STANDARDISATION OF AYURVEDIC MEDICINES-

DASAMULAM KASAYAM*

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ABSTRACT: In a project on the analysis and standardization of Ayurvedic medicines, a chemical methodology for Dasamulam Kasayam for the comparison of market samples with a laboratory sample of Dasamulam Kasayam, and recording of characteristics like colour, consistency, smell, taste acidity, density, water soluble content and ash content. Adsorption of the Kasayam on silicagel, followed by extraction with selected solvents (petroleum ether, CHCL3, EtOAc and EtOH) as well as TLC pattern of each extract, together with the TLC pattern of total crude aglycones formed by the acid hydrolysis of the ethanol extract are experimentally determined. Market samples are compared with the reference sample using the same physical and chemical characteristics.

Ayurvedic formulations comprise aqueous extracts or decoctions of crushed raw drugs (Kwathas or Kasayams), raw drugs powders (Curnas), pills or tablets (Gulikas), electuaries (Lehyas), medicated oils and ghees (tailams and ghrtas), aqueous-alcoholic extracts of raw drugs and/or Kasayams, formed in a sugar medium, undergoing alcoholic fermentation (Airstas and Asavams), calcined/sublimed mineral reparation, often made under special treatment with herbal juices/extracts (Bhasmas) etc. three modes of preparation of Kasayams are officially recognized viz. sita, phanda and Kwatha. In the Sita mode, one part of the crushed drug combination is left undisturbed in six parts of water at room temperature for 12 hours and extract strained through cloth. In the Phanda mode, one part of the crushed drug combination is left undisturbed in six parts of water at room temperature for 12 hours and extract strained through cloth. In the Kawatha mode, one part of the crushed mixture of drugs is boiled and slowly evaporated with water, till the volume is reduced to ¼ th, strained through cloth and the filtrate is further concentrated to one half of its volume (~ 75ml of such Kwatha is the usually prescribed single adult dose). In commercial practice, the Kasayam is often offered in 5 times more concentrated from and 15ml of this concentrate, diluted with 60ml of boiled-and-cooled water is the recommended single dose.

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Since Ayurvedic medicines come under the purview of Drugs and Cosmetics Act, there is increased general awareness about the necessity for developing standards for the purpose of quality control by the manufacturers as well as by the Drug control Authorities and for quality assurance to the public. Preliminary standards for a few Curnas have been proposed, but no standards exist for the Ayurvedic aqueous Kwathas (Kasayams). In a project on the standardization of Ayurvedic composite medicines, one of the medicines taken up for study in our laboratory was Dasamulam Kasayam, a broad-spectrum Ayurvedic remedy against a number of ailments, caused by the imbalance of the tridosas. We report here a proposed chemical method of standardisation of Dasamulam Kasayam, which may be of general applicability to other Kasayams also.

**Experimental**

Briefly, the method consists of 4 parts, viz, (1) the preparation of a reference (standard) sample of the medicine as per the methods prescribed in Ayurvedic text, using authentic, raw drug samples*(2) recording preliminary parameters (partly organoleptic) like colour, smell, taste, consistency, acidity etc. as well as more quantitatively, density, (g/ml), water-soluble content (% W/V), and ash content (% W/V)., (3) determining the % extractives on successive extraction of the Kasayam with a selected set of solvents in the increasing order of polarity and (4) running the thin layer chromatography (TLC) of the various extracts and recording the TLC pattern including that of the ‘total crude aglycones’ obtained by acid hydrolysis of the last ethanol extract (which is the major extract from most Kasayams and contains predominantly glycosides).

• We also believe that standardization of the ingredient drugs of each compound medicine is an integral part of the overall standardisation. Data for these component drugs have been collected in a systematic way as per a standard protocol (to serve as proposed standards). This aspect is, for the time being, omitted from this paper.

The general scheme developed is outlined in Chart 1. The parameters thus determined for the reference laboratory sample of Kasayam are used to compare with those obtained under similar conditions for the market samples of the medicine to be standardised.

Dasamulas: Table 1 lists the Sanskrit names of the ten drugs “Dasamulas” along with the botanical names as given in reference, in Ayurvedic Formulary of India – Part I and in Vaidya Yoga Ratnavali. Slight disagreements in botanical identities are noted in these 3 publications. Although Dasamulas literally mean ’10 roots’, by custom, tradition and usage, there appears to be unanimity among Ayurvedic physicians all over India, in using Goksura (Tribulus terrestris) dried fruits instead of roots. There is also discrepancy with respect to the pair of drugs ‘Brhatidwayam” References 2-4 seem to identify these as Solanum xanthocarpam and Solanum indicum. Physicians in Kerala take these as Ksudra and Svetabrhati (Ceruvazhuthina and Venvazhuthina)6. However, in actual ayurvedic practice, handed sown by tradition through many generations, Aerva lanata (Bhadra) has been in use in place of Svetabrhati (especially in north and central Kerala and by major, Ayurvedic house in Kerala), and has been adopted in the present work.

Preparation of reference laboratory sample: Authentic drugs corresponding to the Dasamulas were obtained from the manufacturing unit of Arya Vaidya Pharmacy, Kanjikode (Kerala), where, as pointed out, Ksudra brhati and Bhadra are used for Brhatidwayam. The clean, dried chopped and crushed drugs (160g. each) were mixed with water (32 l) and slowly boiled and evaporated in an aluminum vessel, under controlled heating, with occasional stirring, till the volume was reduced to ¼ th. The resulting Kasayam, after slight cooling, was filtered through cloth on a Buchner funnel, under
pressing and mild suction, and the residue washed with a little hot water. The filtrate was

### TABLE 1

List of drugs corresponding to Dasamulas

| No. | Sanskrit Name | Part used | Ref.2 | Botanical Name | Ref.3 | Ref.4 |
|-----|---------------|-----------|-------|----------------|-------|-------|
| 1.  | Saliparni     | Root      |       | Desmodium gangeticum | Desmodium gangeticum | Desmodium gangeticum |
| 2.  | Prisnaparni   | "         | Uraria picta | Uraria picta | Uraria logopirdes |
| 3.  | Brhati        | "         | Solanum xanthocarpum | Solanum xanthocarpum | Solanum xanthocarpum |
| 4.  | Dwayam        | "         | Solanum indicum | Solanum indicum | Solanum indicum |
| 5.  | Goksura       | Dried fruits | Tribulus terrestris | Tribulus terrestris | Tribulus terrestris |
| 6.  | Vilva         | Root      | Aegle marmelos | Aegle marmelos | Aegle marmelos |
| 7.  | Kasmari or Gambhair | " | Gmelina arborea | Gmelina arborea | Gmelina asiatica |
| 8.  | Syonaka       | "         | Oroxylum indicum | Oroxylum indicum | Oroxylum indicum |
| 9.  | Patala        | "         | Cyclea petlata | Stereospermum | Stereospermum tetragonum |
| 10. | Agnimantha    | "         | Clerodendron phlomoides | suaveolens | Premna integrifolia |

Further concentrated to 500 ml on a water bath so that the final concentration conforms to that of he market samples. This was preserved in refrigerator.

**Market samples:**

Sealed bottles of Dasamulam Kasayam manufactured and marketed by different ayurvedic pharmacies, were collected for comparison of physical and chemical parameters, with those of he above reference sample.

Preliminary parameters: Colour, taste and smell were recorded by sensory examination. Density was measured by weighing a known volume of kshayam. Water-soluble content (%, W/V) was determined by evaporating 5 ml of Kasayam, pipette into a weighted petri-dish, evaporating to dryness on a water bath and finally heating to constant weight at 110°-120°C an oven. Ash (%) was determined by evaporating 5 ml of the medicine in a weighed silica crucible, to dryness first on water-bath and finally incinerating the residue to constant weight on an electric Bunsen.

Chemical parameters: After pretreatment to eliminate the benzoate preservative (chart 1) and mixing uniformly with Silicagel into a free flowing powder, the material was successively extracted in a Soxhlet with petroleum ether, CHCl₃, EtOAc, and EtOH as indicated in Chart 1, the solvents distilled off, and weights of each extract (and %) determined. TLC’s were run using unactivated (air-dried) silicagel-G plates (0.25 mm layer) and the solvents of optimum resolution arrived at by trial and error. The spots were visualized by spraying with 0.5% ammonium molybdate in 5% V/V sulphuric acid water and brief heating at 110o. the “total crude aglycone” was prepared by refluxing about 2g of the ethanol extract with ethanolic HCl (19:1,-73 ml) for 3 hrs. and the usual work-up.

The results are summarized in Table 2 and 3. TLC comparison of the solvent extract from various
market samples against the lab-reference sample of Dasamulam kashayam, are represented in Fig.1.

**TABLE 2**

Standardisation of Dasamulam Kasayam-Preliminary physical characteristics

| Code, Batch No.& Mfg. date | Colour (Odour) | Taste (Acidity) | Description | Density (g/ml) | Ash (%w/v) (Water soluble% w/v) | REMARKS |
|-----------------------------|----------------|-----------------|-------------|---------------|---------------------------------|---------|
| LAB-1 30-11-83              | Brownish black (Root like, agreeable odour) | Mildly bittersourastringent (slightly acidic to litmus) | Slightly turbid, nonsyrupy liquid, slight sediment on storage | 1.02 (23.2) | 3.2(15ml+60ml water) | Concentrated so as to conform to 5 times the strength of normal adult dose. No preservative added; stored in refrigerator |
| LAB-2 11-8-84               | -do-           | -do-            | -do-        | 1.06(27.3)    | 4.0(15ml+60ml water) | -do- |
| AVP-2 01606 13-12-84       | -do-           | -do-            | Slightly turbid, slightly viscous slight sediment on storage | 1.06(14.8) | 2.8(do) | Manufacture by evaporation in steam heated kettles, and concentration in steam heated S.S pans, strained through cloth |
| AVP-2 02202 12-12-84       | -do-           | -do-            | -do-        | 1.00(13.5)    | 2.8 (do) | No information on mode of manufacture |
| VOS-1 3566 2-4-84          | -do-           | -do-            | Mobile liquid slight sediment on storage | 1.03 (8.9)  | 1.2 (as directed by physician) | -do- |
| VOS-2 2279 29-11-84        | -do-           | -do-            | -do-        | 1.02(9.3)     | 2.2( as directed by physician) | No information on mode of manufacture |
| SDM-1 0518                 | -do-           | -do-            | Somewhat clear Mobile | 1.05(7.8)    | 1.5(12ml+36ml) | -do- |
The values of density and of the water-soluble content (%) provide a measure of the concentration of the total water extracted material in the Kasayam. It is seen from Table 2 that the densities of the different samples are, in a broad sense, somewhat comparable. The % of water-solubles in the laboratory sample is rather high (compared to market samples),

| Sample Code | Date | Density (g/ml) | Water-soluble (%) | Notes |
|-------------|------|----------------|-------------------|-------|
| SDM-2 0806  | 14-1-85 | 1.02 (10.7) | 1.8 (do) | -do- liquid slight sediment on storage, slightly turbid, somewhat thin liquid. Sediments settle on storage, directly used, undiluted, as prescribed by physician. |
| SSAP-1 55  | May '84 | 1.00 (3.0) | 0.7 (Direct use, undiluted) | -do- |

**Results and Discussion**
### TABLE 3

**Standardisation of Dasamulam Kasayam – Chemical Characteristics**

| Code  | % fraction in W/V          |
|-------|---------------------------|
|       | A  | B  | C  | D  | E  | F  | G  | H  |
|       | (PhCO₂H+ other acids) Ext. (TLC Fig.1) | (TLC Ext. Fig.1) | (TLC Ext. Fig.1) | (TLC Ext. Fig.1) | (TLC Ext. Fig.1) |
| LAB-1 | 0.07 | 0.05 | 0.24+ | 0.11 | 1.11 | 15.6 | 2.13 | Negligible |
| LAB-2 | 0.11 | 0.04 | 0.07 | 0.23 | 0.21 | 12.2 | 2.88 | " |
| AVP-1 | 1.38(117,118)* | Negligible | 0.02 | 0.06 | 0.18 | 10.1 | 0.27 | 0.05 |
| AVP-2 | 0.72 | 0.05 | 0.03 | 0.08 | 0.41 | 6.6  | 0.58 | Negligible |
| VOS-1 | 1.17(109,112,115)* | Negligible | 0.02 | 0.03 | 0.04 | 4.2  | 0.32 | " |
| VOS-2 | 1.08 | 0.04 | 0.05 | 0.13 | 0.33 | 3.6  | 0.18 | " |
| SDM-1 | 1.42(118,118)* | Negligible | 0.02 | 0.02 | 0.12 | 5.3  | 0.19 | 0.13 |
| SDM-2 | 1.61 | 0.03 | 0.03 | 0.04 | 0.51 | 4.4  | 0.22 | Negligible |
| SSAP-1 | 1.07 | Negligible | 0.01 | 0.13 | 0.10 | 2.0  | 0.24 | Negligible |

*Figs in parenthesis are m.p.; m.m.p. with PhCO₂H*

Perhaps because the limited quantity of drugs used in the lab-preparation have been well-crushed and the evaporation is done slowly with care ensuring a more or less efficient and complete extraction of the drugs, as against the commercial practice of using larger pieces of semi-or uncrushed drugs and the rather fast evaporation in steam-heated vessels. The lower values of some of the commercial samples may also imply that the customary, final 5-fold concentration has not been effected. This is particularly so with sample SAPP-1, which it is understood, is meant to be consumed, undiluted with water, in the normal dose. Despite numerical differences, there is a gross order of similarity of the values for water-soluble content for most of the samples.

The ash content again, is grossly comparable for the market and the lab-samples. The low ash value of SAPP-1 may be indicative of its dilute nature (1/5 th of the other commercial concentrations). By examining a large number of genuine samples from different pharmacies and different batches of the same pharmacies as well as standard lab-samples, it should be possible to fix limits of variability for final, acceptable standards.

The extracts with successive solvents in the order of polarity represent the “group” of chemical constituents of increasing polarity, present in Kasayam, derived from the drugs. The technique of leaching these out (Soxhlet) from silica gel in the order of solvent polarity, perhaps helps to ensure a broad segregation of these constituents further into groups of ascending polarity. Determining the %’s of these extracts imparts a quantitative status to this chemical characterization. From Table 3, the % values are somewhat high for lab-sample (especially for the alcohol extract and crude aglycone) for possible reasons mentioned above. However, in general, the %’s of the solvent extracts show a gross general similarity among the different market and lab-samples.

Although the groups of compounds comprising each extract have not been identified, the TLC patterns (Fig 1) of corresponding extracts from market samples compare fairly well with those of lab-sample, in a gross sense. For standardization purpose, the identification of each an every spot revealed by TLC may not be...
necessary – rather a comparison of the overall TLC patterns may be sufficient. By using a recording HPLC and/or HPTLC, these TLC spots could possible be elaborated into graphical profiles, introducing a more quantitative dimension into the standardization and affording ‘fingerprint’ standards. For practical purpose, the TLC patterns should suffice and the ranges of variability for final standards could be fixed by inter-laboratory collaborative studies.

The method described appears to be of general applicability to other Kasayams and to many other categories of Ayurvedic composite medicines like Curnas, Asavas, Gulikas etc. (with appropriate modifications/adaptations).

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