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PHARMACEUTICO -ANALYTICAL STUDY OF RUDRA TAILA

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ABSTRACT

Sneha kalpana is one of the unique and commonly prescribed *Ayurvedic* dosage forms in day-to-day practice having increase potency, palatability, shelf life etc. Although varities of *Snehas* are described in Ayurvedic texts, the most common amongst them are *Taila & Ghrita kalpana*. The research work entitled "**A Pharmaceutico - Analytical Study of *Rudra Taila* and Its Clinical Efficacy on *Vicharchika* W.S.R. To Eczema**." was planned to standardize as per the reference of *Bhaishajya Ratnavali*. the sample was analyzed based on Organoleptic Parameters, i.e., Appearance, Colour, Odour, Touch, etc. and Physico-chemical Parameters i.e., Foreign Matter, Specific gravity, Saponification Value, Peroxide Value, Mineral oil Test, Viscosity, Total fatty Matter, Refractive Index, Rancidity, Acid Value, Iodine Value. The findings for these parameters were found to be satisfactory for quality assurance. Assay of heavy metals (Pb, Cd, As, Hg), Total bacterial count and Total fungal count are under the permissible limit depicted in the study. Specific pathogens and aflatoxins (B1, B2, G1, G2) are absent in all samples. HPTLC is an important tool to generate the standardization parameter for quality control purposes. Sample was analysed on different wavelengths 510 nm, 366 nm (Long) & 254 nm (Short). It confirmed 2 distinct spots at 510 nm, 5 distinct spots at 366 nm and 11 spots at 254 nm of *Rudra Tail*.

Keywords: *Sneha Kalpana, Rudra taila, vicharchika.*

INTRODUCTION

Ayurveda the science of life, uses natural resources to fulfill the fundamental objectives i.e., *Swasthya Rakshana* and *Vikar Prashamana*.1 Ayurveda has given greatest emphasis to comprehensive knowledge of drugs. This science of manufacturing drugs is classified under two branches as *Rasa Shastra & Bhaishajya Kalpana. Bhaishajya kalpana* is a branch dealing with formulations mainly of herbal origin. *Panchavidha kashaya kalpana* such as *Swarasa, Kalka, Kwatha, Hima & Phanta* are the basic pharmaceutical preparations described in *Ayurvedic* Pharmaceutics and used since ancient times in some or other form to treat various diseases. Thus, in this way they are serving to human species and also fulfilling the aim of *Ayurveda* to keep human being healthy. The drug having quality to produce *Arogya* is the best drug as per ancient *Acharya*. 2 Keeping this view in mind a number of preparations known as secondary kalpanas have been derived from these five basic preparations e.g., *Asav Arishta, Lepa, Churna, Vati, Sneha kalpana* etc.

Sneha kalpana is one of the unique and commonly prescribed *Ayurvedic* dosage forms in day-to-day practice having increase potency, palatability, shelf life etc. Sneha Siddha (fat soluble) drugs have better pharmacokinetic action in comparison to other dosage forms, because the use of *Taila* base is presumably to extract or hold lipid soluble active ingredients from the herbal drugs used and these lipid soluble substances readily permeate into the bio membrane of cells due to its lipid nature.

Contemplation of ancient literature reveals that Taila are predominately used for internal and external application. Although, Acharyas were fully conscious of the standards for quality and shelf-life of Ayurvedic formulations and quality control such as *Sneha Siddhi Pareeksha* have been described in ancient texts.

Rudra Taila is an example of *Sneha Kalpana*. *Rudra Taila* is mentioned in *Bhaishajya Ratnavali*. Many formulations are referenced in many *samhitas* and *granthas*, but only a few are commercially available to treat certain diseases, as well as to know and validate their clinical effects as described in texts.

I finalized *snehakalpana* for my dissertation work while keeping all of these considerations in mind.to ensure the quality of selected *snehakalpana*, I decided to develop standard operating procedure standard criteria. Because the preparation was unavailable in the market, I decided to conduct an analysis of it.

Need of the study

Rudra Taila was chosen for research because *vicharchika* is the *rogadhikar* of this *taila*. *Vicharchika* degrades not just a person's appearance but also their selfconfidence,and no medical research has yet produced a permanent, safe, and complete solution for the disease.

Aims and Objectives: -

The main study was carried with the following aims and objects –

1.To standardize the suitable method of preparation of *Rudra Taila*

2.To prepare *Rudra Taila* according to classical text.

3.To analyze organoleptic and physico-chemical parameters of *Rudra Taila*.

Material and Methods: -

1) Pharmaceutical study

2) Analytical study

Pharmaceutical study: -

Collection of raw drugs-

All raw medications specified in this preparation were obtained from the M.M.M. Govt. Ayurveda College, Udaipur pharmacy, where the procedure is carried out. The Ketaki flower was collected from a temple near Badi Dam in Udaipur, while the Nalika flower was collected from a garden in our college campus.

Place of study- Pharmacy of M.M.M govt. college, Udaipur.

In this study, the following processes were carried out: -

1.*Taila Murchchhana*

2.Taila kalpana nirmaan

Tila Taila murchchhana

***Reference: Bhaishajya Ratnavali,*5/1268** [1]

TableNo.1: -Showing Ingredients of *Tila Taila Murchchhana*.

S.No	Name of Drugs	Part used	Quantity
1.	*Manjistha*	*Root*	625gm
2.	*Nagarmotha*	*Rhizome*	156gm
3.	*Haritaki*	*Fruitpulp*	156gm
4.	*Amlaki*	*Fruitpulp*	156gm
5.	*Vibhitaki*	*Fruitpulp*	156gm
6.	*Hriver*	*Roots*	156gm
7.	*Vatankur*	*Aerialroots*	156gm
8.	*Haridra*	*Rhizomes*	156gm
9.	*Lodhra*	*Bark*	156gm
10.	*Nalika*	*Stem*	156gm
11.	*Ketaki*	*Flower*	156gm
12.	*Tiltaila*	*Seedoil*	10lt
13.	*Water*	-	40lt

Procedure:

- After making all of the *kalka dravyas* into *yavkut* form, prepare the *kalka*.
- *Tila Taila* was placed in a steel vessel and cooked over *madhyamagni* till the water content was completely evaporated.
- After a brief cooling period and stirring, the *kalka*(balls) were added to the *Taila* followed by the addition of water.
- It is heated with intermediate stirring after the addition of water.
- The heating procedure continued until *Sneha siddhi lakshana* appeared, after which the vessel was removed from the fire and *Taila* was filtered through a clean cloth while still hot.
- After cooling, *Murchhita Tila Taila* was stored in a different container.

Observations during *Murchchhana:*

- Specific smell of *Tila Taila* was smelt.
- Huge froth appears when *kalka* was added.
- Colour of *Taila* was changed into reddish brown.
- During *Sneha Paka*, a bubble and a sound arise. During the heating procedure, the smell of *kalka dravya* emerges.
- At the top of the vessel, a layer of *Taila* remains.
- *Taila* has thickened in consistency.
- A layer of fine particles of *kalka* occurred over *Sneha* during *Snehapaka.*
- After *Murchchhana*, more water was used to extract oil from the *kalka*.
- In the final stage the sound disappeared and frothing subsided.

Precautions:

- Continuous stirring was carried out to protect the burning of *Kalka* especially in the last stage.
- The large vessel was used to prevent *Taila* loss, especially when *kalka* boluses were introduced, creating Phenodgam in *Taila*.
- When froth appears in the *Taila*, the temperature was maintained to protect the *Taila* from coming out from vessel.

TableNo.2: -Showing observation of total loss in *Tila Taila Murchchhana*.

S.No	Initial Amount of *Tila Taila*	Obtained *Murchchhita Tila Taila*	Loss	% of Loss
1.	10kg	9.5kg	0.5kg	5%

Rudra Taila Nirmaan

त्रिफला निम्बभण्टाकीबृहत्यः सपुनर्नवाः। हरिद्रे वृषनिर्गुण्डयौ पटोलकनकाह्वयौ ॥ हरितालं शिलाकुष्ठो लाङ्गलीदाडिमाह्वयौ । अपामार्ग विषं चैव जयन्ती पूतिकटफलौ ॥ एषां कर्षद्वयैः कल्कैस्तैलप्रस्थं विपाचयेत् । चतुर्गुणे गुडुच्याश्च रसै वैद्यः समाहितः॥ चतुर्गुणन्तु गोक्षीरं वृषपत्ररसं तथा । दत्वाऽवतारयेद्वैद्यो रूद्रमन्त्रं समाजपेत् ॥ दद्रुकुष्ठं कुष्ठव्रणं विसर्पं विद्रधिं तथा । नाड़ीव्रणं व्रणं घोरं वातरक्तं सुदुजयं ॥ सन्निपातज्वरं चैव शिरोरोगं । च गलगण्डंच श्लीपदन्त्वर्बुदं तथा॥ वातरोगानशेषांश्च अन्त्रवृद्धिं सुदारूणं । पीनसश्वासकासश्च सुदारूण भगन्दरम् ॥ उपदंश महाघोरं चक्षुःशूलंच नाशयेत् । चर्मोत्थान् सर्वरोगांश्च तैलमेतद्विनाशयेत् ॥ रुद्रतैलमिदंनाम्ना स्वयं रूद्रेण भाषितं ॥ भै.र. (54 / 328-336)

Reference of *Rudra Taila* is *Bhaishajya Ratnavali*

Equipment's: Same as *Taila Murchchhana.*

TableNo.3: -Showing the name of ingredients and their quantity used to prepare *Rudra Taila*.

S.No	Name	Part used	Quantity
1	***Moorchitatilataila***		9.5kg
2.	Water		40ltr
3.	*Haritaki*[2]	*Fruit*	312gm
4.	*Vibhitaki*[3]	*Fruit*	312gm
5.	*Amlaki*[4]	*Fruit*	312gm
6.	*Neem*[5]	*Bark*	312gm
7.	*Kantkaari*[6]	*Root*	312gm
8.	*Brahati*[7]	*Root*	312gm
9.	*Punarnava*[8]	*Mool*	312gm
10.	*Haridra*[9]	*Rhizome*	312gm
11.	*Daruharidra*[10]	*Stem*	312gm
12.	*Vasa*[11]	*Leaves*	312gm
13.	*Nirgundi*[12]	*Leaves*	312gm
14.	*Patolpatra*[13]	*Leaves*	312gm
15.	*Krishnadhatur*[14]	*Leaves*	312gm
16.	*Hartaal*[15]	*Mineral*	312gm
17.	*Manahshila*[16]	*Mineral*	312gm
18.	*Kushtha*[17]	*Root*	312gm
19.	*Langli*[18]	*Root*	312gm
20.	*Dadima*[19]	*Seed*	312gm
21.	*Apamarga*[20]	*Wholeplant*	312gm
22.	*Vatsnaabh*[21]	*Leaves*	312gm
23.	*Jayanti*[22]	*Leaves*	312gm
24.	*Karanj*[23]	*Seed*	312gm
25.	*Kaayphal*[24]	*Fruit*	312gm
26.	*Guduchiswaras*[25]	*Stem*	40ltr
27.	*Cowmilk*		40ltr
28.	*Vasaswaras*		40ltr

PROCEDURE:

- All *Kalka dravyas* were turned in to *ya-vakut* form.
- *Murchchhita Tila Taila* was placed in a steel vessel and heated over *Madhyam Agni* till the moisture content was completely evaporated.
- Temperature was reduced after complete evaporation of moisture, and boluses of *Kalka* were added to the *Murchchhita Tila Taila* with constant stirring.
- The *Taila* contained three types of *Dra-vadravayas: Guduchiswaras, Cow Milk,* and *Vasa Swaras.*
- *Drava dravya* (40ltr *Guduchi Swaras*) was

first added to the oil.

- *Again, Mandagni* heat was applied while stirring.
- After that 40ltrs. Cow milk was added to the oil.
- *Again, Mandagni* heat was applied while stirring.
- After that 40ltrs *Vasa Swaras* were added to the oil.
- The heating process continued till the *Taila* became free from water and got the *Sneha Siddhi Lakshanas.*
- The vessel was removed from the fire when all the properties of Sneha Siddhi (at *Madhyama Paka*) were observed, and the *Siddha Taila* was filtered through a clean cloth in the warm stage.
- After *Paka*, additional water was used to extract oil from the *kalka.*
- This oil was filled in plastic bottles measuring 50ml. and 100ml. to protect from moisture.

Observations:

- Brownish colour was observed at the time of *Taila Paka* when *Agni* was kept low.
- *Phenudgham* was observed when *Agni* was increased.
- During *Taila Paka* all *Sneha Siddhi Lakshanas* were observed. Precautions:
- To avoid *Kalka Dravyas* sticking to the bottom of the pot, a large vessel was used, and regular stirring was done during *Tailapaka*.
- Average percentage of loss as per volume and weight: -Initial amount (*taila*)9.5kg
- Medicated tail obtained - 8kg 900gm.
- Loss–600gm
- % of loss 6.32%

Analytical study

Parameters are taken according to "Protocol of testing of Ayurvedic, Siddha and Unani Medicines", written by Dr. D.R. Lohar, and API published by Government Of India, Department of Ayush, Ministry of Health and Family Welfare and Pharmacopoeial Laboratory For Indian Medicines, Ghaziabad.

The tests were conducted at **SR Labs, Jaipur**. Following test were conducted: -

Results:

Table No. 4: -Showing result of analytical study.

Parameters	Rudra Taila
General description	
- Color	Brown
- Odour	Characteristic
- Appearance	Oily liquid
Physical analysis	
- Viscosity	43.03 cP
- Refractive index	1.486
- Specific gravity	0.9574
Chemical analysis	
- Acid value	0.67
- Saponification value	274.66
- Iodine value	6.35
- Rancidity	Absent
- Total fatty matter	99.72 %w/w
- Mineral oil test	Absent
- Test of arsenic	67.68 mg/kg

- HPTLC	Data attached
- Aflatoxins	Absent
Microbial contamination	
Total bacterial count	<10 cfu/ml
Total fungal count	<10 cfu/ml
- Peroxide value	1.28

Determination of HPTLC Profile: -

High Performance Thin Layer Chromatography is a sophisticated analytical technique, which is amenable to automate different steps, to increase the resolution achieved and to allow more accurate quantitative measurements and computerization.

Significance: -It is more rapid, inexpensive, efficient and sensitive than other chromatographic techniques and quantification of ingredients can be more precise.

Conditions:

- Stationary phase: pre-coated silicage l60F254 aluminium plates
- Mobile phase: Sample will be used for this ,ashere:-
- Rudra Taila-Toluene: Ethyl acetate: formic acid (9:1:0.1)
- Chamber Saturation Time: 20mins.
- **Test Solution:**

❖ 1 gm of sample dissolved in methanol and then filter the liquid extract. Make the volume up to 10ml with methanol. (For Solid samples).

❖ 0.5 gm of sample dissolved in methanol and then filtered the liquid extract. Make the volume up-to10ml with methanol. (For Oil or Ghrita sample) Take 2gm sample then dried the sample then dissolvedinmethanol and then filter the liquid extract. Make the volume up to 10ml with methanol. (For Liquid Sample) Visualization & Detection: 254nm,366nm and 510nm.

❖ Derivatizing Agents: 5 % v/v Methanolic Sulphuric Acid.

DISCUSSION

Pharmaceutical study-

There are some formulations that contain herbal as well as mineral components as ingredients. *Rudra Taila* is *Snehakalpana* said to be used for treating *Vicharchika* only by external administration. *Rudra taila* has 23 *kalka dravya Haritaki, Vibhitaki, amalaki, Neem, Kantkaari, Brahati, punarnava, haridra, daaruharidra, vasa, nirgundi, patolapatra, dhatura, kushtha, langli, dadima, apamarga, vatsanaabha, jayantipatra, latakaranjbeej, kaayaphal, hartaal, manahshilla*, (21 herbs and 2 mineral), and 3 *Drava Dravayas (Guduchi Swaras*, Cow Milk, *Vasa Swaras), Tila Taila* and water. As *Taila* is prepared in two steps first one *Murchchhana* and second one *Sneha kalpana Nirmaan*. First of all, *Tila Taila Murchchhana* was done and after then *Taila Paka* procedure was started keeping general concepts of *Taila Paka* in center. So *kalka* was kept 1/4th of the quantity of *Sneha* and 4 times water to the quantity of *Sneha* was used for *Tailapaka.*

Standardization and analytical study-

In various *Samhita* and *Rasagrantha* several signs/*lakshan* of steps of any procedure running or completed are mentioned to standardize the procedure as *Mridupaka Lakshan, Khara Paka lakshan* etc. for *Sneha Kalpana*. Time taken to complete *Sneha Paka* using different *Dravadravya* are also mentioned to standardize the procedure. Now a days we are using parameters which can be expressed numerically to standardize the procedure as number of hours, quantity in metric parameters and many more. Even after describing SOPs, *Siddhi Lakshan* is also mentioned in *Grantha*. In the same way I standardized the operating procedure as described in pharmaceutical section as per modern parameters and after that analysis of the sample of formed product 100 ml. was performed in SRLabs, Jaipur in order to check quality of the product.

When derivatized TLC plates prepared by three test sample solutions (10µl, 15 µl&20µl) of the oil i.e., *Rudra Taila* is visualized and scanned in UV at

254nm, 366nm and 510nm to generate the scanning chromatogram.

TableNo.5: -Showing number of peaks found in HPTLC of sample:

S. No	Sample	U.V Wavelength	No. of peaks in 3samples		
			10µl	15µl	20µl
1.	*Rudra Taila*	254nm	11	14	14
2.	*Rudra Taila*	366nm	5	5	9
3.	*Rudra Taila*	510nm	2	4	4

TableNo.6: -Showing number of peaks found in HPTLC of sample after spray:

S. No	Sample	U. VWavelength	No. of peaks in 3 samples after spray		
			10µl	15µl	20µl
1.	Rudra Taila	254nm	15	18	19
2.	Rudra Taila	366nm	15	18	19
3.	Rudra Taila	510nm	17	15	17

The number of peaks was representing the presence of various ingredients in the sample. Extraconstituents are found that may be because of ingredients of *Murchchhana Dravya*. Specific HPTLC fingerprinting was generated for sample as attached.

CONCLUSION

Rudra Taila has 23 *kalka dravya* (21 herbs and 2 minerals), 3 *Drava Dravyas*, *Tila Taila* and water. Nearly 11% loss was found in pharmaceutical preparation of oil that includes loss during *Murchchhana* and *Kalpana Nirmaan*. If classical procedures are followed as they are, then we find all modern analytical parameters within normal range.

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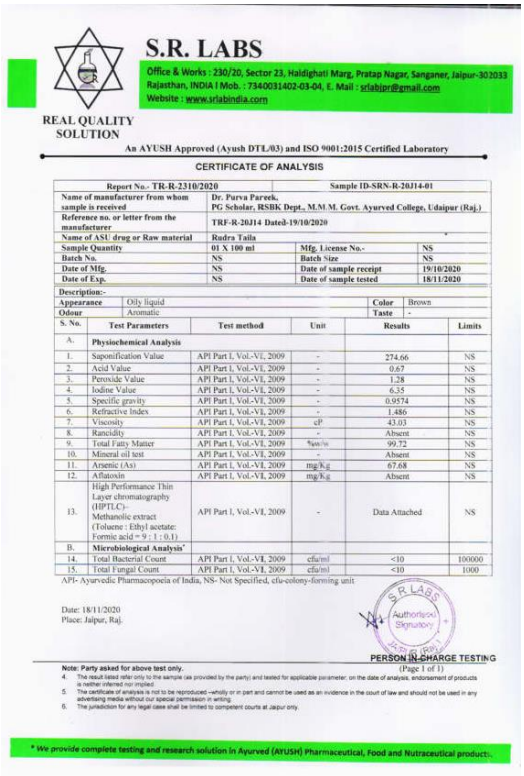

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REAL QUALITY SOLUTION

An AYUSH Approved (Ayush DTL/03) and ISO 9001:2015 Certified Laboratory

CERTIFICATE OF ANALYSIS

Report No.- TR-R-2310/2020			Sample ID-SRN-R-20J14-01
Name of manufacturer from whom sample is received	Dr. Purva Pareek. PG Scholar, RSBK Dept., M.M.M. Govt. Ayurved College, Udaipur (Raj.)		
Reference no. or letter from the manufacturer	TRF-R-20J14 Dated-19/10/2020		
Name of ASU drug or Raw material	Rudra Taila		
Sample Quantity	01 X 100 ml	Mfg. License No.-	NS
Batch No.	NS	Batch Size	NS
Date of Mfg.	NS	Date of sample receipt	19/10/2020
Date of Exp.	NS	Date of sample tested	18/11/2020

Description:-

Appearance	Oily liquid	Color	Brown
Odour	Aromatic	Taste	-

S. No.	Test Parameters	Test method	Unit	Results	Limits
A.	**Physiochemical Analysis**				
1.	Saponification Value	API Part I, Vol.-VI, 2009	-	274.66	NS
2.	Acid Value	API Part I, Vol.-VI, 2009	-	0.67	NS
3.	Peroxide Value	API Part I, Vol.-VI, 2009	-	1.28	NS
4.	Iodine Value	API Part I, Vol.-VI, 2009	-	6.35	NS
5.	Specific gravity	API Part I, Vol.-VI, 2009	-	0.9574	NS
6.	Refractive Index	API Part I, Vol.-VI, 2009	-	1.486	NS
7.	Viscosity	API Part I, Vol.-VI, 2009	cP	43.03	NS
8.	Rancidity	API Part I, Vol.-VI, 2009	-	Absent	NS
9.	Total Fatty Matter	API Part I, Vol.-VI, 2009	%w/w	99.72	NS
10.	Mineral oil test	API Part I, Vol.-VI, 2009	-	Absent	NS
11.	Arsenic (As)	API Part I, Vol.-VI, 2009	mg/kg	67.68	NS
12.	Aflatoxin	API Part I, Vol.-VI, 2009	mg/kg	Absent	NS
13.	High Performance Thin Layer chromatography (HPTLC)- Methanolic extract (Toluene : Ethyl acetate: Formic acid = 9 : 1 : 0.1)	API Part I, Vol.-VI, 2009	-	Data Attached	NS
B.	**Microbiological Analysis'**				
14.	Total Bacterial Count	API Part I, Vol.-VI, 2009	cfu/ml	<10	100000
15.	Total Fungal Count	API Part I, Vol.-VI, 2009	cfu/ml	<10	1000

API- Ayurvedic Pharmacopoeia of India, NS- Not Specified, cfu-colony-forming unit

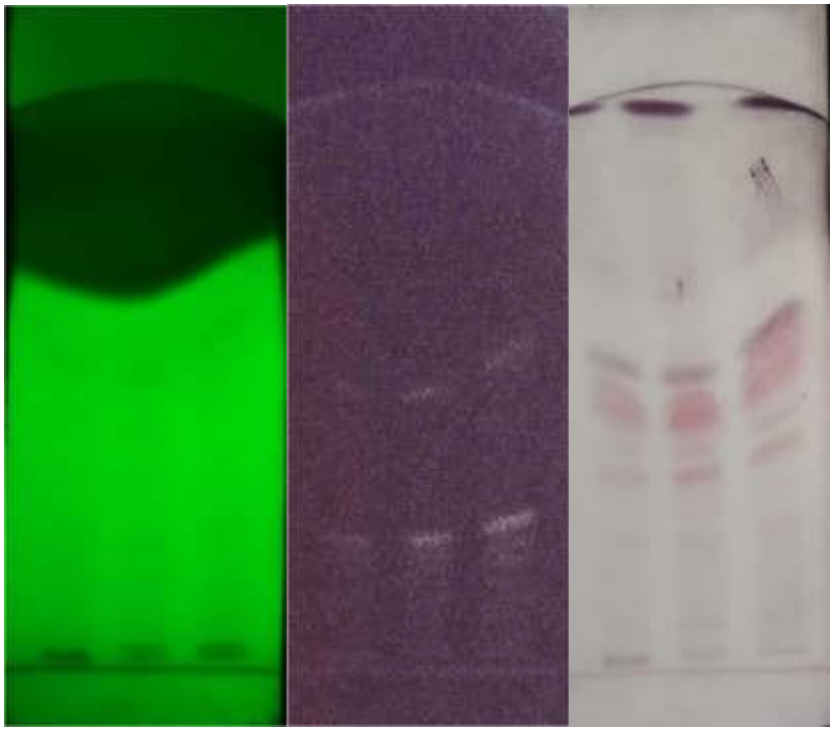
Date: 18/11/2020
Place: Jaipur, Raj.

Authorized Signatory
PERSON IN CHARGE TESTING

(Page 1 of 1)

Note: Party asked for above test only.
4. The result listed refer only to the sample (as provided by the party) and tested for applicable parameter, on the date of analysis, endorsement of products is neither inferred nor implied.
5. The certificate of analysis is not to be reproduced -wholly or in part and cannot be used as an evidence in the court of law and should not be used in any advertising media without our special permission in writing.
6. The jurisdiction for any legal case shall be limited to competent courts at Jaipur only.

* We provide complete testing and research solution in Ayurved (AYUSH) Pharmaceutical, Food and Nutraceutical products.



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