

ASSESSMENT OF EFFECT OF PROCESS OF *MURCCHANA* ON STABILITY OF ARKA
TAILNeha Mulik¹ and Piyush Gandhi^{2*}¹P.G. Scholar, Department of Rasashastra and Bhaishajya Kalpana, College of Ayurved and Research Centre, Akurdi, Pune, Maharashtra.^{2*} Assistant Professor, Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Nanded, Maharashtra.

*Corresponding Author: Dr. Piyush Gandhi

Assistant Professor, Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Nanded, Maharashtra.

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ABSTRACT

Introduction: Stability is a period during which formulations remain physical, chemical and biologically stable. Ayurveda has mentioned special process on *sneha* (Oleaginous substances) to remove its unpleasant properties like odor, to enhance its action and to enhance shelf life of *sneha* formulations (Medicated Oils). **Aim:** To evaluate the effect of process of *Murcchana* on shelf life of *Arka Tailam* (Medicated oil). **Material and Methods:** Three batches of *Murcchita* (MAT) and *Amurcchita Arka Tailam* (AMAT) was prepared by using *Murcchita* and Plain *sarshap tailam* (Mustard Oil). Shelf life of MAT and AMAT was carried out as accelerated study (for 3 months) by storing at 40°C±2°C, 75±5% RH. The organoleptic parameters (Taste, Color) and physicochemical parameters like Specific Gravity, Refractive Index, Acid Value (AV), Saponification Value (SV), Peroxide Value (PV) and Iodine Value (IV) were tested. The sampling was done at 0, 1, 3 months interval. **Results:** Both MAT and AMAT undergoes changes in physicochemical parameters after 3rd month of storage in accelerated type of study. But process of undesirable changes due to hydrolysis or oxidation seems to be faster in AMAT than MAT. **Conclusion:** Process of *Murcchana* may enhance the shelf life of medicated oil. But there is need to analyze by using more sophisticated techniques and to assess biological action to reconfirm the shelf life of medicated oils after process of *Murcchana*.

KEYWORDS: *Murcchita* (MAT) and *Amurcchita Arka Tailam*.

INTRODUCTION

Shelf life is one of the paradigm which comes under the umbrella of quality assurance of any formulation. *Acharya Sharangdhara* was pioneer in explaining the concept of shelf life under the heading *Saviryatavadhi*.^[1] *Saviryatavadhi* is a period during which *Virya* (Potency) of drug remain unchanged or it is period after which formulation may start reducing its *Virya* (potency) which make his unsuitability to achieve desired biological effects. Commentator also highlighted that *Saviryatavadhi* is a period after which there is decrease in properties which are achieved as a result of formulation especially in case of *Sneha Kalpana*.^[2] Different opinions (12 or 16 month)^[3] were there about *Saviryatavadhi* of *Sneha* formulations (Medicated Oil and *Ghruta*). But in contrary older *ghruta* were considered to be best in many neurological disorders.^[4] Shelf life for medicated Oil and medicated *Ghruta* was 3 and 2 yrs respectively as per Rule No. 161-B of D & C act 1940 and Rules 1945 amended in 2016.^[5] *Murcchana* is a special process recommended in the *sneha* formulation to remove blemishes like unpleasant odour, colour from *sneha*, to enhance the biological action by extracting

biologically more active principle and to extend the shelf life of *sneha* formulations.^[6] So there is need to find out the shelf life of *sneha* formulations prepared by using natural *sneha* and *murcchita sneha* on globally accepted criteria for stability testing.

Stability testing aims at providing evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity, light, and to establish a shelf life and recommended storage conditions for the drug substance or drug product.^[7] When a pharmacist or manufacturer plans to design, manufacture and market a drug product, it is his responsibility to provide an assurance that the said drug product would meet all the labeled claims and would be stable till the expiry date to the Regulatory authorities.

So present work is carried out with a aim to find out effect of process of *Murcchana* on shelf life of *Arka Taila* (An medicated oil).

MATERIAL AND METHODS

Identification and Authentication: The different herbs were procured from local vendor from Mumbai. Green leaves of *Arka* (*Callotropis Procerra* Ait.) were collected from local regions and authenticated by the Agharkhar Research Institute. *Sarshap* (Mustard Oil) Oil was procured from Govind mills.

Preparation of *Murcchita Sarshap Taila* (MST): The process of *Murcchana* of mustard oil was carried out by using the paste of herbs and water in specific proportion till desired signs were observed as mentioned in ancient classics.^[8]

Preparation of *Murcchita* (MAT) and *Amurcchita Arka Taila* (AMAT): *Murcchita* and *amurcchita Arka Taila* was prepared by using *murcchita* and plain mustard oil respectively. *Arka Taila*^[9] was prepared by heating *Sarshap* oil (4 Part) along with paste of *Haridra* (*Curcuma Longa* Linn.) (1 part), juice of green leaves of *Arka* (16 part) till desired characteristic (appearance of foam on oil, formation of roll from paste of herbs and disappearance of cracking sound from oil) of *Sneha Kalpana* appears as mentioned in ancient literature.^[10]

Experimental Design

Stability studies: Six transparent pet bottles of plastic (50 ml capacity) with lid containing *Murcchita* and *Amurcchita Arka Taila* was kept in triple stability chamber (Thermolab 90, 90,130 liters, instrument no: PES/MCOP/QAT/2012-13/01). The study was carried out as accelerated study (for 3 months) by storing at 40°C±2°C, 75±5% RH (sampling at 0, 1,3 months).

Sampling: Single bottle of each drug was removed from stability chamber and different test were conducted.

Test conducted: The Organoleptic test and test for physicochemical parameters was conducted on plain *Sarshap Taila*, *Murcchita Sarshap Taila*, *Amurcchita Arka Taila* and *Murcchita Arka Taila*. Test for physicochemical parameters like Refractive Index^[11], Specific Gravity^[12], Acid Value^[13], Saponification Value^[14], Peroxide Value^[15], Iodine Value^[16] were conducted for three times and mean values were taken.

OBSERVATIONS AND RESULTS: The organoleptic character of different samples of *Taila* was mentioned in table No. 1.

Table no. 1: organoleptic parameters of St, Mst, Mat, Amat.

Organoleptic parameters	Month	Color	Smell	Consistency	Appearance	Taste
<i>Sarshap Taila</i> (ST)	0 month	Golden yellow	Pungent	Liquid Oily	Oily	<i>Katu</i>
<i>Murcchita Sarshap Taila</i> (MST)	0 month	Reddish Golden	Smell of <i>Manjishtha</i> and <i>Haridra</i>	Liquid Oily	Oily	<i>Tikta Katu</i>
<i>Amurcchita Arka Taila</i> (AMAT)	0 month	Greenish Yellow	Smell of <i>Arka</i>	Liquid Oily	Oily	<i>Tikta Katu</i>
	1 st month	Greenish Yellow	Smell of <i>Arka</i>	Liquid Oily	Oily	<i>Tikta Katu</i>
	2 nd month	Greenish Yellow	Smell of <i>Arka</i>	Liquid Oily	Oily	<i>Tikta Katu</i>
	3 rd month	Greenish Yellow	Smell of <i>Arka</i>	Liquid Oily	Oily	<i>Tikta Katu</i>
<i>Murcchita Arka Taila</i> (MAT)	0 month	Reddish green	Smell of <i>Haridra</i> and <i>Arka</i>	Liquid Oily	Oily	<i>Katu Tikta</i>
	1 st month	Reddish green	Smell of <i>Haridra</i> and, <i>Arka</i>	Liquid Oily	Oily	<i>Katu Tikta</i>
	2 nd month	Reddish green	Smell of <i>Haridra</i> and <i>Arka</i>	Liquid Oily	Oily	<i>Katu Tikta</i>
	3 rd month	Reddish green	Smell of <i>Haridra</i> and <i>Arka</i>	Liquid Oily	Oily	<i>Katu Tikta</i>

The results of different physicochemical parameters were mentioned in table no.2 and 3.

Table no. 2: Specific gravity, Refractive Index and Iodine Value of Sarshap Taila (ST) and Murcchita Sarshap Taila,(MST) Amurcchita Arka Taila (AMAT), Murcchita Arka Taila (MAT).

Analytical Test	Month	Specific Gravity	Change in %	Refractive Index	Change in %	Iodine Value(IV)	Change in %
Sarshap Taila Standard value ^[17]		0.907 to 0.910	-----	1.4646 to 1.4662	-----	96 to 112	----
Plain Sarshap Taila	0 month	0.9111		1.455		13.1689	
Amurcchita Arka Tailam	0 month	0.9191	↑ 0.087 %	1.456	↓ 0.06 %	6.67	↓ 97.30 %
	1 st month	--		--		--	----
	2 nd month	--		--		--	----
	3 rd month	0.9166	↓ 0.27 %	1.454	↓ 0.13 %	16.958	↑ 154.12%
Murcchita Sarshap Taila	0 month	0.9216	↑ 1.15 %	1.457	↑ 0.13 %	6.4091	↓ 105.62%
Murcchita Arka Taila (MAT)	0 month	0.9207	↓ 0.09 %	1.457	0 %	16.958	↑ 164.84%
	1 st month	--		--		--	----
	2 nd month	--		--		--	----
	3 rd month	0.9166	↓ 0.44 %	1.450	↓ 0.48 %	17.371	↑ 2.43 %

Note : ↑ - indicate increase, ↓ - indicate decrease

Table no. 3: Saponification Value, Peroxide value and Acid Value of Sarshap Taila (ST) and Murcchita Sarshap Taila (MST), Amurcchita Arka Taila (AMAT), Murcchita Arka Taila (MAT).

Analytical Test	Month	Saponification Value (SV)	Change in %	Peroxide value (PV)	Change in %	Acid value(AV)	Change in %
Sarshap Taila Standard Value		168 to 177	----	-----	----	Maxi. 1.5	----
Plain Sarshap Taila (ST)	0 month	201.69		2.24		1.5162	
Amurcchita Arka Taila (AMAT)	0 month	270.66	↑ 34.19 %	10.38	↑ 633.39%	1.4025	↓ 8.10 %
	1 st month	261.06	↓ 3.67 %	12.52	↑ 20.61 %	2.2	↑ 56.86 %
	2 nd month	226.94	↓ 34.12 %	5.38	↓ 132.71 %	1.66	↓ 32.53 %
	3 rd month	276.25	↑ 21.72 %	8.38	↑ 55.76 %	2.242	↑ 35.06 %
Murcchita Sarshap Taila (MST)	0 month	138.99	↓ 45.11 %	12.05	↑ 437.94%	0.4417	↓ 243.26 %
Murcchita Arka Taila (MAT)	0 month	193.29	↑ 39.06 %	17.65	↑ 46.47 %	0.8014	↑ 81.43 %
	1 st month	271.01	↑ 40.35 %	6.67	↓ 164.61 %	1.38	↑ 72.19 %
	2 nd month	230.51	↓ 17.78 %	2.35	↓ 183.82 %	1.225	↓ 12.65 %
	3 rd month	285.95	↑ 24.05 %	4.53	↑ 92.76 %	2.323	↑ 89.63 %

Note : ↑ - indicate increase, ↓ - indicate decrease.

There is increase in sp. gravity and decrease in acid value, saponification and Iodine Value of Sarshap Taila after process of Murcchana. There is increase in acid value and peroxide value of Amurcchita Arka Taila in the first and third month of accelerated stability study. Saponification value and Iodine value is increased in Amurcchita Arka Taila when kept in stability Chamber.

There is constant decrease in peroxide value except in 3rd month of Murcchita Arka Taila when kept in stability chamber. Amurcchita Arka Taila has increase in peroxide value after 1st and 3rd month and decrease in 2nd month of stability study. Saponification value of Murcchita Arka Taila is decreased in 1st and 2nd month with upsurge in 3rd month. While saponification value of

Murcchita Arka Taila is increased in 1st and 3rd month with decrease in 2nd month.

DISCUSSION

Objectivity of stability study as per ICH guidelines is to study the effect of the different environmental factors like temperature, Humidity and light on quality of the drug product.^[18] It also helps to understand the shelf life period or to establish retest period of drug and assessment of recommended storage condition along with other specification like nature and quality of packaging material. 2 and 3 yr is recommended shelf life period of medicated *ghruta* and oil respectively as per rule 161 B of Drugs and Cosmetic act. *Murcchana* is one of the pretreatment recommended not only to remove unpleasant odor from oil, *ghruta* but also to enhance its pharmacological action and its shelf life. So effect of pretreatment *Murcchana* on shelf life of oil was assessed by using different physicochemical parameters under accelerated study design.

Effect of pharmaceutical procedure on oleaginous substances: Protracted open pan heating of oleaginous substances along with water or aqueous extracts may lead to hydrolysis which results into breaking of triglycerides into triacylglycerol which in turns hydrolyzed to form diacylglycerol fatty acid and monoacylglycerol respectively which finally hydrolysis to fatty acid and glycerol.^[19] This makes oil to rancidify which is not good sign in case of vegetative oils.

Vegetative oil with more unsaturated fatty acid was more likely to undergo the process of oxidation.^[20]

Open pan heating may increases the peroxide value due to applied temperature below 100 °C and contact of atmospheric oxygen. Use of different vessels like Cu may act as free radical which initiates the process of oxidation.^[21] Heavy metals like Copper and iron also have pro oxidant effect since their variable valency state causes them to act as catalysts for the initiation step and also influence propagation and termination steps of the autoxidation process.

In short different procedures and use of aqueous extracts and herbal paste during pharmaceuticals of *Sneha* formulation affect different parameters of oily substances which is need to be evaluated.

Stability study should include testing of those attributes of the drug that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy.

No variation is observed in organoleptic characters of ST, MST, MAT and AMAT during storage in stability chambers.

Acid Value (AV): It is measure of free fatty acid which is resulted due to conversion of triglycerides into fatty acid and glycerol as result of hydrolysis or oxidation due

to presence of free radicals like cu. It is also measure of rancidification which results into discoloration and sourness of oil. The lower acid value of MAT than AMAT indicates the decrease in free fatty acid due to use of paste of herbs containing antioxidants for the process of *Murcchana*. The acid value observed in the present study is within acceptable limits up to 2nd month of storage which signifies that formation of free fatty acid is minimum up to 2nd month of storage. Acid values slightly increases after 1st and 3rd month with decrease in 2nd month when kept in stability chamber. The process of hydrolysis of triglycerides to form fatty acid is enhanced after 1st and 3rd month of storage. Even though % of increase and decrease is higher in MAT than AMAT, acid value of both MAT and AMAT is near about same after 3rd month of storage. Acid value of MAT is less than AMAT which may indicate that triglycerides of MAT have low process of hydrolysis than AMAT. The fall in acid value could be because of the antioxidant properties of the drugs used in *Murcchana*. So the chances of rancidity of MAT are less than that of AMAT. Percentage of increase in acid value of AMAT after 3rd month is higher than 20 % which indicate process of rancidity is started.

Saponification Value (SV): It is an index of average molecular mass of fatty acid present as esters in the oil sample. Significant decrease in SV after process of *Murcchana* indicate that some changes has taken place in number of ester bonds due to addition of phytoconstituents from paste of *murcchana* drug. Slightly increase (20%) in SV after 3rd month of storage is observed in both AMAT and MAT group. The rise in SV could be attributed to cumulative generation of saponifiable matter in the oil. The steady SV observed for MAT & AMAT indicates that there is negligible effect of aqueous extracts and the phytoconstituent incorporated in the formulation on the esters present in the oil.

Peroxide Value (PV): Peroxide value is used as a measure of the extent to which rancidity reactions have occurred during storage. It could be used as indication of the quality and stability of fats and oils. PV was found to be elevated in AMAT and MAT; this may be due to the prolonged contact of oil with aqueous extracts during formulation.

Peroxide value also found to increase with the storage time, temperature and contact with air of the oil samples. Decrease in PV after storage at an elevated temperature is due to conversion of primary product of oxidation (Peroxides) in secondary products²² (Ketones, aldehyde and fatty acid).The rate of oxidation of an organic compound increases with increase in temperature of storage. The increase in oxygen concentration will usually promote the rate of reaction, with the net result that, low temperature storage reduce decomposition but not to the extend predicted by application of the rate of reaction-temperature relationship. But there is no increase in acid Value after 2nd month of storage.

Addition of antioxidant properties present in the phytoconstituents (curcumin, demethoxycurcumin and bis-demethoxycurcumin)^[23] of drugs (*Curcuma longa* and *Calotropis Procerra* Ait.) may cause decline in PV value in 1st and 2nd month of storage in MAT. Moreover, the antioxidants present in the formulation are insufficient in resisting the further rise in peroxidation on storage. This is evident from the increased peroxide value on storage after 3 months. AMAT has more peroxide value than MAT after 3rd month of storage which may indicate that process of *murcchana* may help to reduce peroxide value due to addition of antioxidant present in drugs of *murcchana*. This analysis suggest that the oil requires more amount of antioxidant ingredients than current concentration.

Iodine Value (IV): The iodine value is a measure of degree of unsaturation of the vegetable oils and fat. It determines the stability of oils to oxidation and allows the overall saturation of the fat to be determined qualitatively. These low Iodine values may have contributed to its greater oxidative stability. Sharp rise (154 %) in IV is observed after 3rd month of storage in AMAT implies that process of unsaturation is much faster than MAT. Since, there is minimal reduction in the iodine value of MAT before and after stability testing, it proves that the herbs used were effective in maintaining the unsaturation of oil. Also, certain herbs used for the *murcchana* process are already found to be beneficial in maintaining the unsaturation of oils.

An Ayurvedic drug can be considered to be stable if “no significant change” occurs during at any time of testing at accelerated storage condition or at real time storage condition as per guidelines mentioned in API. As per API directions significant change is defined as change in the physico-chemical parameters (moisture, ash, and particle size) shall not vary beyond 25% of the initial value. No significant change (more than 25 %) was observed in Sp. gravity, Refractive Index, Saponification Value of MAT and AMAT. Iodine Value of MAT has not changed as significant level. Acid Value, Peroxide Value of MAT and AMAT, Iodine Value of AMAT was changed significantly. So MAT and AMAT undergoes changes in physicochemical parameters after 3rd month of storage in accelerated type of study. But process of undesirable changes due to hydrolysis or oxidation seems to be faster in AMAT than MAT when compared acid value, peroxide Value and Iodine values. So preliminary conclusion can be drawn that process of *Murcchana* may delay the degradation of oil or have more stable for longer duration specially in case of *Arka Taila*.

Future directions

The present study is a preliminary attempt to analyze the effect of process of *Murcchana* on stability of medicated oils. Here an attempt is made to develop physicochemical parameters to estimate shelf life. But much more study is required to assess the status of different fatty acid, active principle and other parameters

like ketones, aldehyde so much more solid conclusion can be done regarding the effect of *Murcchana* on stability. Also assessment of pharmacological action at different time interval also help to find exact shelf life of oils as sufficient techniques are not available to assess physicochemical parameters.

CONCLUSION

The present study establishes the effect of process of *Murcchana* on different physicochemical parameters. Non-significant changes in Peroxide value, Acid Value and Iodine value upto 2nd month of storage implies that process of hydrolysis or oxidation takes place after 3rd month of storage on accelerated stability model. Process of *Murcchana* may increase the stability of medicated oil for certain period when compared the percentage change in value of PV, IV and AV. Our study reveals that to make more stable oil product, the concentration of herbs with antioxidant potential needs to be increased. This is preliminary work on effect of *Murcchana* process on stability which is need to be confirmed by using more sophisticated techniques to assess physicochemical parameters and pharmacological activity.

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