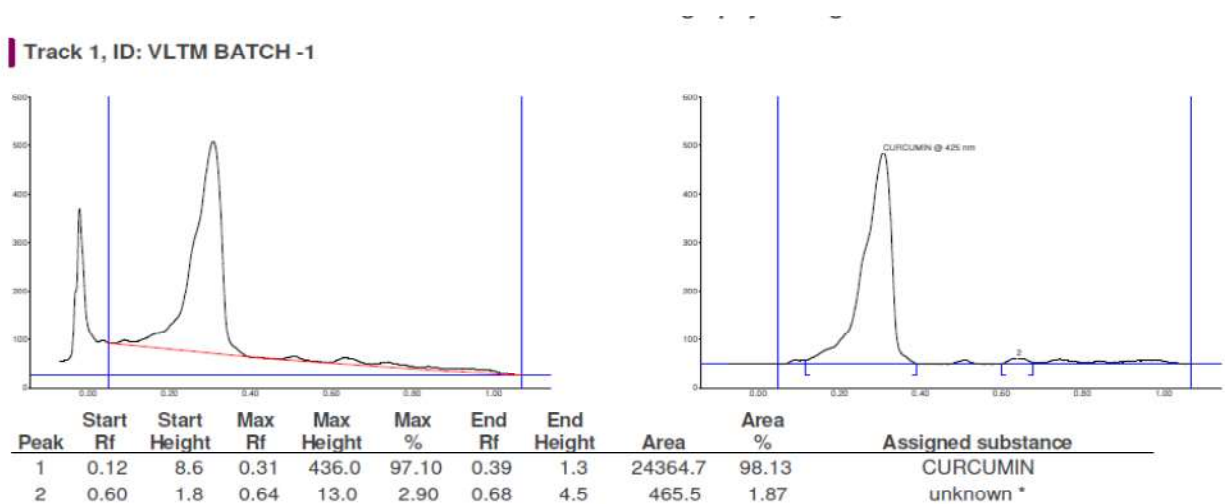
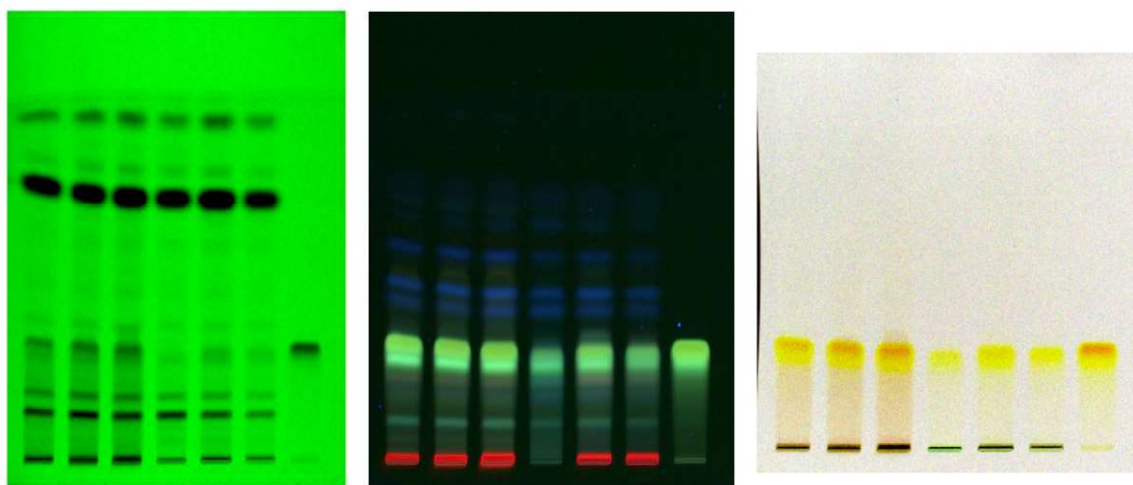


Figure 2: HPTLC photo documentation of sample of curcumin fraction of *Vachalashunadi taila*

At 254nm

At 366nm

White R



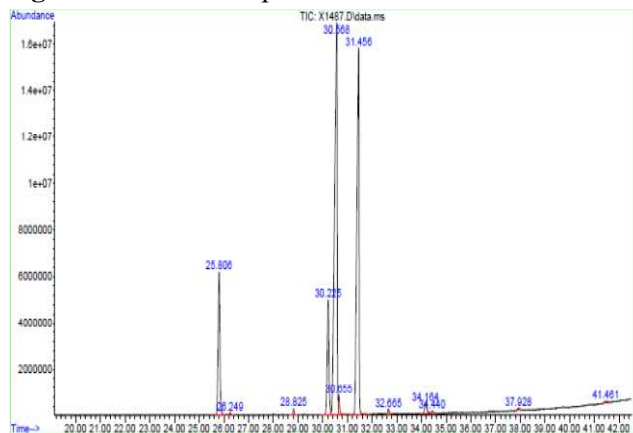
GCMS STUDY

Table 6: Showing GCMS Values

PARAMETERS	
FATTY ACID PROFILE	RESULT
Myristic acid	0.05%
Palmitic acid	11.08%
Palmitoleic acid	0.17%
Margaric acid	0.06%
Stearic acid	8.88%

Elaidic acid/Oleic acid	42.40%
11-Octadecanoic acid	1.06%
Linoleic acid	34.42%
Linolenic acid	0.33%
Arachidic acid	1.0%
Eicosenoic acid	0.16%
Behenic acid	0.23%
Lignoceric acid	0.15%

Figure 3: GCMS Graph



DISCUSSION

The present study was planned with the consideration of the fact that *Taila Kalpana* is widely used medicine preparation method useful in variety of *vata* disorders. It is one of the best drug delivery systems adopted in *Ayurveda*. An attempt was made to prepare a proper Standard operative procedure that could be framed after the study. Time duration and temperature pattern, final yield of the product, organoleptic characters and various physico chemical and analytical parameters were validated. Dry (*Vacha*) ingredient used in the formulation was subjected to qualitative and quantitative analysis at every step of pharmaceutical work. Sample was subjected to organoleptic characters like odour, taste, colour etc. and physico chemical parameters like viscosity, acid value, iodine value, saponification value, etc. evaluation. In organoleptic characters, it showed Brownish with reddish yellow tinge. Loss on Drying showed the values within acceptable limits, there is a marginal increase in specific gravity was observed along with the lapse of time which may be slight increase in the density, however the change

is negligible. Refractive index showed the observation of the sample stable with an average readings. Acid value indicates that amount of free fatty acids increase along with the time and the value is almost similar. In HPTLC curcumin was selected as a bio-marker for the study as it is easily available and identified phyto-chemical constituent in the taila. It showed a prominent peak with maximum Rf value was observed which correspond to standard curcumin. GC-MS analysis of the present study showed the sample Elaidic acid, Oleic acid, Linolenic acid in major form of fatty acids apart from this stearic acid, palmitic acid were also observed.

CONCLUSION

Sahasrayogam is the only classic which explains about *Vachalashunadi Taila*. In that the method of preparation is not explained. So we are accepting the basic rule for *taila kalpana* as mentioned in *Sharangadhara Samhita sneha kalpana* chapter. *Murchchita tila taila* is used in the preparation for getting better results as *murchhana* can increase the shelf life of preparation to an extent. *Vachalashunadi* is an easier preparation which is widely used for its efficacy in *Karna rogas* (ear diseases) and a safer medicine to prescribe for any period of time and any age group of patients. Hence the study efforts to standardize the medicine have been done.

ACKNOWLEDGEMENT

I thank principal and teaching staff of post graduate studies in *Rasashastra* and *Bhaishajya Kalpana* of MIAMS Manipal for their support and encouragement.

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Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Gopakumar. P. M & M. B. Shivakumar: Pharmaceutico-Analytical Standardization Of Vachalashunadi Tailam. International Ayurvedic Medical Journal {online} 2019 {cited July, 2019} Available from: http://www.iamj.in/posts/images/upload/1805_1811.pdf