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PHARMACEUTICAL AND ANALYTICAL STUDY OF ANILARI RASA – A KHARLEEYA RASAYANA

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ABSTRACT

Background: Anilari Rasa is a distinctive herbo-mineral formulation mentioned in Rasaratna Sammuchaya in the context of Amavata. It is classified under kharaleeya rasayana. Pharmaceutical and analytical standardization of Anilari Rasa has not been carried out yet, hence this study aims to focus on its preparation and analytical evaluation. **Materials & Methods:** Authentic raw materials were selected and evaluated according to classical Grahya Lakshana and Anilari Rasa was prepared according to the classical reference. Organoleptic, Physico-chemical and Instrumental analysis were conducted for Anilari Rasa. **Results:** Anilari Rasa analysis showed pH-4.09, Loss on Drying LOD-12.06% w/w, Total Ash- 3.95% w/w, Acid Insoluble Ash-0.381% w/w, Water Soluble Ash- 3.09% w/w. Average weight-363mg, Disintegration time- 47 mins, Water soluble extractive-31.83%, Alcohol soluble extractive- 22.68% and Friability-0.139%. TLC (Thin Layer Chromatography) showed 3 spots at Rf -0.2,0.3, 0.75. FT-IR (Fourier Transform Infrared Spectroscopy) demonstrated the presence of different organic functional groups such as phenols, carboxylic acid, sulfonamides, aromatic compounds, etc.

KEYWORDS: Anilari Rasa, Kharaleeya Rasayana, Physico-Chemical Analysis, Instrumental Analysis.

INTRODUCTION

Rheumatoid Arthritis is a chronic systemic inflammatory polyarthritis primarily affecting small diarthrodial joints of hands and feet in a symmetrical pattern.[1] It affects 0.5 to 1% of adult population worldwide and occurs more commonly in females than males with a 2- 3:1 ratio.[2] Accrording to the clinical features Amavata closely resembles with the Rheumatoid Arthritis. The therapeutic regimens for RA (Rheumatoid Arthritis) are becoming increasingly complex and demands careful monitoring to minimize risk of side effects or complications of chronic immunosupression. Prevention and treatment of RA will likely benefit from multidisciplinary approach. Though there are ayurvedic formulations and medicines prescribed in Amavata, a definitive and targeted treatment is always welcomed.

Rasaoushadhis are renowned for their long/infinite shelf life with a minimum administration dose. They are categorized into four types based on their formulation process: kharaleeya rasayana, parpati rasayana, pottali rasayana, kupipakwa rasayana. Anilari Rasa[3] is one such kharaleeya Rasayana referenced in Rasaratna Sammuchaya used to treat Amavata. The ingredients in this preparation is quite similar to those found in Simhanada Guggulu.[4] Anilari Rasa is prepared using ingredients such as Gandhaka, Guggulu, Trikatu and Eranda taila. Among these, Eranda taila is exaplained as agryaoushadhi in Amavata.[3] Gandhaka posses amasoshana[5] property while Guggulu exhibits vatahara, soothahara[6] and shoolahara[7] effects. Trikatu has dipana, samahara[8] properties which aids in treating Amavata.

Standardization of Herbal/Herbo mineral formulation is much more difficult. However drug/formulation standardization mainly intended to guarantee the quality, efficacy and uniformity of the final product. This can be done through Physico –chemical and instrumental analysis. Hence, this study aims to develop pharmaceutical and analytical standardization of Anilari Rasa.

MATERIALS AND METHODS

Gandhaka, Guggulu, Shunti, Pippali, Maricha, Amalaki, Haritaki, vibhitaki were sourced from Kajrekar Ayurvedic raw drug Depot, Belgaum. Ingredients required for Eranda taila Murchana were obtained from Amrith kesari Ayurvedic Drug Depot in Bangalore. All the raw materials were authenticated and verified by the department of Dravya Guna. Eranda taila was extracted through cold press in a rural area near Bangalore. Associated drugs for purification of raw drugs like Godugdha, Gogrutha were procured from the local market in

Bangalore. Pharmaceutical work and organoleptic evaluation was carried out in the practical hall of Rasashatra and Bhaishajya kalpana department.

Pharmaceutical study

Anilari rasa was prepared by using the ingredients specified in Rasaratna sammuchaya[3] by following Anukta mana mentioned in sharangdhara,[9] for deciding the ratio of ingredients. Shunti, Pippali, Maricha were used in equal amounts[10] while Guggulu was taken equivalent to the total amount of powders.[9] Eranda taila was used after subjecting it for Murchana process. The other ingredients like trikatu in the form of fine powder (Passed through 80 number mesh), Triphala shodhita Guggulu, Go-dugdha shodhita Gandhaka were used for the preparation.

Murchana of eranda taila[11]

250ml of raw Eranda taila was heated in a wide mouth vessel, until foam appeared. A Homogeneous paste was prepared by mixing water with the powdered ingredients, which was added to the taila after the foam subsided. Subsequently, 500ml each of Dadhi and kanji were added to the Eranda taila. The mixture was heated for the duration of three days, until the stage of madhyama paka was achieved. The processed taila was filtered through a cotton cloth and stored in air tight container for further use.

Table No. 1: Results of eranda taila murchana.

Intial weight of *raw eranda taila*	Weight of *murchita eranda taila*	Loss	Yield
250ml	240ml	10ml	96%

Gandhaka shodhana[12]

500g of finely powdered Shodhana Gandhka was melted in 500 gms of goghrita and poured into a mud pot containing godugdha through white clean cloth. After each dhalana process Gandhaka was washed thoroughly with hot water to remove the content of milk and ghee, then dried and powdered. This process was repeated for two more times. After proper drying, the Gandhaka was powdered, weighed and stored in air tight container for further use.

Table No. 2: Results of gandhaka shodhana.

Weight of *Gandhaka before Sodhana*	Weight of *Gandhaka after Sodhana*	Loss	Yield
500g	473g	27g	94.6%

Guggulu sodhana[13]

Guggulu Sodhana was carried out by swedana method. 200g of asuddha Guggulu was cleaned of any foreign particles and tied into a potalli of thin cotton cloth. Pottali was immersed into a vessel containing Triphala kwatha and heated for three hours, until the Guggulu passed into the fluid through the cloth. The liquid was filtered and the filtrate was continuously boiled to form thick mass. This mass was collected, dried and stored.

Table No. 3: Results of Guggulu sodhana.

Intial weight of *Guggulu*	Final Weight of *Guggulu*	Gain	Total yield
200g	350g	150g	175%

Preparation of *Anilari Rasa vati*

The proportion of ingredients for preparing *Anilari rasa vati* was determined through pilot studies with different ingredient ratios to achieve a stable and administerable dosage form. When the V*ati* was prepared using equal quantities of the ingredients, namely *Gandhaka, guggulu, trikatu and Eranda taila*, it led to the oozing of *Gandhaka* from the *vati* along with *Eranda taila.* This was evident from the appearance of yellowish slimy liquid at the bottom of *the kalka*(later used to roll into pills) and also from *vatis* after placing them on the plate. When these *vatis* were placed on paper, part of paper soaked up the liquid that was in contact with vati.

When *mardana in khalwa yantra* or *kutana in ulukhala yantra* was performed after adding *Eranda taila* to the other ingredients in the prescribed quantity, more liquid was oozing out which was roughly proportional to the intensity of Mardana or kuttana. The *kalka f*rom this process remained moist due to deposition of a slimy mixture (*gandhaka and eranda taila).* This also resulted in loss of *Gandhaka and Eranda taila*, both of which have a major role in treating *Amavata.*

Method Adopted

Table No. 4: Contents of anilari rasa.

Sl. no	Drug	Scientific name/chemical name	Part used	Quantity
1	Gandhaka	Sulphur		10g
2	Shunti	*Zingiber officinale*	Rhizome	10g
3	Pippali	*Piper nigrum*	Fruit	10g
4	Maricha	*Piper longum*	Fruit	10g
5	Guggulu	*Commiphora mukul*	Gum resin	40g
6	Eranda taila	*Ricinus communis*	Seed oil	10ml

Shoditha Gandhaka, fine powders of Shunti, Pippali, Maricha and Murchita Eranda taila were taken in khalwa yantra and mixed thoroughly to form a homogenous mixture. Shoditha Guggulu was melted by adding an adequate amount of water and the melted guggulu was then incorporated into the mixture of powders. This mixture was measured and rolled into pills weighing 375 mg. To prevent sticking, the fingers and palms were smeared with Murchita Eranda Taila before rolling. The prepared vatis were shade-dried in a well ventilated room, avoiding direct exposure to sunlight for 30 days and stored in air tight container for further use.

Analytical study

Physico-chemical Analysis was carried out at Drug Testing Laboratory, Government central Pharmacy, Jayanagar, Bangalore. Friabilty test and TLC was conducted at PES university, Electronic city, Bangalore. FT-IR was conducted at Indian Institute of Science, Malleshwaram, Bangalore.

RESULTS

Table No. 5: Organoleptic characterstics of anilari rasa.

Character	Result
Varna	Brownish black
Rupa	Round shaped tablet
Rasa	Amla kashaya.
Gandha	Characterstic odour
Sparsha	Moderately hard and smooth surface.

Table No. 6: Physico-chemical analysis of anilari rasa.

Parameters	Results
pH	4.09
Loss on drying	12.06% w/w
Total ash	3.95%w/w
Acid Insoluble Ash	0.381%w/w
Water soluble Ash	3.09%w/w
Average weight	363mg
Disintegration time	47 mins
Water soluble extractive	31.83%
Alcohol soluble extractive	22.68%
Friability	0.139%

Instrumental analysis

TLC results

TLC of Anilari Rasa @ 254nm in a Toulene: Acetone(9:1) solvent system demonstrated 3 Rf values at 0.26, 0.3 and 0.75.

FT-IR Analysis of Anilari Rasa

FT-IR showed the presence of various functional groups such as primary alcohol, tertiary alcohol, alkyl-aryl ether, vinyl ether, fluoro compound, sulfone, sulfonic acid, sulfonamide, sulfonate, ether, Aromatic amine, carboxylic acid, conjugated aldehyde, conjugated alkene, monosubstituted benzene derivative, ester, phenol, amine salt, alkyne, aldehyde etc.

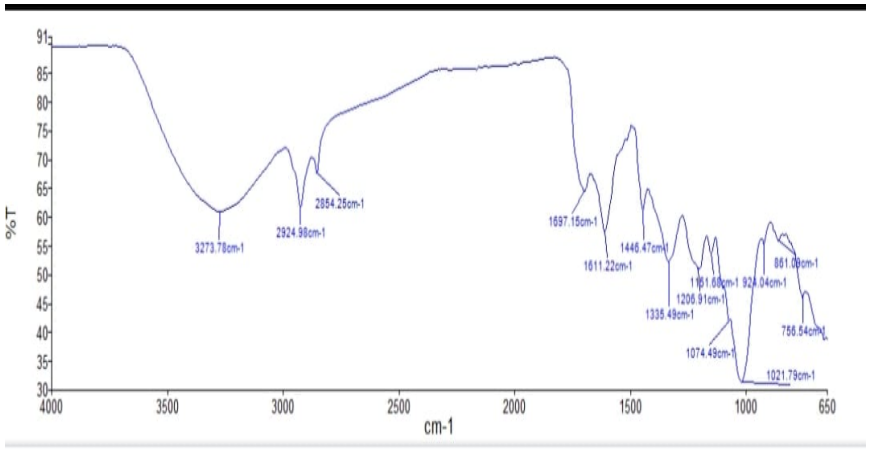

Figure No. 1: FT-IR Graph.

DISCUSSION

Guggulu is an oleogum resin that naturally exudes from the bark of commiphora wightii following an injury. It has proven to possess significant anti-inflammatory, anti-oxidant and anti-arthritic activity.[14] Guggulu has been widely incorporated into various pharmaceutical preparations such as vatis, ghrutas and dhupas etc. It also serves as binding agent for preparing vati. However, when a Guggulu based formulation contains ingredients such as Gandhaka and eranda taila, as seen in Simhanada Guggulu,[4] rolling the mixture into Vati becomes challenging due to its sticky consistency. This observation emerged during pilot studies conducted with different ratios of ingredients for Anilari rasa. In the adopted preparation method, Shunti, Pippali, Maricha and Gandhaka were taken in equal parts, while Guggulu was taken in four parts by considering Anukta mana quoted in Sharangadhara samhitha.[9] Eranda taila was added as required while mixing the ingredients and applied over the palm and fingers while rolling the pills. The primary intention was to maximize the use of

Eranda taila, as it plays a critical role in treating Amavata. This approach resulted in minimal oozing of gandhaka and Eranda taila with the addition of trikatu powder aiding in proper blending and lodging of Gandhaka and reducing direct contact between Eranda taila and Gandhaka. Vatis produced using this method exhibited proper consistency without soaking the paper excessively during drying. Vatis retained the uniform colour, odour and compressive properties after drying, as confirmed through hardness test. In conclusion, formulations containing Gandhaka, Eranda taila and Guggulu need not necessarily be rolled into pills, they can also be administered in semisolid form, with Eranda taila or including Eranda taila in other pharmaceutical procedure of the formulation. pH of Anilari rasa was 4.09, indicating it is a weak acid compound. Weak acid drugs are best absorbed in stomach as stomach is an acidic medium and drug exists in unionized form that is lipid soluble and easily absorbed.[15] The total ash % resulted for Anilari rasa was 3.95%.

Standards are unavailable for Anilari rasa. Total ash content might be due to the presence of inorganic content in the formulation. The acid insoluble ash value of Anilari rasa found was 0.381%w/w. This indicates that the formulation has less acid insoluble ash which indicates presence of fewer inorganic matter in the preparation that are not soluble in acid. Water soluble ash of Anilari rasa found was 3.09%w/w. As water soluble ash value is higher than acid insoluble ash, the formulation might contain higher level of certain soluble inorganic minerals and salts that may contribute to the drug's therapeutic efficacy. Loss on drying at 110°C of Anilari rasa was 2.06% w/w. Hence it can be stated that Anilari rasa has considerable amount of moisture content, likely due to the moisture content of triphala kashaya used in Guggulu sodhana. As per pharmacopoeia 5% variation is allowed on average weight of tablets. Average weight of Anilari rasa is 363mg. Average weight complying with the uniformity of weight test assures that the fixed dose of the sample can be delivered to the patients. Time duration taken to disintegrate Anilari rasa was 47mins. Usually conventional dosage units are expected to disintegrate in 15 min for uncoated tablets; 30 minutes for film coated tablets, 60 minutes for sugar coated ablets. The disintegration time of vati is less than Guggulu because Guggulu itself acts as a binding agent due to which DT is prolonged. Since Eranda taila is one of the major ingredients in the formulation and its oily property do not allow water easily to penetrate into tablets, which can be considered as one more factor for DT prolongation. The tablets disintegrated completely in 47 minutes highlighting the importance of Guggulu as a sustained realease dosage form in Ayurveda for prolonged action as analgesics, anti – inflammatory etc. Water soluble extractive value of Anilari rasa is

31.83%. Alcohol soluble extractive value of Anilari rasa is 22.68%. High extractive values of Anilari rasa could be due to the presence of herbal ingredients like trikatu, guggulu, eranda taila etc. Conventional compressed tablets that lose less than 0.5% to 1% of weight are considered acceptable. Some compressed hard tablets tend to cap or lose their crown portions on attrition hence hardness test is not a reliable indicator thus friability test is employed for the tablet. Friabilty of Anilari rasa tablets is 0.139%. Loss of weight was within the range i.e, 1%.

FT-IR analysis of Anilari Rasa revealed the presence of various functional groups with therapeutic potential. Phenolic compounds are common natural products found in plants, exhibits significant Anti-oxidant, Anti-microbial, Immune modulating & Anti-infammatory properties.[16] Castor oil is known to contain fatty acids[17] such as Ricinoleic acid, oleic acid, linolenic acid along with phenolic compounds and esters that possess anti-inflammatory and anti-oxidant properties . Sulfonamides, also known as “sulfa drugs” are used to treat various conditions, with sulfasalazine[18] being particularly effective in managing chronic inflammatory diseases like rheumatoid arthritis due to its anti-inflammatory and immune-modulating effects. Trikatu[19] contains aromatic compounds, phenolic amides, such as gingerols, piperine, piperidine which posses anti-inflammatory, anti-oxidant and bio-enhancing activities. The presence of Organic functional groups highlights the drug’s favorable acceptance and enhanced bioavailabilty.

CONCLUSION

- The Pharmaceutical methodology for Anilari Rasa was developed by conducting pilot studies with different ratio of ingredients to achieve a stable vati consistency, based on classical text references. The Physico-chemical Analysis of Anilari Rasa demonstrated its stability, suitability for absorption and adherence to quality standards. The diverse functional groups and bioactive constituents such as sulfonamides etc, identified through FT-IR analysis of Anilari Rasa, highlights its significant therapeutic potential, showcasing anti-inflammatory, anti-oxidant and bio-enhancing properties that collectively enhance its efficacy and bioavailabilty.

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