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Standardisation of classical Kerala ayurvedic *Pravahi kwatham* (decoction) formulation: *Saptasaram kashayam*

Rajesh S Mony

Abstract
There is a broad and increasing interest in the development of analytical methods for developing fingerprints for establishing phytochemical fidelity of polyherbal Ayurvedic formulations, in order to assure the batch-to-batch quality consistency in terms of Phytochemical molecules. A comprehensive pragmatic attempt is made to generate quality specification that can assure the standards of the product which in turn correlate to clinical efficacy of a typical classical Ayurvedic poly herbal decoction formulation.

Keywords: *Saptasaram Kashayam/Pravahi kwatham*, *Sashasrayogam*, HPTLC

Introduction
A central theme of this work is to point out the chemical complexity of Ayurvedic formulations of commercial use, which necessitates considerable ingenuity on behalf of the analyst in harnessing the resolution and sensitivity of the procedures that are applied.
Ayurvedic Ployherbal formulations have multiple constituents including Active compounds, Inactive compounds, Unknowns, Novel compounds and the Ones, which are dietary rather than therapeutic. Stability is more difficult to monitor and reference standards are more difficult to establish and obtain than for chemically synthesized drugs like allopathic medicines. Since approach of accessing the quality and efficacy of Ayurvedic formulations like single chemical entity is not possible.
Planar Chromatographic finger printing has been widely used to highlight standard and impurity profiles. This also tends to focus on identification and assessment of the stability of the chemical constituents observed by chromatography. Along with general physicochemical parameters, phytochemical species quantification (eg. Total Phenolics, Total Flavonoids, Total Alkaloids etc)), an apt finger print identification and quantification (unique for particular formulation) will help to assess the formulation in the following manner.

1. To ensure as far as possible uniformity in Physical, Chemical properties and Active constituents/Chemical Markers.
2. To arrive at a more scientific methodology to identify the quality, stability and genuineness of the formulations.
3. To derive such parameters that can reflect the quality of clinical efficacy of the Polyherbal Ayurvedic formulations.

The design of these methods typically necessitates considerations of Extraction, Evolving the procedures for Fractional and Differential extraction, Solvent partitioning and Chromatographic identification. The ideal solvent of extraction of *Saptasaram* Phytomolecules is chosen to be Methanol. Since the formulation is the aqueous extractives of the compound herbs bearing highly polar molecules, methanol can take care of the extraction of all category of Phytochemical population in toto, that can be profiled by Chromatographic tool.

Materials and Methods
Sapthasaram Kashayam is a decoction prepared with the ingredients in the Formulation Composition as per Classical Ayurvedic reference Text ***Sahasrayogam***.

B.1. Formulation Composition
1. *Varshabu*, *Boerhaavia diffusa*, Rt. 1 part, (*Raktapunarnava* API)

2. *Bilva* API, *Aegle marmelos*, Rt. 1 part
3. *Khalva-purana*, *Dolichos biflorus*, Sd. 1 part, (*Kulattha* API)
4. *Urubu*, *Ricinus communis*, Rt. 1 part, (*Eranda* API)
5. *Sahachara* API, *Barleria prionitis*, Pl. 1 part
6. *Sunthi* API, *Zingiber officinale*, Rz 1 part
7. *Agnimantha* API, *Clerodendrum phlomidis*, Rt. 1 part

B.2. Method of Preparation

Taken all the ingredients of pharmacopeial quality. Cleaned, weighed and washed the raw materials listed 1 to 7. Crushed all the ingredients into pieces of 1 3 cm. Boiled them together in water (item no. 8) of volume 16 times of the total weight and reduced to 1/8. Filter and concentrated further to 1/4 of the original volume, allow to cool. Added preservatives 0.3% benzoic acid and 0.1% Sodium benzoate. Stored in food grade PET bottle and sealed airtight to protect it from air and sun light.

Specifications

C.1. Raw material Quality

The quality monographs of the individual ingredients are already included in the Ayurvedic Pharmacopoeia of India (Part-I, Vol.I-VII, Ministry of Health and Family Welfare, Department of AYUSH, New Delhi). Each ingredient of *Kwatha/Kashayam* has been checked against its Monograph in the respective volumes of API and found in compliance in Macroscopy and Microscopy.

Table 1: List of Ingredients with Their Parts and API Classifications

S. N.	Ingredient	Part API	Vol.	Page
1	*Boerhaavia diffusa* L.	Root	III	157
2	*Aegle marmelos* Corr.	Root	III	29
3	*Dolichos biflorus* L.	Seed	I	75
4	*Ricinus communis* L.	Root	I	34
5	*Barleria prionitis* L.	Whole Plant	III	165
6	*Zingiber officinale* Roxb.	Rhizome	I	103
7	*Clerodendrum phlomidis* L.	Root	III	3

C.2. Description of the product

Dark brown coloured liquid with slight sweet taste.

C.3. Planar/HPTLC Chromatography finger printing of the Product

Extracted 1 ml Kashayam with 10 ml methanol (10 ml x 4) and 5 g of anhydrous sodium sulphate in a 100 ml beaker, mix vigorously with the help of a glass rod. Filtered the extracts, combined and concentrate to 10 ml. Applied 15 µl as bands at a height of 10 mm from the base of two 10 x 10 cm TLC plates and developed up to 8 cm from the base of the plate using ethyl acetate: acetonitrile: water (7: 5: 2) and 0.5 ml formic acid as solvent separator. Dried the plate in air and examine under UV 254 nm and under UV 366 nm. Sprayed one plate with anisaldehyde-sulphuric acid reagent and second plate with ferric chloride reagent and heat at 105 deg. C till the colour of the spots / bands appear without charring.

C.4. HPTLC profiles of Kwatham/Kashayam without Preservatives

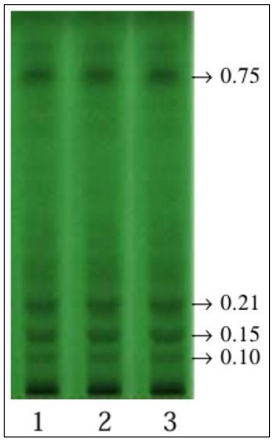


Fig 1: HPTLC finger print view of Methanol extract of three batches of *Saptasaram Kashayam* at 254 nm

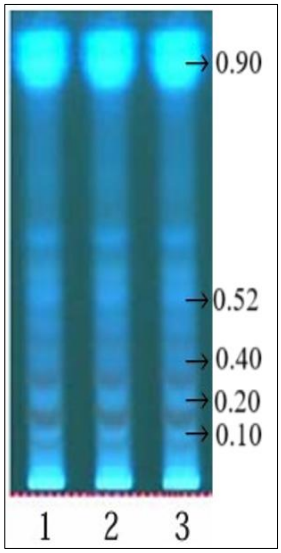


Fig 2: HPTLC finger print view of Methanol extract of three batches of *Saptasaram Kashayam* at 366 nm

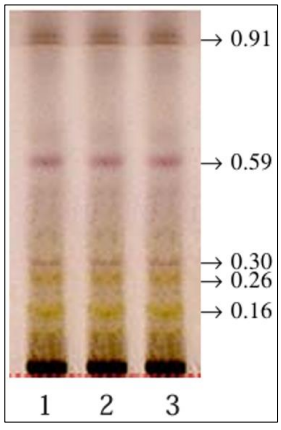


Fig 3: HPTLC finger print view of Methanol extract of three batches of *Saptasaram Kashayam* after derivatisation with Anisaldehyde sulphuric acid reagent at visible light

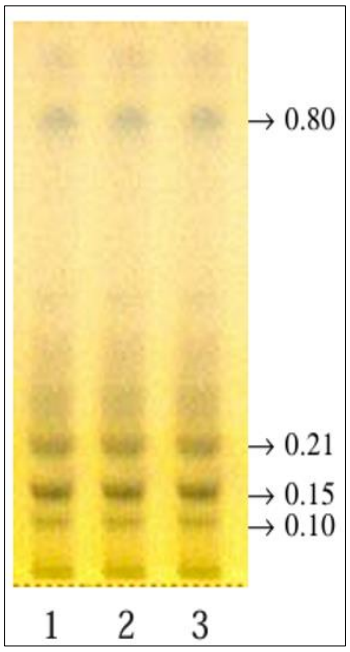
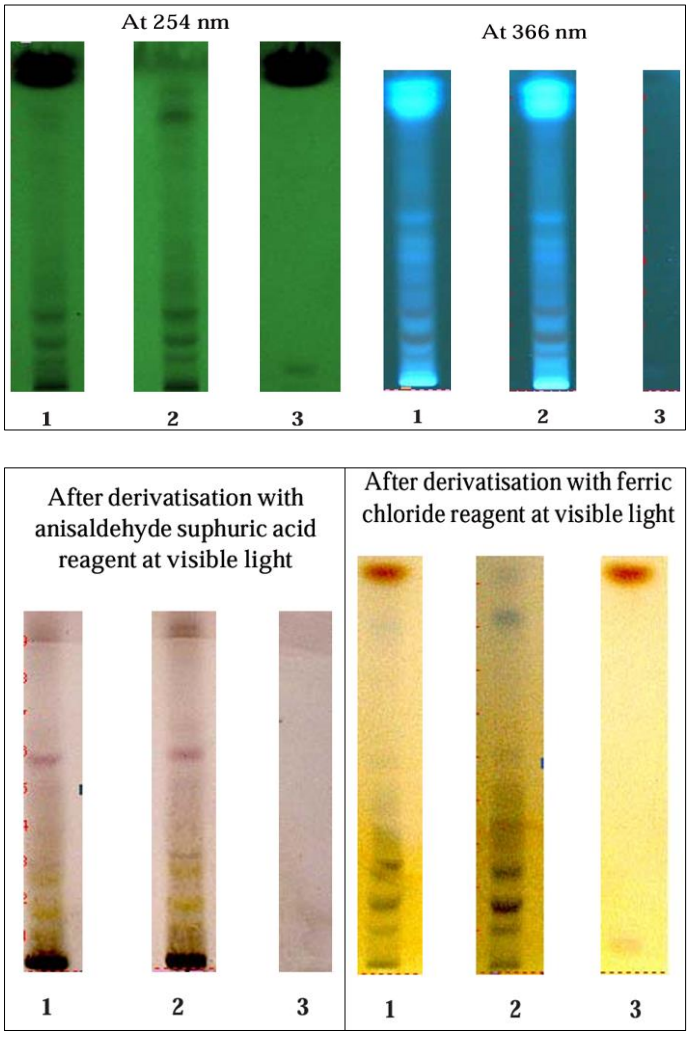


Fig 4: HPTLC finger print view of Methanol extract of three batches of *Saptasaram Kashayam* after derivatisation with Ferric chloride reagent at visible light

C.5. Comparison of profiles of *Saptasaram Kwatham/Kashayam* Methanol extractives (with and without preservatives) against that of preservative alone
1. *Saptasaram* with preservatives 2. *Saptasaram* without preservatives 3. Preservative alone



Preservative component is not visible at 366 nm and derivatisation with AS reagent. The Preservative spot is visible at 254 nm and F C derivatisation. The two preservatives used Sodium Benzoate and Benzoic acid appear as single spot after extracting in methanol

C.6. Physico-chemical parameters of the Product

Table 2: Physico-chemical parameters of the Product

S. N.	Parameter	Observed Value	Specification	Reference
01	pH	5.2	Not more than 6.0	API (Appendix : 3.3)
02	Specific gravity	1.041	1.04 - 1.09	API (Appendix : 3.2)
03	Total solids	13.5% w/v	Not less than 13%w/v	API (Appendix : 3.8)
04	Assay of Phenolics	0.25% w/v	Not less than 0.2%w/w	API (Appendix : 5.1.1)
05	Heavy Metals	Complies	As per API Limits	API (Appendix : 2.5)
06	Microbial Limits	Complies	As per API Limits	API (Appendix : 2.4)
07	Aflatoxins	Complies	As per API Limits	API (Appendix ; 2.6)

Conclusion

It is very well established either therapeutic or nutraceutical attributes of traditional formulations of Ayurveda are because of various Phyto molecules present in the formulations. But due its complexity of such species and difficulty in identifying and quantification generating such QC specification in accordance with the modern cartician science is not possible.

By applying the Planar/HPTLC Chromatographic finger print profiles for such Poly herbal formulations, the Phytochemical fidelity can be ascertained and used to maintain batch to batch with an allowable quantum of variation that are normal for products of natural origin.

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Conflict of Interests

The authors have declared no conflict of interest.

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