STANDARDIZATION OF A POLYHERBAL AYURVEDIC FORMULATION, 
SULAHARAN YOGA
Sahoo Rashmibala *, Swain Pramod Kumar, Acharya Rabinarayana
State Drug Testing & Research Laboratory (ISM), Govt. Ayurvedic Hospital Campus, BJP Nagar, Bhubaneswar, India

Received on: 11/04/2011 Revised on: 22/05/2011 Accepted on: 08/06/2011

ABSTRACT
The recent global resurgence of interest in traditional systems of medicines has led to an increase in the demand for them. These medicines are effective but commercialization of the manufacture of these medicines to meet this increasing demand has resulted in a decline in their quality, primarily due to lack of adequate regulations pertaining to this sector of medicine. The need of the hour is to evolve a systematic approach and to develop well-designed methodologies for the standardization of herbal formulations. In the paper, attempt has been made to evaluate Sulaharana Yoga, a Ayurvedic formulation. One sample was procured from manufacturers and subjected to macroscopic, microscopic characterization, physico-chemical screening, thin layer chromatography (TLC) studies and was compared using in-house preparation formulation. It was observed that the commercial samples matched exactly with that of in-house preparation after performing the standardization.

KEYWORDS: Sulaharana Yoga, Ayurvedic drug, Standardization, TLC chromatogram

*Corresponding author
Rashmibala Sahoo, Scientific officer, State Drug Testing & Research Laboratory (ISM), Govt. Ayurvedic Hospital Campus, BJP Nagar, Bhubaneswar-751014 E mail-rashmibalasahoo.sahoo@gmail.com

INTRODUCTION
The Indian System of Medicine, mainly comprising of Ayurveda, Siddha and Unani, is one of the oldest holistic management system with thoroughly documented remedies. Of all these, Ayurveda is being practiced by a large population in India and abroad1. Botanical constitute of major part of these traditional medicines. The development of these traditional systems of medicines with the perspectives of safety, efficacy and quality will help not only to preserve the traditional heritage but also to rationalize the use of natural products in the health care2, 3. In Indian System of Medicines (ISM) majority of the remedies are based on plants and plant products. The plant materials generally work on human system to improve the immunity, resistance and strength and there by cure the diseases. Majority of rural and to a great extent the urban population depends on ISM to overcome the health disorders. The subject of herbal drug standardization is massively wide and deep. There is so much to know and so many seemingly contradictory theories on the subject of herbal medicines and their relationship with human physiology and mental function. India can emerge as the major country and play the lead role in production of standardized, therapeutically effective Ayurvedic formulations. India needs to explore the medicinally important plants. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization. As per the estimates of World Health Organization (WHO), more than 80% of Global population use plants or their products as the primary source of medicinal agents2. In many countries of the world the traditional systems of medicine is being practiced. The most important traditional systems of the world are, the Traditional Chinese Medicine (TCM), the Indian System of Medicine (ISM), the Japanese Kampo and the African folklore, where the remedies are compiled and well documented. The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety, and efficacy4. Sulaharana Yoga is official in Ayurvedic Formulary of India (AFI Part I, 12:30) and is prescribed

for the treatment of pain/colic, malabsorption syndrome, diarrhea, abdominal lump, digestive impairment\(^5\) (Table 1). This study reports on the standardization of Sulaharana Yoga based on macroscopic, microscopic, physic-chemical parameters and Thin Layer Chromatographic study (TLC).

**MATERIALS AND METHODS**

**Procurements of Drugs**

Ingredients were procured from the local raw material traders and their identity was confirmed by correlating their morphological and microscopical characters with those given in literature.\(^5\)\(^6\)\(^7\)\(^8\)\(^9\)\(^10\).

**Preparation of in-house formulation**

All the procured and authenticated individual drugs were dried in shade and cleaned by hand sorting. The ingredients were dried below 60°C, powdered, sieved through 85# and stored in air tight containers. Standard in-house reference sample of Sulaharana Yoga was prepared as per the formula given in Ayurvedic Formulary Part -1 and labeled as SHYL.

**Marketed samples**

The marketed sample of Sulaharana Yoga, sample I (SHYS 1) was collected from the physicians, which are being used for the treatment of pain/colic, malabsorption syndrome, diarrhea, abdominal lump, digestive impairment. The market samples were compared to the in-house preparation for macroscopic, microscopic, physicochemical properties and TLC study.

**Macroscopic examination**

It refers to evaluation of the formulation by color, odor, taste, texture, etc. The macroscopic study of the samples was evaluated based on the method described by Siddiqui et al.\(^11\).

**Microscopic examination**

For microscopic study, 10 g of the drug sample was taken, powdered. The powdered material was taken on a 85 mesh sieve and allowed in slow running water for washing away the minerals. The materials were cleared in chloral hydrate, wash with distilled water and mounted in glycerin, then observed charcters.\(^12\).

**Determination of Physico-chemical parameters**

Physico-chemical parameters such as diameter, thickness, hardness, friability, weight variation, disintegration time, foreign matter, moisture content, total ash, acid insoluble ash, water- and alcohol- soluble extractives were determined according to methods described in the Indian Pharmacopeia\(^12\).

**Thin layer chromatographic studies**

TLC studies of the alcoholic extract was carried out on aluminium plates precoated with silica gel 60 F\(_{254}\) of 0.2 mm thickness using Toluene : ethyl acetate: formic acid ( 5 : 15 : 0.5) as mobile phase and observed under visible light after derivatisation with anisaldehyde sulphuric acid followed by heating the plate at 110°C. The colour and R\(_f\) values of the resolved spots were noted\(^13\)\(^,\)\(^14\).

**RESULTS AND DISCUSSION**

**Macroscopic characters**

All samples are hard in texture, grayish yellow in colour, characteristic of asfoetida in odour and pungent in taste.

**Microscopic characters**

Microscopic analysis of both the samples shows the presence of identifying diagnostic characters, which are not overlapping with the characters of other ingredient that are spherical pitted stone cells, criss cross fibers, elongated pitted sclereids and fibers with peg like out growth indicated the presence of *Terminalia chebula*; endocarp cells and stone cells intercepted with parenchyma cells indicated the presence of *Piper nigrum*; perisperm cells containing compacted masses of starch grains indicated the presence of *Piper longum*; vessels and vessels with parenchyma cells indicated the presence of *Zingiber officinale*; fragments of trichome rods and outer layer of endocarp indicated the presence of *Strychnos nux-vomica* (Figure 1).

**Physico-chemical parameters study**

Physicochemical parameters of Sulaharna Yoga are tabulated in Table 2. The hardness of the tablets is within the acceptable range of 3.2-3.5 kg/cm\(^2\). It observe that the hardness increased with increasing binder concentration. The friability of all the formulations below 1.0%. The tablet thickness of all the formulations are similar and this can be attributed to their similar bulk and tapped densities and same compressional force used. The weight variation of all the formulations are within the range of 2.54-2.44 mg. Disintegration time of all the formulations are within the official limits. The disintegration time of tablets is increases with increase in binder concentration. Loss on drying at 105°C is one of the major factors responsible for the deterioration of the drugs and formulations. Low moisture content is always desirable for higher stability of drugs. The results of Loss on drying at 105°C of prepared in-house formulation showed lower value in comparison to marketed formulation. A high ash value is indicative of contamination, substitution, adulteration, or carelessness in preparing the drug or drug combinations for marketing. The results of ash value revealed that the in-house preparation have higher value when compared with marketed formulation. Water-soluble and alcohol soluble extractive value plays an important role in evaluation of crude drugs. Less extractive value indicates addition of exhausted material, adulteration or incorrect processing during drying or storage or formulating. The extractive value of in-house
formulation showed higher values, when compared with marketed formulation.

**Thin Layer Chromatographic Study**
The TLC profiles of both the formulations are superimposable indicating the presence of all the constituents in the marketed and in-house formulation. Thin Layer Chromatogram of the ethanolic extract after derivatisation with anisaldehyde sulphuric acid reagent showed eight major spots major spots at Rf 0.15, 0.25 (green), 0.33 (green), 0.35 (light brown), 0.50 (yellow) and 0.70 (violet) (Figure 2).

**CONCLUSION**
After analysis of samples of Sulaharana Yoga by different parameters such as diameter, thickness, hardness, friability, weight variation, disintegration time, foreign matter, moisture content, total ash, acid insoluble ash, water- and alcohol- soluble extractives and TLC chromatogram shows good co-relation between them. The study of microscopic characters of different samples shows the presence of diagnostic identifying characters for presence of each ingredient. So it can be concluded that these parameters can be used for the evaluation of Sulaharana yoga. Purity and potency of the materials and formulations following the procedure given could be performed in QC/QA laboratory of pharmaceutical house.

**ACKNOWLEDGEMENT**
The authors wish to thank the Head, State Drug Testing & Research Laboratory (ISM), for providing the house.

**REFERENCES**
5. Pharmacopoeial Standards for Ayurvedic Formulations; Central Council for Research in Ayurveda & Siddha, Ministry of Health and family welfare (Govt. of India), New Delhi, 1987.

**Table 1. Sulaharana Yoga contains following ingredients**

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Ingredients</th>
<th>Latin name</th>
<th>Part used</th>
<th>Part</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Haritaki</td>
<td>Terminalia chebula</td>
<td>Pericarp</td>
<td>1 part</td>
</tr>
<tr>
<td>2.</td>
<td>Sunthi</td>
<td>Zingiber officinale</td>
<td>Rhizome</td>
<td>1 part</td>
</tr>
<tr>
<td>3.</td>
<td>Maricha</td>
<td>Piper nigrum</td>
<td>Fruit</td>
<td>1 part</td>
</tr>
<tr>
<td>4.</td>
<td>Pippali</td>
<td>Piper longum</td>
<td>Fruit</td>
<td>1 part</td>
</tr>
<tr>
<td>5.</td>
<td>Kuchila (Visamusti-suddha)</td>
<td>Strychnos nux-vomica</td>
<td>Seed</td>
<td>1 part</td>
</tr>
<tr>
<td>6.</td>
<td>Hinga</td>
<td>Feronia foetida</td>
<td>Exudates</td>
<td>1 part</td>
</tr>
<tr>
<td>7.</td>
<td>Saidhava lavana</td>
<td>Rock salt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Gandhaka - suddha</td>
<td>Purified sulphur</td>
<td></td>
<td>1 part</td>
</tr>
</tbody>
</table>

**Table 2. Physico-chemical parameters of Sulaharana Yoga**

<table>
<thead>
<tr>
<th>Sl.No</th>
<th>Parameters</th>
<th>In house preparation SHYL</th>
<th>Market sample SHYS 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Diameter (mm ± SD)</td>
<td>10±0.021</td>
<td>10.2±0.014</td>
</tr>
<tr>
<td>2.</td>
<td>Thickness (mm ± SD)</td>
<td>3.1±0.040</td>
<td>3.5±0.043</td>
</tr>
<tr>
<td>3.</td>
<td>Hardness (kg/cm² ± SD)</td>
<td>3.5±0.010</td>
<td>3.2±0.013</td>
</tr>
<tr>
<td>4.</td>
<td>Friability (%)</td>
<td>0.61</td>
<td>0.65</td>
</tr>
<tr>
<td>5.</td>
<td>Weight variation Mg (Mean ± SD)</td>
<td>2.54±2.29</td>
<td>2.44±2.09</td>
</tr>
<tr>
<td>6.</td>
<td>Disintegration time</td>
<td>29 mm</td>
<td>25 mm</td>
</tr>
<tr>
<td>7.</td>
<td>Loss on drying at 105°C</td>
<td>5.64 % w/w</td>
<td>6.64 % w/w</td>
</tr>
<tr>
<td>8.</td>
<td>Total ash</td>
<td>16.35 % w/w</td>
<td>14.35 % w/w</td>
</tr>
<tr>
<td>9.</td>
<td>Acid insoluble ash</td>
<td>2.56 % w/w</td>
<td>2.26 % w/w</td>
</tr>
<tr>
<td>10.</td>
<td>Alcohol soluble extractive</td>
<td>16.52 % w/w</td>
<td>14.48 % w/w</td>
</tr>
<tr>
<td>11.</td>
<td>Water soluble extractive</td>
<td>35.36 % w/w</td>
<td>33.56 % w/w</td>
</tr>
</tbody>
</table>
Figure 1. Microscopic study of Sulaharana Yoga

Figure 2: TLC chromatogram of Sulaharana Yoga T1, SHYL, T2, SHYS 1

Source of support: Nil, Conflict of interest: None Declared