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Research Article

PHARMACEUTICO-ANALYTICAL STUDY OF *ROPANA TAILA* AND ITS MODIFICATION INTO THE OINTMENT

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ABSTRACT

One of the most widely used Ayurvedic dosage forms is *Sneha Kalpana*. An oleaginous medication is prepared through a pharmaceutical process, includes heating of materials (*Drava Dravyas*, *Kwatha, Kalka)* in a prescribed pattern for a preordain duration. This process ensures the extraction of chemical constituents into an oil or fat base. *Acharya Sushruta* mentioned *Ropana Taila* in *Sutrasthana* Ch36/25, which has wound healing activity. It contains *Haridra*, *Agaru, Daruharidra*, *Devdaru*, *Priyangu*, *Agaru*, *Lodhra*, *Tagara,* and *Tila Taila*. **Aim:** The aim of the study was to standardize the pharmaceutical process, perform possible analytical parameters and its modification into ointment with suitable excipients. **Methods:** The general method of preparation of *Taila Paka* according to the classical text has followed for the preparation of *Ropana Taila*. An attempt has made to develop suitable dosage foam, an ointment from *Ropana Taila*. The preliminary analysis of raw materials and *Ropana Taila* has carried out with reference to the API standards. Possible evaluation parameters of the ointment have studied. **Result**: Physico-chemical parameters for *Ropana Taila* included specific gravity, which founded 0.9128, refractive index 1.471, viscosity 37.85, iodine value 110; acid value 4.1, and saponification value 182.33 has noted. HPTLC showed variable numbers of spots when visualized at 254nm, 366nm, and 510nm wavelengths. pH, spreadability, extrudability of ointment founded 6.5, 78mm, good respectively. **Conclusion:** The ratio adopted for the preparation of *Ropana Taila* ointment has found suitable as the ointment fulfilled the evaluation parameters for the quality of the ideal ointment.

INTRODUCTION

In Ayurveda, the process of combining the medications into various forms by various pharmaceutical operations is referred as *Bhaishajya Kalpana. Sneha Kalpana* is a process to get lipid and water-soluble constituent of plant in oil or fat base. *Sneha* (*Taila*) served as both a vehicle and base. Using *Taila* as a base to extract the chemical constituents of the drugs that add into the *Taila,* increase the therapeutic potency of the preparation. *Ropana Taila* is mention in *Sushruta Samhita Sutrasthana* Ch. 36/25. [1]

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It is used in wound healing. It is prepared by general method of preparation of *Taila Paka* mention in classical texts.

Three batches of *Taila* and ointment were prepared. Same resemblances between two or more batches of the same medication are essential in pharmaceutical operations. In order to obtain this resemblance Standard Manufacturing Procedure (SMP) is applied. *Ropana Taila* contains *Haridra, Daruharidra, Devdaru, Agru, Priyangu, Lodhra, Tagara*, and *Tila Taila*. Sometime dosage form as if *Taila* and *Ghrita* are not convenient or suitable for external application especially in case of wound. Classical texts provides a nice description of *Taila* as an external application. But now a day's patients may find its way of application inconvenient. Generally, *Malahara*, ointment, cream and gel are ideal dosage conversation for any *Taila* and *Ghrita* formulation. The main aim for the dose modification

is patient's complacence and eases of the application with derisible therapeutic effect. In light of this, an approach has made to modify the *Taila* into ointment analytical study including preliminary physico-chemical analysis and HPTLC performed for both *Taila* and ointment, for setting standards for its quality.

AIMS AND OBJECTIVE

1. Pharmaceutical study of *Ropana Taila* and modify into ointment.
2. Physico-chemical analysis and chromatographic analysis of *Ropana Taila* and ointment.

MATERIALS AND METHODS

Following study was divided into two sections

1. Pharmaceutical Study 2. Analytical Study

1. Pharmaceutical Study

Collection and Authentication of Raw Materials

Haridra, Daruharidra, Devdaru, Agaru, Priyangu, Lodhra, Tagara, and *Tila Talia are* procured from the pharmacy at I.T.R.A. Jamnagar. Raw materials authenticated and identified macroscopically at I.T.R.A. Jamnagar in the department of pharmacognosy. Pharma grade excipients used in the ointment preparation purchased from market.

Methods

Ropana Taila was prepared in the Department of *Rasa Shastra* and *Bhaishajya Kalpana*, I.T.R.A., Jamnagar. Ointment was prepared in pharmaceutical technology laboratory at I.T.R.A Pharmacy.

Preparation of *Ropana Taila*

Equipment used

Wide mouth stainless steel vessel, *Khalwa Yantra*, cotton cloth, ladle, gas stove, mixture grinder.

Table 1: Ingredients for Preparation of *Ropana Taila*

S.No.	Components of *Sneha*	Ingredients	Latin/English name	Ratio (Quantity)
1.	*Kalka Dravya*	*Haridra*	*Curcuma Longa* Linn.	1/4th Part (Total 125 Each 18)
		Daruharidra	*Berberis Aristata* Dc.	
		Devdaru	*Cedrus Deodara* Roxb. Loud	
		Agru	*Aquilaria Agallocha* Roxb	
		Lodhra	*Symplocos Racemose* Roxb	
		Tagara	*Valeriana Wallichi*	
		Priyangu	*Callicarpa Macrophylla* Vahl	
2.	*Sneha Dravya*	*Tila Taila*	*Seasamum Indicum* L	1 Part (500ml)
3.	*Drava Dravya*	Water	-	4 Part (2000ml)

Procedure

- *Yavakuta* of all ingredients were pound in *Khalva Yantra* and processed in a mixer grinder to prepare a moderately fine powder. Powder was passes through sieve no. 44#. Moderately fine powder was taken in a mortar pestle and triturate with water to make a thick paste to form bolus of *Kalka*.
- *Tila Talia* in the above-mentioned quantity was taken in a stainless-steel vessel and heated over mild flame (85–100°C) till complete moisture evaporated, after slightly cooling (65–75°C), the boluses of *Kalka* were added to *Tila Talia* at 75°C. After mixing *Kalka* into *Talia,* water in mention quantity added at 72°C. Heating given maintaining the temperature 85-150°C, until *Sneha Siddhi Lakshanas* has obtained.
- The heating duration was adjusted, and the mixture has left undisturbed after stopping heating until the next heating. The *Talia Paka* was complete in two days.
- After observing *Sneha Siddhi Lakshana*, heating has stopped, and *Talia* filtered through two-folded cotton cloth, measure and stored in dry, airtight container with proper labeling. Likewise, three batches of *Ropana Taila* were prepared to ensure standard manufacturing procedures.

Observation

- Prepared *Kalka* was dark brown in color. *Kalka* had the characteristic smell of all ingredients, especially the very strong smell of *Tagara* observed.

- When *Tila Talia* heated to remove moisture, the typical smell of *Tila Talia* and slight smoke were observe. At the end, point approached *Kalka* began to accumulate in the center, forming a lump like structure. At the stage of *Madhyam Paka*, *Kalka* when rolled between fingers, formed wicks. *Kalka* became non-sticky. When the wick lit, it burned silently, producing no crackling sound. *Phenodgama* (foaming) started appearing on the surface of *Talia*.
- The final product was greenish-yellow in color with a characteristic smell of ingredients.

Result

Table 2: Result of Preparation of *Ropana Taila*

Observation	Batches			
	1	2	3	Average
Initial quantity	500ml	500ml	500ml	500ml
Final quantity	470ml	475ml	468ml	470ml
Total loss in (ml)	30ml	25ml	32ml	29ml
Total loss in (%)	6%	5%	6.4%	5.8%

Preparation of *Ropana Taila* Ointment

Equipment used

Mortar and pestle (porcelain), beaker (borosilicate), spatula, measuring cylinder (glass), water bath (12 holes), digital weighing balance, glass pipette.

Ingredients

Table 3: Formulation Composition of Ointment [1]

Sr.No.	Ingredients and Excipients	Use	Quantity
1.	*Ropana Talia*	API	50 Ml
2.	Emulsifying wax	Base	10 G
3.	White bees wax	Base	9 G
4.	White petroleum jelly	Base	9 G
5.	Soy lecithin	Emulsifier	1 Ml
6.	Glycerine	Humectant	3 Ml
7.	HEC	Gelling agent	0.5 G
8.	Polysorbate 80	Surfactant	0.5 Ml
9.	Distilled water	Vehicle	27 Ml
10.	Phenoxyethanol	Stabilizer	0.1 Ml

*API – Active Pharmaceutical Ingredient, * HEC- Hydroxyethyl cellulose

Procedure

- First glassware and equipments was clean and sterilized properly, to avoid any kind of microbial contamination.
- Oil Phase - Mention quantity of *Ropana Talia* and base (emulsifying wax, white bees wax and white petroleum jelly) taken in separate glass beaker then it was heated on water bath at 65°C. Mix *Tail* in base at the same temperature.
- Water Phase – Simultaneous, mention quantity of water has taken in beaker and heated on water bath at 65°C. When water was boiling, add glycerin, Tween 80 and HEC with stirring.
- Both phases were move into the mortar at same temperature (65°C), with continuous trituration. After cooling add stabilizer (phenoxyethanol) at room temperature (25°-30°C), and triturate the content until uniform mixture obtain. The finish product was stored in airtight PP, PET or HDPE container or in collapsible tube.

Observation

- *Ropana Talia* was greenish yellow in colour with specific smell. Final product was light yellow in colour. Ointment having specific smell of oil.
- Approximately 25 minute of continuous trituration is needed to obtain homogenous

mixture of both phases. Average time to finish the whole procedure was 1 hour.

Precaution

- Both phases should be mixed at same temperature (65°C) to avoid the phase separation. Trituration has been done continuous manner and in uniform direction to obtain homogeneous final product. Temperature should be maintained, and never increases more than 70°C, to get good quality yield.

Result

Table 4: Result of *Ropana Talia* Ointment

Batches	1	2	3	Average
Initial weight (g)	100 g	100 g	100 g	100 g
Final weight (g)	97.1 g	96.4 g	97 g	96.8 g
Loss (g)	2.9 g	3.6 g	3 g	3.1 g
Loss in %	2.9 %	3.6 %	3 %	3.1 %
Reason for loss	Due to sticking to the vessel			

Analytical Study

There is a need to set quality standards of any medicinal product. To achieve quality of the prepared dosage form, analytical study was performed. By performing the physico-chemical analysis, chemical changes of raw and final product after the process can observe.

Entire Analytical Study Divided in Following Parts

Raw Material Preliminary Physico-chemical Analysis

Physico-chemical parameters of raw materials include

- Total ash and acid insoluble ash [3]
- Alcohol-soluble extractive value and water-soluble extractive value [4]

Result

Table 5: Physico-Chemical Parameters of *Kalka Dravya*

Drug	Total Ash (%)	Acid Insoluble Ash (%)	Water-Soluble Extractive (%)	Alcohol Soluble Extractive (%)
Haridra	7.5	0.6	25.1	12.6
Daruharidra	13.5	1.5	11.75	15.23
Devdaru	1.7	0.91	30.45	42.24
Priyangu	5	0.98	28.3	35.9
Agaru	8.4	1.5	17.12	14.50
Lodhra	5.5	0.83	52.5	40.1
Tagara	9.01	7.02	25.4	30.98

Table 6: Physico-Chemical Parameters of *Tila Taila*

Parameters	Specific Gravity At 25° C	Refractive Index	Viscosity	Acid Value	Iodine Value	Saponification Value
Tila Taila	0.918	1.469	37.75	3.9	113	185

Finished Product Analysis

Organoleptic Characteristic

The organoleptic characteristics noted through sensory observation. It includes *Rupa* (colour), *Rasa* (taste), *Gandha* (odour) and *Sparsha* (texture).

Physico-Chemical Parameters

It included

- Specific gravity [5]
- Refractive index [6]
- Viscosity [7]
- Acid value [8]
- Iodine value [9]
- Saponification value [10]

Observation and Result

Table 7: Organoleptic Characteristic of *Ropana Taila*

Organoleptic Characteristic	Observation
Colour	Greenish yellow
Odour	Characteristic
Taste	Slightly astringent, bitter
Touch	Non-irritant

Table 8: Physico-Chemical Parameters of *Ropana Taila*

Parameters	*Ropana Taila*
Specific gravity At 25° C	0.9128
Refractive index	1.471
Viscosity	37.85
Acid value	4.1
Iodine value	110
Saponification value	182.33

Evaluation Parameters of *Ropana Taila* Ointment include

Colour, odour, consistency, pH, [11] spreadibility, [12] extrudability,[13] homogeneity,[14] washability[15]

Table 9: Result Obtain for *Ropana Taila* Ointment

Parameters	Observation
Colour	Light yellow
Odour	Characteristic
Consistency	Thick and little greasy
Texture	Smooth
pH	6.5
Spreadibility	78 mm
Extrudability	Good (>80% extrudability)
Homogeneity	Homogenous
Washability	Easily washable

High Performance Thin Layer Chromatography

Table 10: Data of Diagnosis of chromatogram of *Ropana Taila* and ointment

Ropana Taila				
Solvent System	**Wavelength**	**No. of Spots**	**R_f Value**	**Area Under Curve (%)**
Toluene : Ethyl Acetate: Hexane (6:3:1)	254	1	0.04	100
	366	3	0.04 0.42 0.49	13.87 38.34 47.79
	510	7	0.04 0.27 0.41 0.49 0.74 0.80 0.92	4.24 4.77 10.34 4.42 58.61 12.61 5.01

Ropana Taila Ointment				
Solvent System	**Wavelength**	**No. of Spots**	**R_f Value**	**Area Under Curve (%)**
Toluene: Ethyl Acetate: Hexane (6:3:1)	254	2	0.04 0.71	81.16 18.84
	366	2	0.04 0.58	48.80 51.20
	510	5	0.04 0.13 0.73 0.84 0.90	33.34 6.89 10.87 40.47 8.44

Fig 1: Raw material and Sequential Steps in the Preparation of *Ropana Taila*

1. *Lodhra*

2. *Daruharidra*

3. *Tagara*

4. *Haridra*

5. *Priyangu*

6. *Agaru*

7. *Devdaru*

9. Heating of *Tila Taila*

10. Adding *Kalka* into *Taila*

11. Adding Water into *Taila*

12. Appearance of Foam

13. *Varti* of *Kalka* Formation

14. Filtration of *Taila*

15. *Ropana Taila*

Fig 2: Sequential Steps in the Preparation of *Ropana Taila* Ointment

1. Ingredients

2. Heating On Water Bath At 65°C

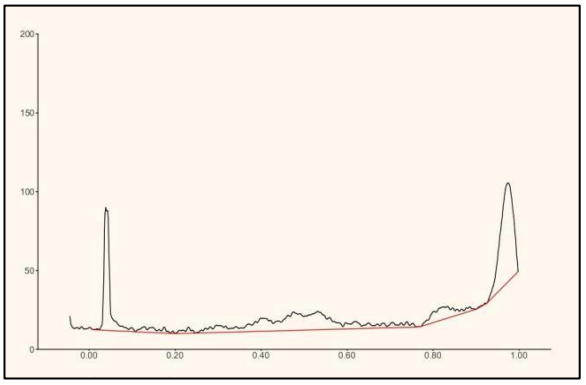
3. Adding of Oil into the Base

4. Adding Water Phase Into Oil Phase

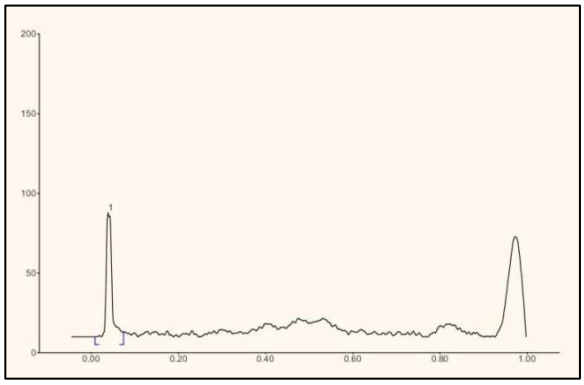
5. Trituration

6. Proper Consistency of Ointment

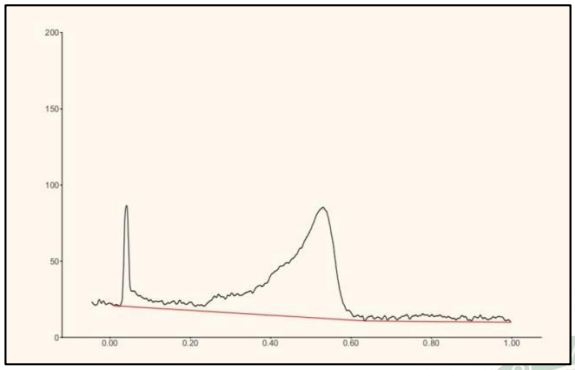
Fig 3: Densitogram of Absorption Spectra of *Ropana Taila*



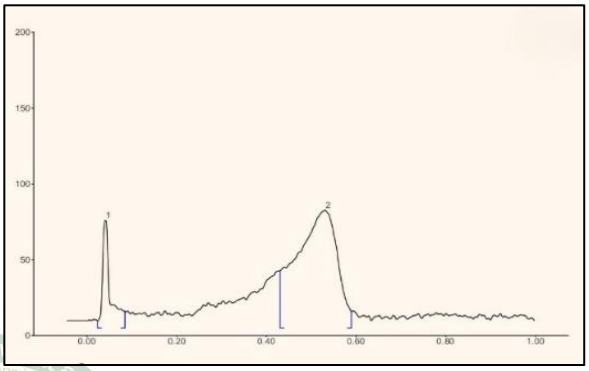
1. Peak at 254 nm



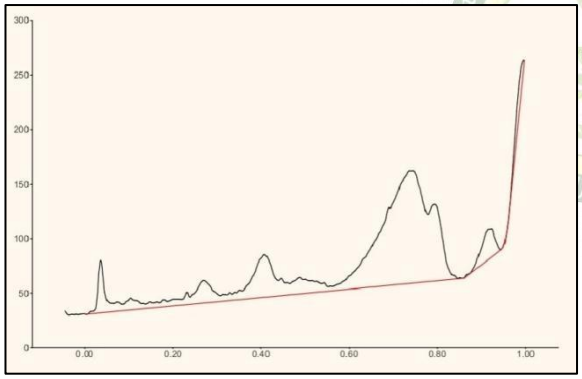
2. AUC at 254 nm



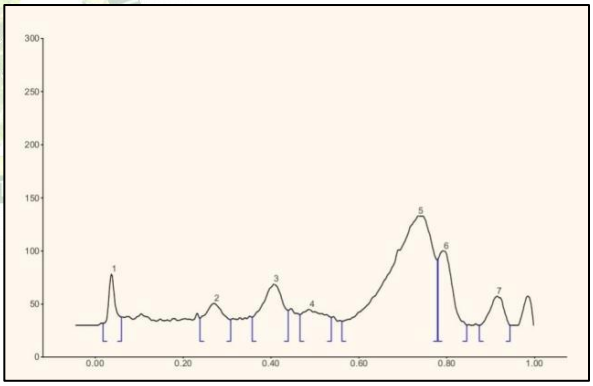
3. Peak at 366 nm



4. AUC at 366 nm

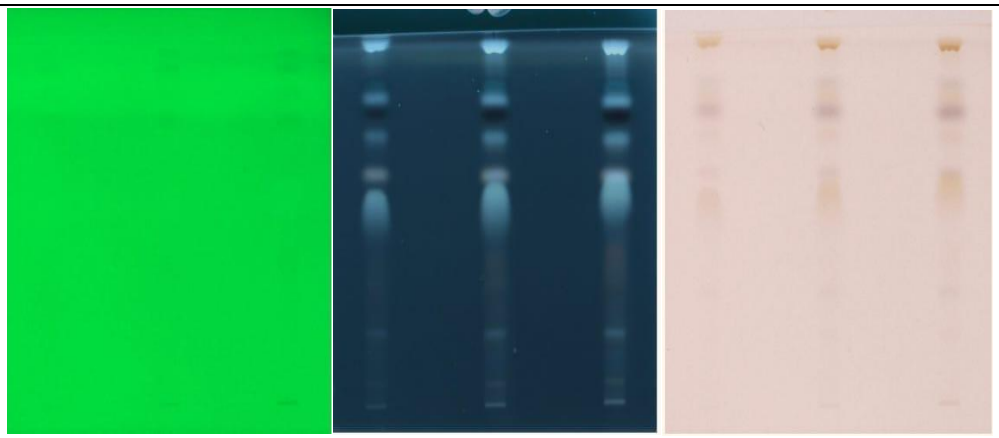


5. Peak at 510 nm



6. AUC at 510 nm

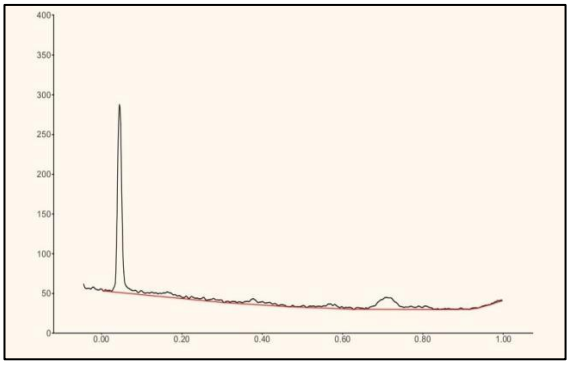
Derivatization Of HPTLC Plate Under Different Wave Length



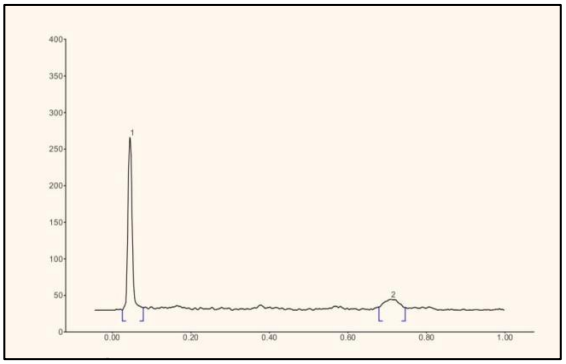
254 nm **366 nm** **White Light**

*AUC- Area Under Curve

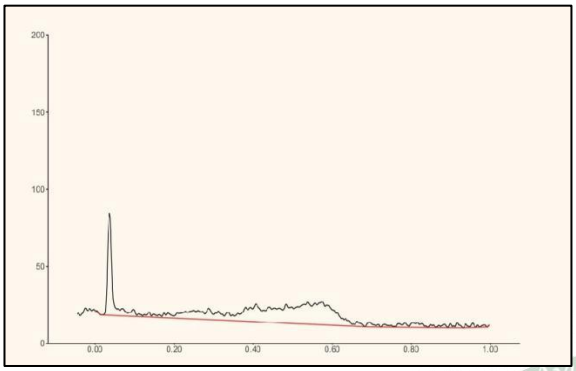
Fig 4: Densitogram of Absorption Spectra of *Ropana Taila* ointment



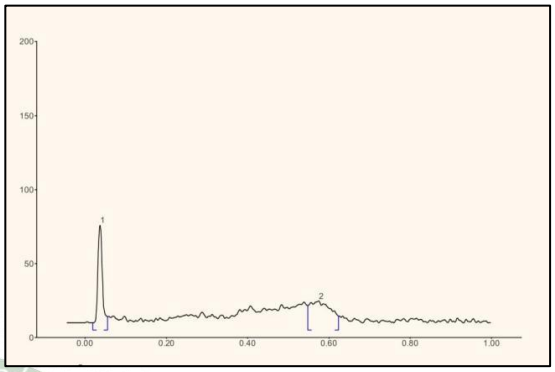
1. Peak at 254 nm



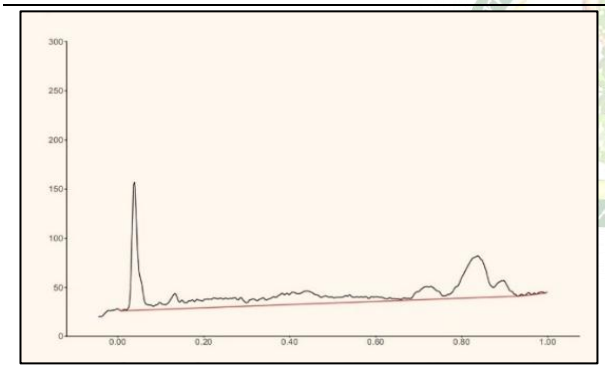
2. AUC at 254 nm



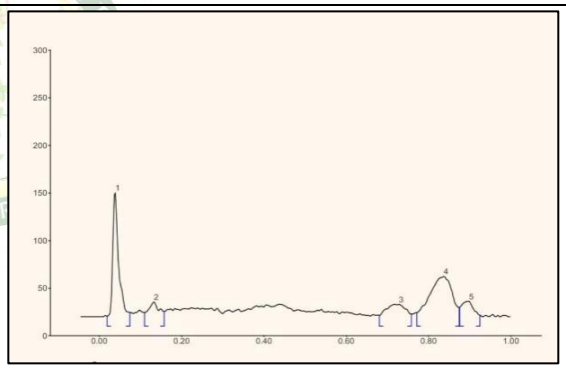
3. Peak at 366 nm



4. AUC at 366 nm

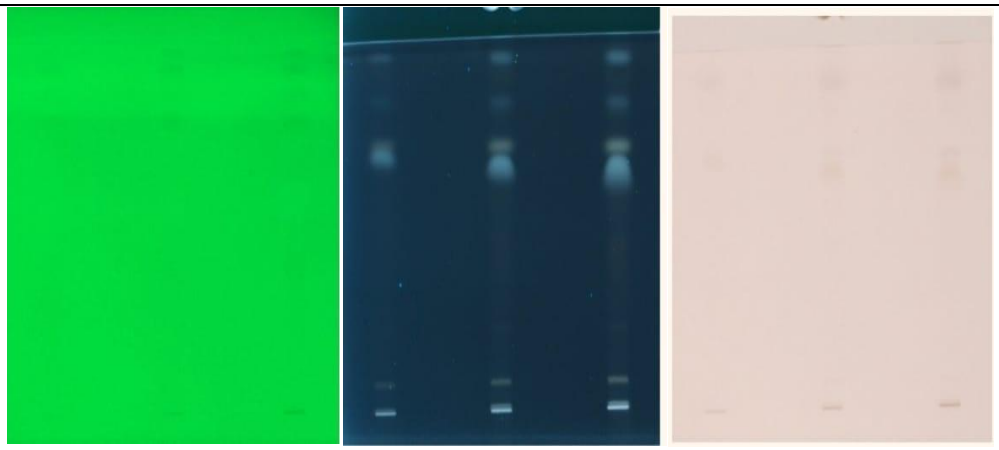


5. Peak at 510 nm



6. AUC at 510nm

Derivatization Of HPTLC Plate Under Different Wave Length



254 nm **366 nm** **White Light**

*AUC- Area Under Curve

In the chromatogram of *Ropana Taila* at 254nm observed one major spot and R_f value was 0.04. At 366 nm showed three spots and R_f value are 0.04, 0.42, 0.49. At 510nm, seven major spots were observed and R_f value are 0.04, 0.27, 0.41, 0.49, 0.74, 0.80, 0.92. Densitometric Scan at 366nm, showed peak with R_f value 0.49 contributed major area 47.79%. In 510nm, peak with R_f value 0.74 contributed major area 58.61%. In HPTLC, Study of ointment at 254nm observed two major spots and R_f value are 0.04, 0.71. At 366nm showed two spot and R_f value are 0.04, 0.58. At 510nm, five spots were observed and R_f value are 0.040, 0.13, 0.73, 0.84, 0.90. Densitometric scan at 254nm, showed peak with R_f value 0.04 contributed major area 81.16%. In 366nm, peak with R_f value 0.58 contributed major area 51.20%. In 510nm, peak with R_f value 0.84 contributed major area 40.47.

DISCUSSION

Ropana Taila is mention in *Sushruta Samhita Sutrasthana* Ch. 36/25. It is used in wound healing. It is prepared by general method of preparation of *Taila Kalpana*. *Taila Paka* carried out with seven different *Kalka Dravyas.* In original, reference *Drava Dravya* is not mention, thus considering general rule of *Sneha Paka* mentioned in *Sharangdhar Samhita*, water has taken as *Drava Dravya*. *Ropana Taila* was prepared with one part of *Tila Taila,* 1/4th part of *Kalka* of all ingredients and four part of water. In the first step, *Yavakuta* was prepared and after that, *Kalka* was prepared in moderately fine powder form to obtain paste as if consistency also smaller particle size can facilitate the interaction between *Kalka Dravya* and liquids (*Drava* and *Sneha Dravya*s). *Kalka* was taken in V/V percentage to that of *Sneha*. Pilot batch size 500ml was taken for the *Taila* preparation in all three batches. In three batches, average quantity obtain was 470ml and average 5.8% loss has observed due to, filtration, absorption by cloth and *Kalka*. These could be probable reasons behind the loss that occurs in final product. Colour of *Tila Taila* changed from golden yellow to greenish yellow and having characteristic smell of ingredients especially instance smell of *Tagara* has felt during process and in final product. The whole process of *Taila Paka* carried out for two days to facilitate the more contact time between solid and liquid materials and to increases the extraction of chemical constituents from the drugs.

Emulsifying wax (10g), white bees wax and white petroleum jelly (9g) used as base for oil phase, emulsifying wax binds oil and water. In addition, fasten and prevent separation of both phases. Water phase contain glycerine (3ml) as humectant, HEC (0.5g) as gelling agent and polysorbate 80 (0.5ml) as surfactant. Surfactants in topical products play many functional roles such as emulsifiers, permeation enhancers, and solubilizes.[16] Average 3.1% loss observed, in three batches it was due to sticking of product to the vessel. Has slightly oily consistency because the percentage of oil is more in the adapted formula. Both phases must be added at the same temperature to avoid the phase separation. Preliminary analysis of raw material and analysis of *Ropana Taila* carried out, with reference to the API standards. Physico-chemical analysis of raw *Tila Taila* showed 0.918 specific gravity at 25°C, 1.469 refractive index, 37.75 viscosity, acid value 3.9mgkoh/g, 113mgi/g iodine value, 185mgKOH/g saponification value. Specific gravity, viscosity and refractive index of *Ropana Taila* was slightly increased than the raw *Tila Taila,* which are noted 0.912, 1.471, and 37.85 respectively. Acid value determines the presence of free fatty acids in oils and fats. Free fatty acids are less stable then natural oil, and they are more susceptible to the oxidation. Acid value of *Ropana Taila* found 4.1mgKOH/g, which slightly increased than the raw *Tila Taila* this was due to the exposure to moisture and heating duration. Normally in sesame oil, at 200°C degradation in chemical bond accurse its repercussions seen in its increased acid value.[17] Here during the *Paka* the temperature was to maintain at 85-150°C to avoid more degradation. The iodine value indicates the degree of unsaturation of oil sample. Iodine value of *Ropana Taila* found 110mgI/g, which slightly decreased than the raw *Tila Taila.* The saponification value is the number of mg of potassium hydroxide required to neutralize the fatty acids, resulting from the complete hydrolysis of 1gm of the oil or fat, it indicate the average molecular chain length of all fatty acids present.[18] Saponification value of *Ropana Taila* found 182.33mgKOH/g.

The pH of prepared ointment was 6.5. For the spreadability testing, Parallel-Plate method used, 78mm spreadability value noted. Spreadibility is the one of the important characteristic of any semisolid dosage forms. It indicates the how easily the dosage form can spread on skin. Ointment has good extrudability (>80% extrudability). Extrudability is important measure to determine the ease of application and removal of any semisolid dosage forms. Ointment was also having good homogeneity and washability.

The HPTLC fingerprinting of *Ropana Taila* showed different number of spots at different wavelength. The solvent system used for the HPTLC

was Toluene: Ethyl Acetate: Hexane (6:3:1 V/V %) utilized for *Taila* and ointment. For *Ropana Taila,* chromatographic fingerprinting was done without using chemical or biomarkers, so only qualitative analysis has done to set certain standards.

CONCLUSION

Finished product shows difference in various analytical values when compared with raw *Tila Taila*. This difference could be the result of processing. All the physico-chemical parameters of raw *Tila Taila* and prepared *Ropana Taila* founded to within the permissible limit according to Bureau of Indian standard for sesame oil and Pharmacopeia (API) respectively. The ratio adopted for the preparation of *Ropana Taila* ointment were found suitable as the ointment having good constituency and fulfilled the evaluation parameters like pH, spreadability, extrudability, homogeneity and washability for quality of the ideal ointment.

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