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PHARMACEUTICO-ANALYTICAL STUDY OF MANJISHTADYA TAILA AND ITS MODIFIED FORM OF TOPICAL APPLICATION

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ABSTRACT

Sneha Kalpana is defined as the pharmaceutical process where the fat soluble and water-soluble active principles are extracted from the basic ingredients into the Sneha. Sneha incorporates the qualities of the drugs added to it without losing its own qualities. Manjishtadya taila is formulation from Chakradutta Kshudraroga chikitsaprakaranam, which is a Sneha Kalpana prepared using murchitha tila taila indicated in neelika, pidaka, vyanga, vali, palitha resulting in mukha prasadana, and the same is selected for analysis and pharmaceutical modification. Total 3 batches of Manjishtadya taila followed by 3 batches of Manjishtadya taila cream was prepared, analysed and evaluated. Standard operative procedure of taila preparation is done followed by its pharmaceutical modification in form of cream on the basis of trial-and-error. Analytical study including organoleptic parameters, physico-

chemical parameters and chromatography was performed on the base guidelines of standardization parameters of ASU drugs for *Taila* and cream preparation. These parameters provide crucial information about product quality. Topical applications have different therapeutic indications and when used appropriately, it gives tremendous result. The results of pharmaceutical and analytical study of *Manjishtadya taila* are the standards for the preparation of any modification. And this modification helps in easy acceptability with the evolutionary changes in the present era.

KEYWORDS: *Manjishtadya taila*; *Tila taila*, Pharmaceutical modification; cream.

INTRODUCTION

Indian system of medicine i.e., Ayurveda is serving man kind since ages. Ayurveda has a variety of dose forms, which increases its effectiveness and popularity.

Concept of beauty varies from individual to individual. It is truly said that beauty is bought by the judgement of eyes. Cosmetology is the science of alteration and modification of appearance and beauty. The beauty and attraction of individual is reflection of one's healthy skin. Skin conditions not only affect the physical body but can cause significant psychological problems.

Sneha Kalpana is defined as the pharmaceutical process where the fat soluble and water-soluble active principles are extracted from the basic ingredients into the Sneha. Sneha incorporates the qualities of the drugs added to it without losing its own qualities. In Sneha Kalpana, both water soluble and fat-soluble active principles of the individual ingredients can be extracted. So, it is sure that the fat-soluble active principles of the drugs added to Taila can be easily extracted into the Taila. This process ensures absorption of active therapeutic properties of the ingredients used.

Manjishtadya taila is formulation indicated in *neelika*, *pidaka*, *vyanga*, *vali*, *palitha* resulting in *mukha prasadana*, and the same is selected for analysis and pharmaceutical modification.

Topical application mentioned in modern cosmetics containing synthetic or chemical substances are known to have several adverse effects including local hypersensitivity reactions. Hence there is always a demand for safe and effective topical application to manage hyperpigmented skin diseases.

OBJECTIVES

- 1. Preparation of *Manjishtadya taila* as per classical reference
- 2. To modify *Manjishtadya taila* into a topical application form
- 3. To comparatively analyse *Manjishtadya taila* and its pharmaceutical modified form of topical application.

METHODOLOGY

Pharmaceutical study

- *Tila taila* is collected from known source and analysed in department of Research and Development of Muniyal Institute of Ayurveda Medical Sciences, Manipal.
- Raw drug for preparation of formulation is collected from known sources, identified by experts of department of Dravyaguna and analysed in department of Research and Development of Muniyal Institute of Ayurveda Medical Sciences, Manipal.
- Preparation of formulation is carried out in Rasashastra and Bhaishajya Kalpana practical lab of Muniyal Institute of Ayurveda Medical Sciences, Manipal.

Practical 1 - Tila taila murcchana.

Practical 2 - Manjishtadya taila as per classical reference.

Practical 3 - Manjishtadya taila in its modified form of topical application.

Pharmaceutical procedure number 1

- Name of the procedure *Tila Taila Murcchana*^[2]
- Reference Bhaishajya ratnavali jwara chikitsaprakaranam

Table no. 1: Ingredients and Quantity used for murchita tila taila preparation.

| Drug name | Botanical name | Family name | Parts used | Proportion | Quantity |
|-----------------|---|--|----------------|-------------------|-------------------|
| Tila taila | Sesamum indicum | Pedaliaceae | Seed oil | 1 part | 2500ml |
| Manjishta | Rubia cordifolia | Rubiaceae | Dry root | 1/16 part | 156.25gm |
| Haridra | Curcuma longa Linn | Zingiberacem | Dry rhizome | 1/64 part | 39.0625gm |
| Lodhra | Symplocos racemosa | Symplocaceae | Dry root | 1/64 part | 39.0625gm |
| Mustaka | Cyperus rotundus | Cyperaceae | Dry root | 1/64 part | 39.0625gm |
| Nalika | Cinnamomum tamala | Lauraceae | Dry leaf | 1/64 part | 39.0625gm |
| Triphala | Terminalia chebula Terminalia bellirica Emblica officinalis | Combretaceae Combretaceae Phyllanthaceae | Dry fruit | 1/64 part each | 39.0625gm each |
| Vatankura | Ficus benghalensis | Moraceae | Dry shoot | 1/64 part | 39.0625gm |
| Hribera | Coleus vettiveroides | Lamiaceae | Dry root | 1/64 part | 39.0625gm |
| Suchi pushpa | Pandanus odorattissimus | Pandanaceae | Dry flower | 1/64 part | 39.0625gm |
| Jala | | | | 4parts | 10000ml |

- Pharmaceutical Procedure of *Tila taila Murchhana*:
- o DAY-1:

- For the *Murchhana*, *Tila taila* and *Manjistha* and each other *Murchhana* drugs are taken in the ratio 1: 1/16: 1/64 parts separately.
- At first, all the herbal drugs mentioned above in specified ratio of oil is taken, washed and the fine powder of each material is prepared separately.
- All these coarse-fine powders, other than *Manjistha* are mixed and paste is prepared with adding required amount of water. then *Manjistha* paste is prepared separately.
- Beginning with, *tila taila* is heated over *mandagni* in a strong, clean and dry vessel till *nishphena bhava* and *shaithya bhava* of *taila* is observed.
- Now the *taila* is again placed over *agni* and added with 4 parts of *jala* and heated, followed by addition of *kalka* with constant stirring for homogenous mixing.
- o DAY-2 DAY-4:
- Heating is continued until all the *Sneha siddhi lakshanas* are observed, *taila* becomes *aruna varna* and attains aromatic *gandha*

> Pharmaceutical procedure number 2

- Name of the procedure Manjishtadya Taila
- Reference Chakradutta Kshudraroga chikitsaprakaranam

Table no. 2: Ingredients and Quantity used for manjishtadya taila preparation.

| Drug name | Botanical name | Family name | Parts used | Proportion | Quantity |
|------------|--------------------|---------------|------------|------------|----------|
| Manjishta | Rubia cordifolia | Rubiaceae | Dry root | 1 karsha | 630ml |
| Madhuka | Glycyrrhiza glabra | Fabaceae | Dry root | 1 karsha | 39.375gm |
| Laksha | Laccifer lacca | Lacciferridae | Dry resin | 1 karsha | 39.375gm |
| Mathulunga | Citrus medica Linn | Rutaceae | Fresh pulp | 1 karsha | 39.375gm |
| Yashtika | Glycyrrhiza glabra | Fabaceae | Dry root | 1 karsha | Q.S. |
| Tila Taila | Sesamum indicum | Pedaliaceae | Seed oil | 1 kudava | 39.375gm |
| Aja dugda | Capra aegagrus | Bovidae | Milk | 2 kudava | 1260ml |
| Jala | | | | | 2520ml |

- Pharmaceutical procedure of *Manjishtadya Taila*:
- o DAY-1:
- At first, all the herbal drugs mentioned above in specified ratio of oil is taken, cleaned and washed and the coarse-fine powder of each material is prepared separately.
- The above-mentioned amount of oil is heated in a mild temperature till the initially observed froth subsides. Then, after cooling up to room temperature, required amount of water is added followed by *Aja dugda* and then with earlier prepared pastes and continued to heat at mild temperature.

- o DAY-2 DAY-3:
- Heat is being provided till all the assessing criteria for *Sneha paka* becomes competent with the oil and oil looks *Aruna* (reddish) colour with pleasant odour and the oil becomes free from the moisture and foul smell.

Manjishadya taila preparation

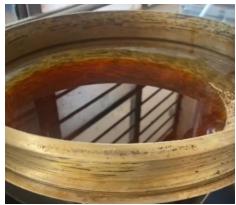


Figure no. 1: Murchitha tila taila.



Figure no. 2: Kalka dravya.





Figure no. 3: Addition of DRAVA-DRAVYA to Murcchita tila taila.



Figure no. 4: Manjishtadya taila.

Completion test of *Sneha Kalpana / Sneha siddhi lakshana*:^[3]

- 1. Taila Fire test Burns without any cracking sound
- 2. *Kalka* Fire test No cracking sound.

Consistency – Soft, Non-sticky, made in to Varti form, Finger print is seen

Colour - Reddish

Sneha paka siddhi lakshana





Figure no. 5: Vartivat sneha kalka angulya vimardita.

Figure no. 6: Shabdahino agni nikshipta.

Precautions taken during the preparation

- ➤ Continuous stirring of the *taila* was done as there was continuous frothing or bubbling during the preparation.
- ➤ To avoid spillage due to frothing wide mouthed sufficiently big vessel was taken for the preparation.

Note: Even though the quantity of water is not mentioned in the above reference, as per the reference for use of *drava-dravya* for extraction of complete active principles four times of water to that of Sneha was taken.

Pharmaceutical procedure number 3

- Name of the procedure *Manjishtadya taila* cream
- ➤ Pharmaceutical procedure Water in oil emulsion cream^[4]
- The oil soluble components and the emulsifier are taken in one beaker and melted.
- In another beaker water and water-soluble components are taken and melted.
- After melting, water phase is taken in a beaker and slowly oil phase will be added and blended till clicking sound is heard.

- To this, required amount of preservative is added.
- And when the temperature of the cream is getting cooled, then the preparation is filled into desired containers.

| | T_1 | T_2 | T_3 | T_4 | T_5 | T_6 | T_7 | MNJTC |
|----------------------------|-------|-------|-------|-------|-------|-------|-------|-------|
| Water phase | | | | | | | | |
| Demineralised water (ml) | 29 | 30 | 30 | 15 | 28 | 28 | 30 | 300 |
| Glycerine (ml) | 1 | 2 | 2 | 2 | 2 | 2 | 3 | 30 |
| Oil phase | | | | | | | | |
| Manjishtadya taila (ml) | 5 | 10 | 10 | 15 | 10 | 10 | 10 | 100 |
| Shea butter (g) | | | 20 | 20 | 18 | 16 | 15 | 150 |
| Steric acid (g) | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 20 |
| E-wax (g) | | | 2 | 5 | 3 | 3 | 3 | 30 |
| Lanolin (g) | 10 | 5 | | | | | | |
| Bee wax (g) | 1.5 | 2 | | | | | | |
| Preservative | | | | | | | | |
| Sodium benzoate (g) | | | | | | 0.1 | 0.05 | 0.5 |
| Result → | fail | fail | pass | fail | pass | pass | pass | |



Figure no. 7: Trials of topical dosage form.



Figure no. 8: Topical dosage form of cream.

Analytical study

Manjishtadya Taila and Manjishtadya Taila cream was analysed for Organoleptic characteristics, Physico-chemical parameters, Chromatographic parameters.

Materials: Raw drugs, Tila taila - 1 sample, Manjishtadya taila(MNJT) - 3 samples, *Manjishtadya taila* cream(MNJTC) – 3 samples

Raw material standardization includes total ash, acid insoluble ash, water soluble extract, alcohol soluble extract.

Analysis of raw drugs



Figure no. 9: Water and Alcohol-soluble extractives of raw drug analysis.

Taila analysis includes organoleptic parameters such color, as appearance, consistency/texture, odor, taste. Physico-Chemical analysis such as adulteration, rancidity, moisture content, specific gravity, refractive index, acid value, ester value, iodine value, peroxide value, free fatty acid / oleic acid, total fatty matter, saponification, unsaponifiable matter. Chromatography i.e., GC-MS.

Analysis of tila taila

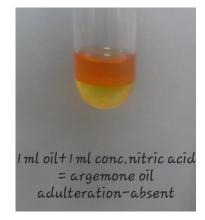


Figure no. 10: Test for adulteration.

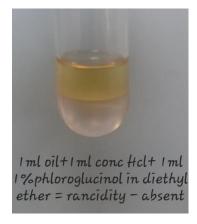


Figure no. 11: Test for rancidity.

Manjishtadya Taila Cream analysis includes organoleptic parameters such as appearance, color, consistency/texture, odor, homogeneity. Physico-Chemical analysis such as pH, stability test, spread-ability, solubility test, irritancy test, dissolution test, phase separation, viscosity test, melting temperature. Chromatography i.e., GC-MS.

OBSERVATIONS AND RESULTS

Table no. 4: Observations during various stages of taila paka for murchana.

| Stage of taila paka | Time duration (mins) | Temperature (°C) | Observations |
|---------------------|----------------------|------------------|------------------------------------|
| Luke warm state | 15 | 45 | Light yellow colour |
| (DAY - 1) | | | Jala and kalka is added |
| | | | Reddish yellow colour |
| Starts boiling | 30 | 90 | Kalka mixes with taila and jala |
| | | | leaving its colour |
| | | | Reddish colour |
| Ama paka | 6hma | 94 | Water is reduced, <i>Kalka</i> is |
| (DAY - 2) | 6hrs | 94 | completely mixed with taila |
| | | | forming semisolid paste like |
| Mrudu paka | 1.5hrs | 90 | Dark red colour |
| (DAY - 3) | 1.51118 | 90 | Taila starts separating from kalka |
| | | | Dark Red colour |
| Madhyama paka | Abra | 90 | Taila is completely separated |
| (DAY - 4) | 4hrs | 90 | from kalka, Varti can be formed |
| | | | from kalka |

Table no. 5: Observations during various stages of manjishtadya taila paka.

| Stage of taila paka | Time duration (mins) | Temperature (°C) | Observations |
|---------------------|---------------------------------------|------------------|---|
| Luke warm state | 15 | 60 | Red colour |
| (DAY - 1) | 13 | 00 | Dugda, Jala and kalka is added |
| | | | Red colour |
| Starts boiling | 45 | 80 | Kalka mixes with taila, dugda and |
| | | | jala leaving its colour |
| | | | Water is reduced, <i>dugda</i> is thickened, |
| Ama paka | 6hrs | 90 | Kalka is completely mixed with taila |
| (DAY - 2) | OHS | 90 | and <i>dugda</i> forming semisolid paste |
| | | | like |
| | | | Dark red colour |
| Mrudu paka | 1.15hrs | 94 | Dugda is completely incorporated |
| (DAY - 3) | 1.131118 |) | with taila |
| | | | Taila starts separating from kalka |
| | · · · · · · · · · · · · · · · · · · · | | Dark red <i>taila</i> is completely separated |
| Madhyama paka | 3hrs | 90 | from kalka, Varti can be formed from |
| | | | kalka |

Table no. 6: Final quantity of manjishtadya taila obtained in 3 batches.

| | Quantity taken | Quantity obtained | Percentage of loss |
|---------------------|----------------|-------------------|--------------------|
| Murchita tila taila | 2500ml | 2250ml | 10% |
| Batch 1 | 630ml | 500ml | 20.63% |
| Batch 2 | 630ml | 530ml | 15.87% |
| Batch 3 | 630ml | 525ml | 16.66% |

Table no. 7: Final quantity of manjishtadya taila cream obtained in 3 batches.

| | Quantity taken | Quantity obtained |
|---------|----------------|-------------------|
| Batch 1 | 430ml + 200g | 585g |
| Batch 2 | 430ml + 200g | 590g |
| Batch 3 | 430ml + 200g | 582g |

Table no. 8: Physico-chemical standardization of raw drugs. [5]

| Drug name | Total ash | Acid insoluble ash | Water soluble extract | Alchohol soluble extract |
|-------------|-----------|--------------------|-----------------------|--------------------------|
| Manjishta | 7.392% | 0.899% | 17.92% | 15.99% |
| Haridra | 6% | 0.2% | 11.04% | 8.55% |
| Lodhra | 8.65% | 1.25% | 11.59% | 4.16% |
| Musta | 3.535% | 1.89% | 13.03% | 14.8% |
| Nalika | 11.124% | 16.367% | 3.744% | 0.249% |
| Haritaki | 2.64% | 2.196% | 61.335% | 68.105% |
| Vibhitaki | 3.64% | 0.199% | 47.33% | 38.63% |
| Amalaki | 2.74% | 0.399% | 33.81% | 42.29% |
| Vatankura | 9.166% | 9.12% | 6.65% | 0.5% |
| Hribera | 3.65% | 0.55% | 9.76% | 5.198% |
| Suchipushpa | 14.331% | 7.36% | 6.490% | 0.599% |
| Yastimadhu | 5.391% | 0.599% | 28.24% | 19.996% |
| Laksha | 1.299% | 0.499% | 2.717% | 103.5% |

Table no. 9: Organoleptic parameters.

| | Tila taila | MNJT1 | MNJT2 | MNJT3 |
|-------------|----------------|----------------|----------------|----------------|
| Colour | Yellow | Red | Red | Red |
| Consistency | Unctuous | Unctuous | Unctuous | Unctuous |
| Odour | Characteristic | Characteristic | Characteristic | Characteristic |

Table no. 10: Physico-Chemical analysis. [6]

| | Tila taila | MNJT1 | MNJT2 | MNJT3 |
|------------------|------------|----------|----------|----------|
| Adulteration | Absent | Absent | Absent | Absent |
| Rancidity | Negative | Negative | Negative | Negative |
| Moisture content | 0.0790 | 0.0797 | 0.0796 | 0.1186 |
| Specific gravity | 0.911 | 0.918 | 0.9085 | 0.9106 |
| Refractive index | 1.4655 | 1.465 | 1.465 | 1.464 |
| Acid value | 6.513 | 9.98 | 7.116 | 6.659 |
| Iodine value | 78.22 | 112.924 | 121.26 | 111.823 |
| Saponification | 124.44 | 120.576 | 105.997 | 114.482 |

| value | | | | |
|-----------------|---------|---------|--------|---------|
| Peroxide value | 1.123 | 57.459 | 24.254 | 19.685 |
| Ester value | 117.927 | 110.596 | 98.881 | 107.823 |
| Free fatty acid | 3.256 | 4.99 | 3.558 | 3.329 |

Table no. 11: Physical parameters of cream.

| | MNJTC1 | MNJTC2 | MNJTC3 |
|-----------------|-------------------|--------------------|-------------------|
| Form | Semisolid | Semisolid | Semisolid |
| Appearance | Creamy / opaque | Creamy / opaque | Creamy / opaque |
| Colour | Yellowish | Yellowish | Yellowish |
| Odour | Characteristic | Characteristic | Characteristic |
| Consistency | Unctuous | Unctuous | Unctuous |
| Touch | Soft | Soft | Soft |
| Homogeneity | Present | Present | Present |
| Stickiness | Greasy | Greasy | Greasy |
| pН | 5-6 | 5-6 | 5-6 |
| Spread ability | Easily spreadable | Easily spreadable | Easily spreadable |
| | 22.5g.cm/sec | 30g.cm/sec | 30g.cm/sec |
| Solubility test | Soluble | Soluble | Soluble |
| Irritancy test | Non irritant | Non irritant | Non irritant |
| Viscosity test | >30000 cps at | >30000 cps at 27°c | >30000 cps at |
| | 27°c | | 27°c |
| Melting | 72°c | 70°c | 69°c |
| temperature | | | |

DISCUSSION

In the entire process, the temperature maintained was between 90-98^oC. It took an average of 8 hours with an average of two days to prepare each batch of *Manjishtadya taila*. During modification of *Manjishtadya taila*, cream was showing better features than other forms of topical applications in trial and error. On an average, 82.28% of *taila* was obtained, 99% of cream was yield.

Organoleptic parameters are sensory parameters, even though these tests look to be simple they give adequate crucial information regarding quality of the product.

Manjishtadya taila(MNJT) sample looks red in colour, oily in consistency with characteristic odour. Red colour is mainly because of Manjishta which is used in murcchana and is also as a key ingredient in MNJT. Tila taila sample was yellow in colour with characteristic faint odour. Cold pressed fresh sesame oil is found to have yellow colour.

MNJT has minimum moisture content with average of 0.0926% w/w which is within acceptable limits. *Taila* samples are expected to have minimum moisture content as higher

moisture may lead the product rancid. Specific gravity of samples varied between 0.9085-0.918 making and average of 0.9124. This results clearly indicated that specific gravity of all the samples were slightly higher than that of pure *Tila taila* (0.911) which may be due to dissolving components. Refractive index of all samples was almost same i.e., 1.464-1.465 i.e., slightly less than that of pure *Tila taila* which is negligible. Acid value indicates the amount of free fatty acid in oil. In this study, acid value of samples was similar with an average of 7.92 which is slightly higher than that of *Tila taila* (6.3), however within acceptable limits. Iodine value indicates the total amount of double bonds present in fat i.e., high iodine value in a fat indicates it contains greater number of double bonds than lower iodine value fat. In present study, average iodine value of sample was 115.336 which is higher than that of pure Tila taila 78.22. Saponification value is measure of fatty acids present as esters in oil. In the present study, there was no major variation in saponification value among samples (average of 113.685). However, slight lower value (105.997) was observed in sample 2. This suggests that in sample 2 molecular weight of fatty acids is slightly higher which may be the cause of lesser degree of hydrolysis. Peroxide value is direct indicator of rancidity happened to taila. In present study, peroxide value of substance was on average 33.8. Esters are fatty acids with glycerol. As esters are increased, rancidity chances decrease. The average ester value of MNJT is 105.77 which is less than plain Tila taila (117.927), which indicates low chance of rancidity. Liberation of free fatty acid of taila is due to hydrolysis of triglycerides and promoted by reaction of *taila* with moisture. [7] Here fatty acid value is 3.959 which is almost same as that of plain *Tila taila* (3.256).

Manjishtadya taila cream (MNJTC) was analysed with organoleptic and physico-chemical parameters. All the cream samples prepared were yellowish in colour, creamy, semisolid, opaque in appearance. They were soft to touch and slightly greasy and exhibited characteristic odour. Prepared cream was applied to skin and checked for effect, MNJTC did not cause any irritation to skin. Cream should spread easily without too much drag and should not produce greater friction in rubbing process. Here Spread ability was good as 27gm/cm/sec on an average. pH is used as a measure of the acidity-alkalinity ratio with a scale ranging from 0-14. Here pH of MNJTC was in range of 5-6 ideally, the topical product should stay within pH range of skin and sit around 4.5-6. Centrifugation procedure for presence of any possible phase separation. No phase separation was seen in the cream. The viscosity test of cream preparation aims to see the thickness of the cream preparation that have been made. The value was found to be >30000cps at 27°C which is within acceptable range. MNJTC

showed average melting point of 70.3°C which is acceptable and expected to melt easily on application to skin liberating the medicament.

All the three samples of MNJT have shown similar fatty acid composition and also phytoconstituents to similar retention time. Fatty acids detected includes decanoic acid or capric acid methyl ester, lauric acid, myristic acid methyl ester, palmitic acid, margaric acid, oleic acid, linoleic acid, eicosanoic acid.

11 compounds were detected in samples. Under phytoconstituents, cream sample-1 showed 8 peaks, sample-2 showed 6 peaks and sample-3 showed 11 peaks. Compound with retention value 23.962 in sample-1, 23.236 in sample-2 and 23.755 in sample-3 are similar compounds in *taila* preparation. However, first and second samples of MNJTC show the presence of component with retention value 15.056 in sample-1 15.064 in sample-2 had maximum peak height with 100% values. However, these phytoconstituents are unidentified. However, MNJT had a greater number of components.

CONCLUSION

Sneha Kalpana has unique place in pharmaceutics and therapeutics as they are special oleaginous preparations used both internally and externally.

Pharmaceutical preparation part forms an important area of research in the present study. Always the quality of a pharmaceutical product depends on standard operative procedures followed during manufacture. Present study is involved in standardization of *Manjishtadya taila* by preparing three batches to derive the standard operative procedure minimizing the error, then *Manjishtadya taila* is converted into pharmaceutically modified form i.e., *Manjishtadya taila* cream using excipients of approved safe additives for topical application forms.

Analysis of prepared products by using classical and contemporary scientific parameters is an important objective of current study. Quality of input materials decides quality of final product to great extent. Hence testing purity and quality of raw materials is essential. Here the organoleptic, physico-chemical, chromatographic parameters are carried out to understand phytoconstituents, physicochemical constituents and efficacy of the product. These parameter analyses are necessary as these have a direct impact on therapeutic values.

Even though the classical method of *taila* and its usage remains undisputed, new techniques like conversion into cream cannot be side-lined. It is evident from the study that cream possess significant moisturizing and *varnya* property.

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