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STANDARDIZATION OF PIDANGUNAARI KUDINEERCHOORANAM- A CLASSICAL SIDDHA FORMULATION

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ABSTRACT

Standardization of herbal formulations is essential in order to assess the quality of drugs on the basis of the concentration of their active principles, physical and chemical standards. This work reports the standardization of *Pidangunaari KudineerChooranam* (PKC), an herbal based classical *Siddha* formulation used to treat splenomegaly (*pileegaviruthi*). The drug was prepared by the methods as reported in the literature. Then, the formulation was standardized using physical and physico-chemical properties. In this study, we first report the standards for PKC which can be used to lay down pharmacopeial standards that will help to increase the quality of this classical *siddha* drug.

KEYWORDS: Standardization; *Sastric*; Polyherbal; Physico-chemical

INTRODUCTION

World Health Organisation (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and evolved guidance to support the member states in their efforts to formulate national polices on traditional medicine and to study their potential usefulness including evaluation, safety and efficacy.[1] The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicine. One of the major problems of wider acceptance of traditional medicines is the unavailability of rigid quality control profiles for herbal materials and their formulations.Regulatory bodies have laid down the standardization procedures and specifications for traditional preparations. In India, the Ministry of AYUSH of the

Government of India has launched a central scheme to develop Standard Operating Procedures to develop pharmacopeial standards of *Siddha* preparations.[2] India is the one of the largest herbal suppliers and consumers for the herbal products of the world. In such scenario, the standardization of the herbal drugs using sophisticated modern techniques becomes necessary. It has become extremely important to make an effort towards standardization of the raw drugs used as medicine using pharmacognostic studies.[3] *Pidangunaari Kudinner Chooranam* (PKC) is a classical siddha drug which given to treat splenomegaly (*pileegaviruthi*) and mentioned in the Siddha Formulary of India (Part 1).[4] In this study an effort was made to standardize PKC by identifying the ingredients using physico-chemical and phytochemical parameters. The HPTLC finger-printing profile and the analysis for heavymetals were also done for PKC.

MATERIALS AND METHODS

Plant material and preparation of the drug

PKC consisted of three ingredients viz., three to four fresh leaves of *Premna tomentosa* Wild., (*Pidangunari*), Two grams of dried rhizomes of *Curcuma longa* L., (*Manjal*) and four grams of outer rind of *Terminaliachebula* Retz. Fruits (*Kadukkaithole*). The leaves of *Premna tomentosa* was collected from the Siddha Medicinal Plants Garden, Mettur, Tamil Nadu and authenticated by the Taxonomist at SMPG. The other crude drugs were purchased from the local market and authenticated by the Pharmacognosist at Siddha Central Research Institute, Arumbakkam, Chennai. The ingredients were shade dried, coarsely powdered, mixed in the above mentioned ratioas per the classical siddha literature[4] and stored at 25 °C, till used.

Proximate analysis of PKC

Physico-chemical parameters such as the estimation of ash value (total ash, water soluble ash and acid insoluble ash), pH and loss on drying were done in accordance to the guidelines of WHO.[2,5,6] The levels of heavy metals such as lead, cadmium and mercury levels were analyzed using AOAC official methods.[7]

HPTLC finger printing of PKC

Two grams of PKC was soaked in 20 mL of rectified spirit, overnight. The solution was boiled for 10 minutes and filtered through a Whatman No. 1 filter paper. The filtrate was concentrated and made upto 10 mL in graduated test tube. From this stock solution, 3 – 5 µLwas taken and applied on a HPTLC plates pre-coated silica gel 60-F_{254} as the chromophore (Merck) of 0.2 mm thickness. Samples were spotted using CAMAGLinomat IV Automatic

Sample Spotter (Camag Muttenz, Switzerland) equipped with syringe (Hamilton, 100 µL). The plates were developed in glass twin trough chamber (CAMAG) pre-saturated with the mobile phase. Toluene: Ethyl acetate (1:1) mixture was used as the mobile phase.The developed plates were dried and visualised in UV_{254} nm and UV_{366}nm and photographs were taken. Some plates were developed with vanillin sulphuric acid as the spray reagent.[8,9]

RESULTS AND DISCUSSION

The use of herbal drugs is increasing worldwide in the form of medicine, cosmetics and nutraceuticals. In such scenario, standardization of herbal drugs is essential for the supply of quality drugs on the basis of their active constituents and also on their physical and chemical quality.World Health Organization encourages and recommends the use of traditional medicine in national health care programs, because of their low cost and efficacy. It also recommends the use of modern techniques to ensure the quality of the herbal drugs.[10] Standardization is essential to minimize batch to batch variations and to assure the quality of the poly herbal formulations.[11]

The results of proximate and heavy metal analyses of PKC were given in Table 1. Ash values are one of the important standardization parameters for herbal drugs which represent the inorganic salts naturally occurring in the drug and adhering to it. The ash values vary in a narrow range for a specific drug. Incineration of an herbal drug produces ash which constitutes inorganic matters and the acid insoluble ash represents the silica. It can be used as a measure for soil present in the herbal drug. PKC showed 0.76% acid insoluble ash content, which was incompliance with the limits.Deterioration of the plant drugs mainly depends on the moisture content which favors the growth of microorganisms.[12] The low water content indicated the stability of PKC.

Heavy metals such as lead, cadmium and mercury are present in the natural environments in negligible amounts, also by the pollution with some pesticides. Depending on the individual characteristics of some plants, the bioaccumulation of these metals will be high in them which pose a hazard to human health. Based on the accepted limits of heavy metals proposed by various countries WHO proposed the limits; they were 10 mg/kg for lead, 0.3 mg/kg for cadmium and 0.1 mg/kg for mercury [13]. Heavy metal analysis showed that PKC contained low quantities of heavy metals, which were in the accepted limits.

HPTLC fingerprint profile is one of the important tools in herbal drug standardization; it is

used for deciding the identity, purity and strength of the polyherbal formulations and also for fixing standards those formulations.[14] TLC pattern (Figure 1) and HPTLC finger print of PKC (Figure 2) were analysed. TLC profile showed the presence of one major component with R_f value of 0.66.

Tables & Figures

Table 1: Physico-chemical parameters of PKC

S.No	Parameters	Results
1	Loss on drying at 105°C	1.24%
2	Total Ash	4.36%
3	Acid insoluble ash	0.76%
4	Water insoluble ash	29.61%
5	Alcohol insoluble ash	27.82%
6	pH	4.27
	Heavy metals	
7	Lead	6.27ppm
8	Cadmium	0.13ppm
9	Mercury	< 10ppb

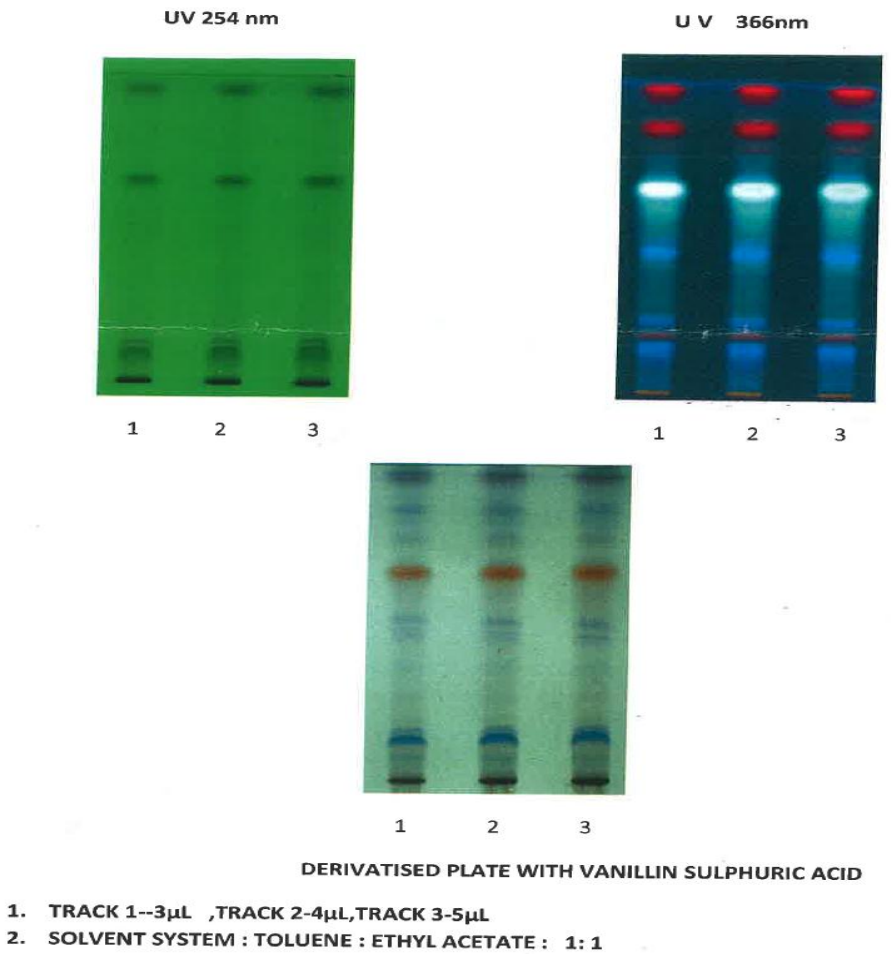

Figure 1: TLC pattern of PKC under different conditions

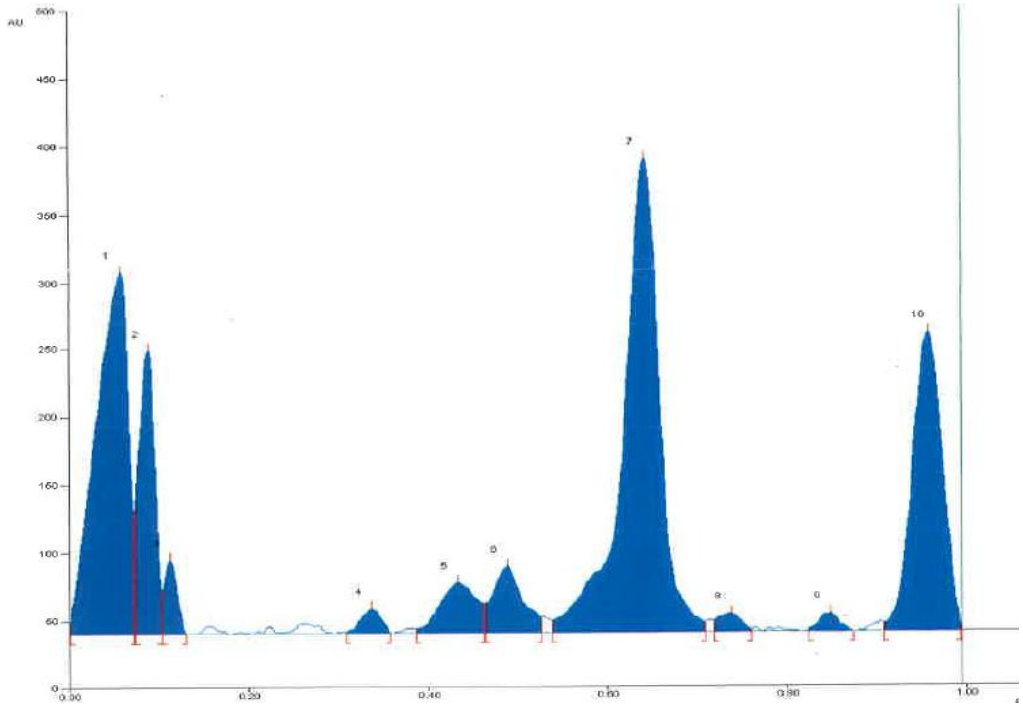

Figure 2: HPTLC fingerprint of PKC

Table 2: Number of bands found in PKC under different visualization modes

S.No	254 nm		366nm		Dipped in vanillin sulphuric acid	
	Colour	Rf	Colour	Rf	Colour	Rf
1	Green	0.10	Blue	0.14	Blue	0.12
2	Green	0.13	Brown	0.19	Blue	0.17
3	Green	0.65	Blue	0.23	Blue	0.49
4	Green	0.95	Blue	0.44	Brown	0.66
5			Shiny White	0.66	Blue	0.77
6			Brown	0.80	Blue	0.86
7			Red	0.84	Violet	0.95
8			Red	0.97		

CONCLUSION

In this study, we first report the physico-chemical and phytochemical standards of PKC which can be used to lay down pharmacopeial standards for PKC, which will help the industries to increase the quality and to minimize the batch to batch variations of this classical *siddha* drug.

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