PHARMACOPOEIAL STANDARDS OF SNEHAKALPANA

Dr. Parvathy Mohan, Dr. Rajam. R
PG Scholar, Professor and HOD,

Department of Rasasastra and Bhaishajya Kalpana, Government Ayurveda College, Thiruvananthapuram.

ABSTRACT
Quality of the product is the focus point nowadays, especially in the pharmaceutical industry. To provide standard value, to generate faith, to provide quality control, safety and efficacy of Ayurvedic formulations, standardization is essential tool. Therapeutic utilization of medicated taila and ghrita is explained under snehakalpana in Ayurvedic pharmaceutics. This work aims to review the standards of sneha kalpana mentioned in pharmacopeial laboratory for Indian medicines (PLIM) and Ayurvedic pharmacopeia of India. This will help in adopting proper standards while preparing the formulations to keep its safety, efficacy and reproducibility.

Key words: Sneha kalpana, PLIM, Ayurvedic Pharmacopeia of India.

I. INTRODUCTION
Standardization is a numerical value or specific property that quantifies the purity and quality of drug and formulated medicine. Standardization describes all measures, which are taken during the manufacturing process and quality control leading to reproductive quality.

Ayurvedic pharmaceutics is rich with its unique concept panchavidha kashaya kalpana - swarasa, kalka, kwatha, hima and phanta. These kalpanas are used in various therapeutic purposes. These panchavidha kashaya kalpanas are basic kalpana for all other kalpana; snehakalpana, avaleha kalpana etc.

Ghritakalpana and taila kalpana are included in sneha kalpana. In this, oil or ghee is boiled in prescribed drava (kashayas etc) and kalka of drugs according to the formula. This process ensures absorption of active therapeutic principles of the ingredients. Generally if kalka is one part by weight, sneha should be four parts and the dravadravya should be sixteen parts. Sixty three different medicated tailas and forty four different medicated ghrita preparations are listed in official Ayurvedic Formulary of India.

II. AIMS AND OBJECTIVES
Study aims to review about different standards of snehakalpana.

III. MATERIALS AND METHODS
This work is a literature review on various standards of snehakalpana detailed in different pharmacopoeia.

3.1 Standardization
Certain standards or parameters are necessary for raw drugs, procedures and end products to provide quality assurance. For systematic study of standardization of Ayurvedic Drugs and formulations, standardization in this context can be divided into three steps – Standardization of Raw Drugs, Standardization of Process and Standardization of Finished Products.

3.2 Pharmacopeial standards of taila / ghrita

3.21 PLIM Standards
- Description
- Colour
- Odour
- Weight/ml (in case of taila)
- Refractive index at 25°C
- Viscosity
- Iodine Value
- Saponification value
- Acid value
- Peroxide value
- Identification GLC/ TLC/ HPTLC
- Test for heavy metals
- Microbial contamination
- Test for specific pathogen
- Pesticide residue
- Test for Aflatoxins

3.22 Colour and Odour
The examination which can be done by sense organs. Any deviation from normal colour and any unpleasant smell in sample signify that due to some chemical reaction sample is changing its normal phenomenon.

3.23 Weight per Milliliter
Wt/ml of a liquid is the weight in g of 1 ml of a liquid when weighed in air at 25°C (unless otherwise specified).

3.24 Refractive Index
R I of a substance with reference to air is the ratio of the sine of angle of incidence to the sine of the angle of refraction of beam of light passing from air into the substance. It varies with wavelength of light used in its measurement. Unless otherwise prescribed, the RI is measured
at 25°C +/- .5. Temperature should be carefully adjusted and maintained. Since the RI varies significantly with temperature. Apparatus required: Abbe refractometer

3.25 Iodine Value

Iodine value (Iodine number/iodine index) is the weight of iodine absorbed by 100 gms of a chemical substances. Significance – the most important application of iodine value is to determine the amount of unsaturation. Unsaturation is in the form of double bonds which react with iodine compounds. Higher the iodine value, less stable the oil and more vulnerable it is to oxidation and free radical production.

3.26 Saponification Value

The number of milligram of potassium hydroxide required to neutralize the fatty acids, resulting from the complete hydrolysis of 1 g of the oil or fat. Significance – the saponification number depends on the molecular weight and the % concentration of fatty acid component present in oil. ie; SV collectively used to determine the average relative molecular mass of Oils and fats.

3.27 Acid Value (Neutralization number / Acidity)

The number of mg of KOH required neutralizing the free acid in 1 gm of the substance. Significance – One of the important parameter related to the oil quality. High AV indicates the deterioration of oil.

3.28 Peroxide Value

The number of mille equivalents of active oxygen that expresses the amount of peroxide contained in 1000g of substance. Significance – PV is used as a measurement of the extent to which rancidity reactions have occurred during storage. Oils with high degree of unsaturation are more susceptible to auto oxidation. The best test for auto oxidation (oxidization rancidity) is peroxide test. Useful for assessing the extent to which spoilage has advanced.

3.29 Specific Gravity

Specific gravity of a liquid is the wt of a given volume of the liquid (at 25°C unless or otherwise specified) compared with the weight of an equal volume of water at the same temperature.

3.210 Detection of Mineral oil test (Holde’s test)

Principle – Presence of mineral oil is indicated by the development of turbidity when hot distilled water is added to a freshly made alcoholic solution of soap formed by the oil.

3.211 Congealing Point (Gritha Only)

The temperature at which a sample being cooled develops a set or resistance to flow. ie; at congealing point there exist a mixture of the liquid phase of a substance and a small but increasing proportion of the solid phase.

3.211 Thin Layer Chromatography (TLC)

TLC is a simple, quick and inexpensive procedure that gives a quick answer as how many components are in a mixture. TLC also used to support the identity of a compound in a mixture when the retention factor of a compound is compared with the RF of a known compound (preferably both run on the same TLC plate).

3.212 High Performance Thin Layer Chromatography (HPTLC)

HPTLC is an analytical technique based on TLC, but with enhancements intended to increase the resolution of the compounds to be separated and to allow quantitative analysis of the compounds.

3.213 Test for Heavy Metals

<table>
<thead>
<tr>
<th>Heavy Metal Content</th>
<th>Permissible Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>10 ppm</td>
</tr>
<tr>
<td>Arsenic</td>
<td>3 ppm</td>
</tr>
<tr>
<td>Cadmium</td>
<td>3 ppm</td>
</tr>
<tr>
<td>Mercury</td>
<td>1 ppm</td>
</tr>
</tbody>
</table>

3.214 Atomic Absorption Spectrophotometry (AAS)

AAS used in the determination of heavy metal elements and some nonmetal elements in the atomic state.

3.215 Inductively – Coupled Plasma Mass Spectrometry (ICP - MS)

This method is provided to determine arsenic, cadmium, lead, mercury and copper in traditional herbal medicinal substances.

3.216 Test for Afla Toxins

This test is designed to detect the possible presence of afla toxins. B1, B2, G1 and G2 which are highly dangerous contaminants in any material of plant origin.

3.217 Microbial Limit Tests

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Permissible limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>Absent</td>
</tr>
<tr>
<td>Salmonella SPP</td>
<td>Absent</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Absent</td>
</tr>
<tr>
<td>E. Coli</td>
<td>Absent</td>
</tr>
<tr>
<td>Total microbial plate count (TPC)</td>
<td>$10^5$ /gm</td>
</tr>
<tr>
<td>Total yeast and mold</td>
<td>$10^3$ /gm</td>
</tr>
</tbody>
</table>

In API totally 20 grithas and 37 tailas are explained.
Table 3.3 Parameters of Various Ghrithas and Tailas in API

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Range</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractive index at 40</td>
<td>1.43 – 1.53</td>
<td></td>
</tr>
<tr>
<td>Weight per ml at 40</td>
<td>.829 – .985</td>
<td>Sukumara ghritha (213 - 277) Kottamchukkadi (150 - 175) Mahathriphaladya ghritha (.2100 - .2147)</td>
</tr>
<tr>
<td>Saponification value</td>
<td>180 – 225</td>
<td>Kottamchukkadi – NM 8 Dadiimadi ghritha – a) NM .9 b) NM .33 Tiktaka ghritha – NM .56 Parinathakera ksheeradi taila – NM 9 Brihath saindavadi taila – NM 10</td>
</tr>
<tr>
<td>Iodine value</td>
<td>30 – 100</td>
<td>Dasamula ghritha (120 - 150)</td>
</tr>
<tr>
<td>Acid value</td>
<td>2 – 6</td>
<td></td>
</tr>
<tr>
<td>Peroxide value</td>
<td>1 – 10</td>
<td>Mahathriphaladya ghritha - 15.8 Karpasasthyadi taila - .4</td>
</tr>
<tr>
<td>Congealing point (grhitha)</td>
<td>21 – 17</td>
<td></td>
</tr>
</tbody>
</table>

IV. DISCUSSION AND CONCLUSION

For standardizing a product, the classical as well as modern parameters should be taken into consideration. First classically mentioned lakshanas (morphology) of the finished product should be considered and confirmative test mentioned to assess quality of the particular formulation is also very essential to provide vital information in standardization of that formulation. Other modern parameters like organoleptic characters, physical constants such as acid value, acid insoluble ash, water insoluble ash, specific gravity, moisture content etc; qualitative analysis and quantitative analysis by using sophisticated instruments like AAS, ICP – AES, ESCA etc, particle size assessment and structural cell shape study can be utilized for evaluation of finished products and the values are to be compared with the established standards.

Quality of a product is an important parameter, especially in the pharmaceutical industry. Indeed the regulatory authorities have paid special attention to quality, due to high risk of damage to life and health of patients possible, and developed many guidelines to insure a sufficient level of quality. Need for quality control methods for Ayurvedic drugs is must due to commercialization of the Ayurvedic pharmacies during the current century and also due to the inclusion of Ayurvedic drugs under the drugs and cosmetic act. Achieving complete and wholesome standardization of herbal formulations is the need of the hour and its implementation will be a historic leap towards India's health securities

V. REFERENCES