Research Article

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FORMULATION DEVELOPMENT AND PRELIMINARY PHYSICO-CHEMICAL CHARACTERIZATION OF VATAPATRADI MALAHARA: A MODIFICATION

N. Nayana [1]*, B.K. Prashanth.[2]

[1]P.G. Scholar, Department of Bhaishajya Kalpana, Alva's Ayurveda Medical College & Hospital, Moodbidri, Karnataka, India

[2] Associate Professor, Department of Rasa Shastra & Bhaishajya Kalpana, Alva's Ayurveda Medical College & Hospital, Moodbidri, Karnataka, India

Received on: 29/05/15 Revised on: 29/06/15 Accepted on: 08/07/15

***Corresponding author**

Dr. N.Nayana, Final year P.G. Scholar, Department of Bhaishajya Kalpana, Alva's Ayurveda Medical college & Hospital, Moodbidri, Karnataka, India
Email: nayanapai79@gmail.com

DOI: 10.7897/2277-4343.066126

ABSTRACT

Vatapatradi lepa is a polyherbal topical formulation mentioned in Ayurvedic classics. Though the formulation is useful, its form poses certain inconveniences. Keeping these points in view the present study has been undertaken with the aim to modify Vatapatradi Lepa yoga into Malahara form and to develop the physico-chemical profile of the product. Malahara form was designed by using Vatapatradi oil as a base and principle of Siktha Taila was adopted for attaining the final product. The prepared Vatapatradi Malahara was evaluated for organoleptic parameters, physico-chemical profiles like pH, loss on drying, Spreadability, Viscocity, Rancidity and also the product was subjected for microbial contamination tests and HPTLC profiles. It was inferred from the results that Organoleptic parameters and Physico-chemical profile of the product were in the acceptable range, the product was found to be free from fungal and bacterial contaminations. HPTLC profile revealed the presence of 3 and 5 spots under 254nm and 366nm respectively. HPTLC Densitometric scan of chloroform extract of formulation was developed at 254nm, 366nm which showed 9 and 2 peaks respectively. Till date no analytical standards are established for this modified formulation, hence this analytical profile may serve as supporting literature for future studies and to maintain standard quality of the formulation.

Key words: Vatapatradi Lepa, Malahara, Analytical, HPTLC, Modification.

INTRODUCTION

Topical applications are the main route of drug administration in dermatological conditions. Importance of these applications were highlighted by ancient seers. Lepa Kalpana enjoys a major place in Twakgata Vikara (Skin disorders). This treatment modality comes under Bahiparimarjana Chikitsa (External applications). Vatapatradi Lepa is a Varnya Lepa (Facial applications which improves complexion) mentioned in Sharangadhara Samhita[1],Vangasena[2],Yogaratnakara[3] and Bhavaprakasha[4] as an external application in Vyanga. Lepa preparations have its own drawbacks like inconvenience in usage, preservation difficulty, non-availability of fresh drugs all the season etc. On contrary topical medications and manmade synthetic cosmetics too have some of the demerits, side effects and limitations. The incorporation of a fresh herb into a stable dosage form is a difficult task. Herbal lepa choorna preserve its potency for 30 days if kept in air tight container[5]. Hence pharmaceutical modification is essential for better enhancement of efficacy, shelf life and acceptability of the product. In the present scenario researches are carried out on modifications and development of herbal cosmetics like herbal lipstick[6], herbal hair dye[7] etc. that highlights the modification trends in the Ayurvedic pharmaceutics. In addition to these to get the products of desired qualities, one must carry the necessary analysis to detect any factors which hinders the genuinity of the product. Hence an attempt has been made to convert classical dosage form into stable Malahara form for better acceptability. Further attempts were made to develop preliminary physico-chemical profile and HPTLC fingerprints of the final product.

Aims and objectives

- Pharmaceutical development of Vatapatradi Malahara
- To develop Physico-chemical profile of the Vatapatradi Malahara

MATERIALS AND METHODS

Procurement of raw materials

The dry drugs required for the preparations were procured from the GMP Certified Pharmacy, Moodbidri, Karnataka, India. Fresh drugs (Ripend leaves of Vata *(Ficus benghalensis* Linn) and fresh leaves of Jati (*Jasminum grandiflorum* Linn.) were collected from local area. The raw material samples were deposited to the Raw drug Museum under P.G. lab of Dravya Guna Department Alva's Ayurveda Medical College, Moodbidri. Their Herbarium specimen number noted as AAMC/PG/DG/HR/2014/ 001 and 002 towards Vata patra and Jati patra respectively. Voucher number for dry drugs noted as AAMC/PG/DG/RD/2014/ 001, 002, 003 and 004 towards Raktha Chandana *(Pterocarpus santalinus* Linn.), Kushta *(Saussurea lappa* C.B. Clarke), Lodhra *(Symplocos racemosa* Roxb) and Daru haridra(*Coscinium fenestratum)* respectively. Tila Taila (Sesame oil) was

procured from genuine sources in local areas of Moodbidri, Karnataka, India.

Method of collection of data

- Vatapatradi Taila was prepared as per the general guidelines of classical Sneha Kalpana (medicated oil preparations) taking Kalka (paste) Taila (oil) and Drava Dravya (liquid media) in ratio of 1:4:16 respectively[8]. Malahara was then prepared by using this oil as a base adopting the principle of Siktha Taila[9].
- The changes occurred during the preparations were noted keenly. The prepared sample was analyzed by organoleptic method, Physico-chemical characters and Chromatographic parameters.

Preparation of Vatapatradi Malahara

The Pharmaceutical methodology of Vatapatradi Malahara comprises two steps namely,

1) Preparation of Vatapatradi Taila – used as a base
2) Preparation of Vatapatradi Malahara by addition of bees wax

The ingredients of Vatapatradi Taila are depicted in Table 1.

Preparation of Vatapatradi Taila

Tila Taila(Sesame oil) was taken in a stainless steel vessel and heated over mild flame (75^0C) till the complete evaporation of moisture, then the Kalka (paste) was added slowly and the mixture was stirred well, followed by the addition of specified proportion of water as Drava Dravya (liquid media). Heating was continued over mild flame with stirring for proper mixing of the contents. On the first day heating process carried out for the duration of 1 hour 30 mins. The Taila was allowed to keep undisturbed over night after covering with clean cloth. Next day Taila was heated over mild flame till the reduction of the contents with continuous stirring. Total duration of heating was 4 hours 30 mins. On the 3rd day of preparation Taila was heated over mild flame till the attainment of Taila Paka Siddhi Lakshana (Characteristic end points of medicated oil preparations). The duration taken was 2 hours. Then the Taila was filtered with a double folded clean cloth while it is in hot state only. After cooling the quantity of Taila obtained was measured and stored in clean air tight container and labeled.

Preparation of Vatapatradi Malahara

No classical reference is found for Vatapatradi Malahara in the classics. It is a modified formulation. The formulation composition of Vatapatradi Malahara is depicted in Table 2.

Method of preparation

The specified quantity of Vatapatradi Taila was taken in a dry clean vessel and heated over mild flame. When the temperature reaches 60-65 ^{0}C small pieces of bees wax was slowly added to the taila and stirred carefully until it dissolves completely. After complete dissolution of bees wax the contents were filtered through a clean cloth to remove the insoluble particles possibly present in the bees wax. The contents were stirred continuously till it becomes cool and later it was stored in a clean sterile container.

Analytical evaluation

The analytical evaluation includes organoleptic evaluation, Physico- Chemical analysis, Test for microbial contamination and HPTLC profile.

Organoleptic Parameters

These tests were performed by using the sensory organs. The Organoleptic characters including Rupa (Colour), Gandha (Odour) and Sparsha (Touch/ Consistency/ Texture) of the formulations were recorded.

Physico-chemical Parameters

The formulation was analysed for pH, Loss on drying, Rancidity, Total fat, Viscosity, Spreadability, Solubility parameters and Chromatographic profiles in SDM Center for research in Ayurveda & Allied Sciences, Udupi and Srinivas college of Pharmacy Valachill, Mangalore, Karnataka as a part of this study. All the tests were done as per the standard pharmaceutical laboratory process given in Laboratory guide for the analysis of Ayurveda and Siddha formulations[10]

pH of the formulation was measured by using Systronic Digital pH meter. Viscosity of the sample were measured using Brookfield Viscometer with spindle.

Spreadability

Spreadability was expressed in terms of time in seconds taken by two slides to slip off from the cream/ ointment, placed in between the slides under certain load. Lesser the time taken for separation of the two slides, better the Spreadability. Spreadability was calculated by using the formula:

$$S = ml/t$$

where, S- Spreadability, m- Weight placed on the upper slide, l – Length of the glass, t- Time for spreading in seconds.

Topical sensitivity test

This test was carried out to check any possibilities of developing skin irritation or other adverse reaction by topical application of the formulation. The formulation was applied to the elbow of the hand in selected human volunteers and observe for the side effects if any as set of parameters like skin inflammation, irritation, reddening of the skin (allergic reaction) etc.

Solubility tests

Solubility of the sample was determined by dissolving the sample in a series of test tubes containing solvents in the increasing order of polarity that is from non-polar to polar and the solubility was visually witnessed with the naked eye.

HPTLC Study

For the HPTLC study, chloroform extract were prepared and labeled as track 1-3 the HPTLC conditions were as below:

The plate was developed in Toluene: Ethyl acetate (9.0:1.0). The developed plates were visualized in UV 254, 366 nm and then derivative with vanillin sulphuric acid reagent and scanned under UV 254 and 366 nm. R_f values, colour of the spots and densitometric scan were recorded.

Test for microbial contamination

The Vatapatradi Malahara was evaluated for total bacterial count and total fungal count. Total aerobic microbial count was carried out by plate count method.

RESULT

The results obtained from the Pharmaceutical and Analytical study were depicted in the tables. Final yield of Vatapatradi Malahara were cited in Table 3, Figure 1 and 2. The Organoleptic parameters were presented in Table 4. The results of Physico-chemical analysis were shown in Table 5 and 6. Tests for Microbial contamination revealed that the product is free from bacterial and fungal contaminations. Results of tests were depicted in Tables 7, 8 and Figure 3 and 4.

HPTLC Study

HPTLC study revealed 3 spots when scanned under 254 nm and 5 spots under 366 nm. Densitometric scan of Chloroform extract of formulation was developed at 254 nm, 366 nm and the solvent system, Toluene:Ethylacetate (9.0:1.0) efficiently resolved the components present in the sample. In total 9 and 2 peaks were obtained at 254 nm and 366nm respectively in the Chromatogram. HPTLC Profile depicted in Table 9 and photo documentations were presented in Figure 5 and densitometric scan of Chloroform extract of the formulation were presented in Figure 6 and 7.

Table 1: Ingredients of Vatapatradi Taila

S.No.	Ingredients	Botanical name	Family	Part used	Quantity used
1.	Vatapatra	*Ficus benghalensis* Linn.	Moraceae	Ripened leaf	100g
2.	Jati	*Jasminum grandiflorum* Linn.	Oleaceae	Leaf	100g
3	RakthaChandana	*Pterocarpus santalinus* Linn.	Fabaceae	Heart wood	100g
4.	Kushta	*Saussurea lappa* C.B. Clarke.	Asteraceae	Root	100g
5.	Daru haridra	*Coscinium fenestratum*	Menispermaceae	Stem	100g
6.	Lodhra	*Symplocos racemosa* Roxb.	Symplocaceae	Bark	100g
7.	Sesame oil				2400ml
8.	Water				9600ml

Table 2: Composition of Vatapatradi Malahara

S.No	Ingredients	Proportion	Quantity taken
1.	Vatapatradi Taila	6 parts	1000ml
2.	Siktha Taila (Bees wax)	1 part	166.6g

Table 3: Depicting the final yield of Vatapatradi Malahara

Initial quantity of Vatapatradi Taila taken	1000ml
Quantity of Malahara obtained	1120g
Percentage of gain	12%

Table 4: Organoleptic characters

Parameters	Vatapatradi Malahara
Colour	Brownish
Odour	Characteristic
Consistency	Smooth, soft, homogenous paste
Texture	Smooth, non-gritty

Table 5: Physico-chemical profile

Parameters	Vatapatradi Malahara
pH	6.27
Loss on drying (%w/w)	1.16
Rancidity	Not oxidized
Viscosity (C_p)	73810
Spreadability (gm.cm/sec)	17.16

Table 6: Solubility parameters of Vatapatradi Malahara

	Hexane	Toluene	Diethyl ether	Ethyl acetate	Chloroform	Ethanol	Methanol	Water
V.M.	+	+	+	**+(Slightly)**	+	-	-	-

V.M.-Vatapatradi Malahara

Table 7: Total fungal count of Vatapatradi Malahara

S.No	Dilutions	Number of Colonies (NOC)			CFU/g
1	1/10 (10^{-1})	0	0	0	0
2	1/100 (10^{-2})	0	0	0	0
3	1/1000 (10^{-3})	0	0	0	0

CFU-Colony forming Units

Table 8: Total bacterial count of Vatapatradi Malahara

S.No.	Dilutions	Number of Colonies (NOC)			CFU/g
1	1/10 (10^{-1})	0	0	0	0
2	1/100 (10^{-2})	0	0	0	0
3	1/1000 (10^{-3})	0	0	0	0

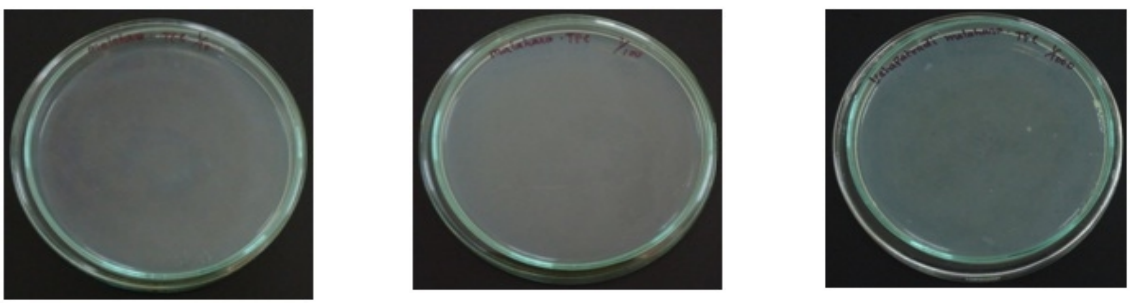
CFU-Colony forming Units

Table 9: HPTLC profile of the Vatapatradi Malahara (V.M.)

Track	Mobile phase	Visualization under U.V. Radiation				Post derivatisation	
	Toluene: Ethyl acetate (9.0: 1.0)	254 nm		366 nm			
		No. of Spots	R_f	No. of Spots	R_f Values	No. of Spots	R_f Values
V.M.		3	0.62, 0.73, 0.83	5	0.27, 0.43, 0.60, 0.76, 0.92	12	0.17,0.25,0.33, 0.42,0.51,0.56, 0.65,0.69,0.78, 0.81,0.84,0.93

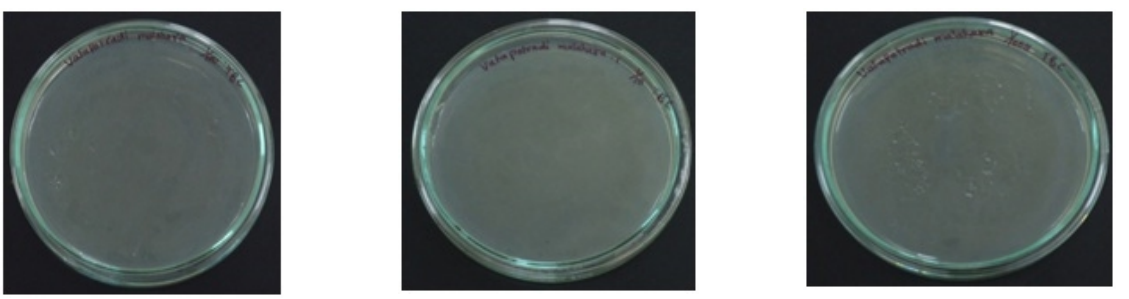
Figure 1: Vatapatradi Taila

Figure 2: Vatapatradi Malahara



10^1 **10^2** **10^3**

Figure 3: Total Fungal Count of Vatapatradi Malahara



10^1 **10^2** **10^3**

Figure 4: Total Bacterial count of Vatapatradi Malahara

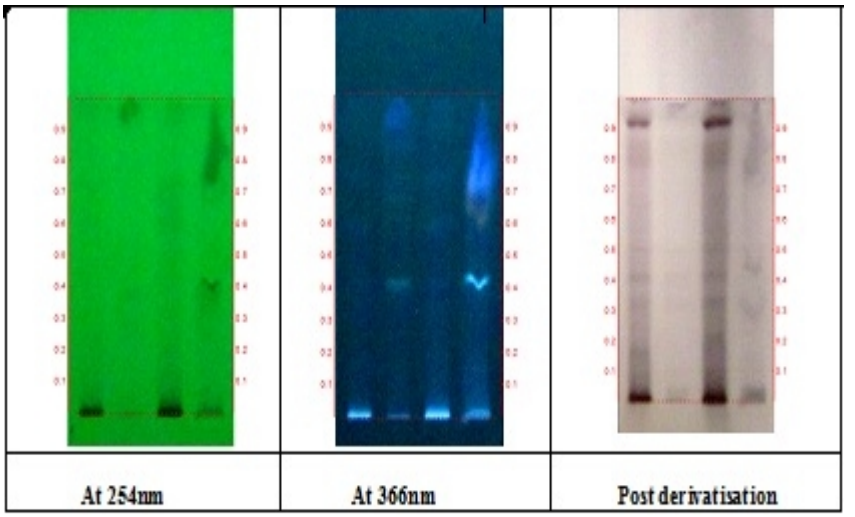
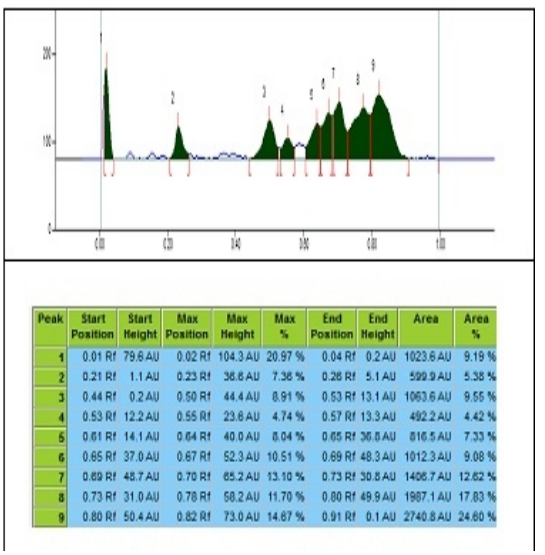
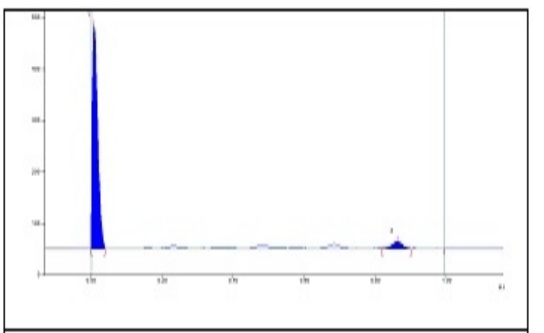


Figure 5: HPTLC Photo documentation of Chloroform extract of Vatapatradi Malahara



Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01 Rf	79.6 AU	0.02 Rf	104.3 AU	20.97 %	0.04 Rf	0.2 AU	1023.6 AU	9.19 %
2	0.21 Rf	1.1 AU	0.23 Rf	36.6 AU	7.36 %	0.26 Rf	5.1 AU	599.9 AU	5.38 %
3	0.44 Rf	0.2 AU	0.50 Rf	44.4 AU	8.91 %	0.53 Rf	13.1 AU	1063.6 AU	9.55 %
4	0.53 Rf	12.2 AU	0.55 Rf	23.6 AU	4.74 %	0.57 Rf	13.3 AU	492.2 AU	4.42 %
5	0.61 Rf	14.1 AU	0.64 Rf	40.0 AU	8.04 %	0.65 Rf	36.8 AU	816.5 AU	7.33 %
6	0.65 Rf	37.0 AU	0.67 Rf	52.3 AU	10.51 %	0.69 Rf	48.3 AU	1012.3 AU	9.08 %
7	0.69 Rf	48.7 AU	0.70 Rf	65.2 AU	13.10 %	0.73 Rf	30.8 AU	1406.7 AU	12.62 %
8	0.73 Rf	31.0 AU	0.78 Rf	58.2 AU	11.70 %	0.80 Rf	49.9 AU	1987.1 AU	17.83 %
9	0.80 Rf	50.4 AU	0.82 Rf	73.0 AU	14.67 %	0.91 Rf	0.1 AU	2740.8 AU	24.60 %

Figure 6: Vatapatradi Malahara at 254nm



Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	0.0 AU	0.01 Rf	433.4 AU	96.79 %	0.04 Rf	1.4 AU	4684.4 AU	93.70 %
2	0.82 Rf	0.7 AU	0.86 Rf	14.4 AU	3.21 %	0.90 Rf	0.5 AU	328.4 AU	6.30 %

Figure 7: Vatapatradi Malahara at 366 nm

DISCUSSION

Vatapatradi Taila was prepared using the ingredients mentioned for Vatapatradi Lepa. Taila was prepared as per the ratio of classical Taila Kalpana. As per the classical reference Vata patra *(Ficus benghalensis* Linn) and Jati Patra (*Jasminum grandiflorum* Linn.) were taken in fresh form and remaining were taken in dry form. The Malahara was then prepared by the addition of bees wax in the ratio of 1:6 following the principle of Siktha Taila. The colour of the final product was dark brown, may be due to the colour of the Vatapatradi Taila. Addition of bees wax to the oil is preferred between 60-65 ^{0}C as melting point of bees wax lies between 60-70 ^{0}C and also increased temperature will not yield a quality product.

Organoleptic inspection of topical formulations is very much mandatory with regards to their physical stability. It provides evidence of physical instability if present in the product, like formation of agglomerates and grittiness; any discolouration; emulsion breakdown; growth, shrinking due to evaporation of water or evidence of microbial growth. From the data of organoleptic analysis of the formulations, it is clearly evident that all the parameters were found to be satisfactory.

Analytical study revealed that the pH was 6.27 which lies in the normal skin pH range (5 and 6.5). The pH of the product can influence not only solubility and stability but also affect its potential to cause skin irritation. Since the pH of the formulation was within the acceptable range it did not produce any skin irritation. Loss on drying gives a good measure of moisture content, the sample showed LOD 1.16% indicating traces of moisture content in the sample. The product found to be non-oxidized indicating the product stability. Viscosity of the product was found to be slightly high may be due to the thick consistency of the product. Spreadability of the product was found to be 17.16. Spredability is a measure denotes the extent of area to which the topical application readily spreads on

application to the skin. HPTLC study revealed 3 spots when scanned under 254nm and 5 spots under 366nm. The formulation was subjected for microbial contamination test to rule out the presence of pathogens in the preparation which may affect the efficacy and stability of the product. The test revealed that the sample was free from bacterial and fungal contamination indicating it can be used safely in therapeutics.

CONCLUSION

Present study focuses modification of Lepa yoga into a convenient form of Malahara with due consideration for acceptability, enhancement of the shelf life and better presentation of the product. The principle of Siktha Taila was adopted where Vatatpatradi Taila was prepared first followed by addition of bees wax in the ratio of 1: 6. This conventional form was found to be non-irritant and free from bacterial and fungal contamination. The other physico- chemical parameters were found to be in the acceptable range. This form may replace the classical Lepa form. HPTLC report revealed the presence of active constituents. As no analytical standards are available till date on this modified form it is not possible to compare with any standards. The current data can be considered for future studies. The therapeutic potentials may encourage the researchers to explore it for its commercial viability.

ACKNOWLEDGEMENT

The authors are thankful to Dr. Vinayachandra Shetty, Principal and Professor, Alva's Ayurveda Medical College and Hospital, Moodbidri, Dr. M.S. Krishnamurthy, HOD and Professor, Dept. of Bhaishajya Kalpana, Dr.Subramanya Padyana HOD and Professor, Dept. of Dravya Guna, Dr. Ravi rao Professor, Dept. of Dravya Guna, Alva's Ayurveda Medical College Moodbidri, and the staffs of SDM Center for Research and Allied Sciences, Udupi, Karnataka for providing facilities to conduct analytical tests and also for their valuable guidance.

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Cite this article as:

N. Nayana, B.K. Prashanth. Formulation development and preliminary physico-chemical characterization of vatapatradi malahara: A modification. Int. J. Res. Ayurveda Pharm. 2015;6(6):676-681 http://dx.doi.org/10.7897/2277-4343.066126

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