

COMPARATIVE STANDARDIZATION OF SIDDHA MEDICATED OIL: *THALANGAI ENNAI*, A POLY HERBAL FORMULATION

S. Vinotha^{1*}, I. Thabrew², S. Sri Ranjani³

^{1,3}Unit of Siddha Medicine, University of Jaffna, Sri Lanka
vsanmuga07@gmail.com

²Institute of Biochemistry, Molecular Biology and Bio technology, University of
Colombo, Sri Lanka

Key words: *Thalangai ennai*, Poly herbal formulation, Medicated Oil, Standardization

Introduction

With the 'retain to nature' call in both, the developed countries as well as developing countries, there is an increase in number of people switching over to the alternative system of medicine and thus it is essential that people get relevant medicines (Kumar & Baxi, 2007). Siddha Medicine is a one of the traditional medicine (Thirunarayanan, 1988) and practiced by Tamil people of Northern and Eastern province in Sri Lanka. An attempt is made to standardize Siddha medicated oil.

Effective management of *vātā* disorders such as rheumatic pain, inflammation, bone degenerative changes and impaired movement of limbs are the important tasks in the field of treatment. Siddhars described *vātā* disorders of different origin and external application is most useful for their management. Among them *Ennai*

(Medicated oil) is one of the medicaments prescribed by them.

Thalangai ennai is one of the Siddha medicated oil mentioned in the Siddha Literature (Ponniappillai, 2000) and it is prepared at Government Indigenous Medicine Drug Unit in Jaffna and supplied to all Government District Ayurvedic Hospital, Rural Ayurvedic Hospitals and Central Ayurvedic Dispensaries in Jaffna District. A marketed formulation of *Thalangai ennai* (Everest product) is available in Jaffna District. The ingredients used in *Thalangai ennai* are juice of the *thalangai* (*Pandanus tectorius*), sesame oil, milk, water, rock salt and seventeen different herbal powdered materials with that it is one of the most effective oil for external applications.

The physicochemical standards available for the standardization of Siddha medicated oils are insufficient. The analytical values available in the

pharmacopoeial standards for siddha formulations are not finger print standards for each of oil (Hepsibah *et al.* 1998). The aim of the present study was fixed and compares the preliminary reference standards of the *Thalangai ennai*. This article reports on comparative preliminary standardization of *Thalangai ennai* (preparation of Drug Unit, Indigenous Medicine and the marketed formulation) have been standardized on the basis of physicochemical properties, organoleptic characters, and Thin Layer Chromatography (TLC) finger print analysis.

Methodology

Marketed samples for external medicine

Thalangai ennai was purchased from a reputed vendor of herbal Medical products, Everest Marunthakam, Usan, Mirusuvil (Registered at Sri Lanka Ayurveda Medical Council). The marketed formulation of *Thalangai ennai* (MFT) was standardized based on their organoleptic characters (physical characteristic), physicochemical properties (pH, specific gravity) and thin layer chromatography (TLC) according to standard procedures and compared with the *Thalangai ennai* of Drug Unit of Indigenous Medicine, Jaffna (DUT).

Ingredients and preparation method of *Thalangai ennai*

Botanically pure and authentic ingredients were used in the preparation of *Thalangai ennai* accordance with the guidelines stated in the Siddha Literature.

Organoleptic evaluation

Both samples of oil (*Thalangai ennai*) and its water and dichloromethane extracts were subjected to the organoleptic characterization such as appearance, touch, colour, clarity and odour and compared with the values of Sesame oil (Which is used as a base in preparing these oils) separately. The organoleptic characters of the samples were evaluated based on the method described by Siddiqui *et al.* 1995.

Physico-chemical investigations

Both samples of oil (*Thalangai ennai*) were subjected for determination of preliminary physicochemical parameters such as pH value and specific gravity.

Development of Thin-layer chromatography (TLC) fingerprints of *Thalangai ennai*

Thin Layer Chromatography (TLC) finger print of the *Thalangai ennai* was studied after dissolving the oil in water and dichloromethane.

Five μ l of dichloromethane extract of each oil (MFT & DUT) was spotted on to TLC plates (8.5 x 5.3 cm) coated with silica gel (pre-coated, GF₂₅₄) and separated using a variety of solvent system. Different solvent systems were used for separation. Although the separation of the extracts occurred in the solvent system comprised of hexane: dichloromethane: 1% methanol in dichloromethane (1:4:5 v/v) as the mobile phase, the best separation of the extracts occurred in the solvent system comprised of pure dichloromethane as the mobile phase. After development visible spots were not found for each oil extract. Numbers of spots were observed under day light and UV light (254 & 366 nm). Visualization was

attempted by spraying with vanillin sulphate reagent for each oil extract and heating the plate for 5-10 minute (100-105°C). The colour and Rf values

of the spots were recorded carefully and the chromatogram was documented by graphical copying (WHO, 1998).

$$R_f = \frac{\text{Distance travelled by solute}}{\text{Distance travelled by solvent}}$$

Results and Discussion

The physicochemical standards available for the standardization of Siddha Medicated oils are insufficient. The analytical values available in the pharmacopoeia standards for siddha formulations are not finger print standards for each of oil. The first step towards this goal, the current preliminary investigation was undertaken to generate data on physico-chemical properties, including organoleptic characters, and chromatographic profiles to determine the quality and purity of *Thalangiennai*. It is very difficult to perform a study on Siddha medicated oils which has a large number of herbs used in the formulation. Hence in this study only *Thalangiennai* was selected. As there is not any evidence for detailed

physicochemical and TLC evaluation on *Thalangiennai* is reported. Therefore present work is taken up in the view to standardize the *Thalangiennai*. In the present study different brands of *Thalangiennai* was subjected to physicochemical parameters, organoleptic characters and TLC finger printing for preliminary standardization.

Organoleptic characters and physicochemical properties

Table 1, summarizes the organoleptic properties, pH values and Specific gravity of the Marketed formulation (MFT) and Drug Unit of Indigenous Medicine (DUT) *Thalangiennai* with Sesame oil at room temperature and Table 2 summarizes the organoleptic properties of its water and dichloromethane extracts.

Table 1: Analytical parameters of *Thalangiennai* MFT & DUT with Sesame oil

Parameters	<i>Thalangiennai</i> (MFT)	<i>Thalangiennai</i> (DUT)	Sesame Oil
Appearance	Viscous	Viscous	Viscous
Touch	Oily	Oily	Oily
Colour	Red	Golden brown	Brown
Clarity	Clear	Clear	Clear
Odour	Characteristic	Characteristic	Characteristic
pH value (29°C)	4.97	4.61	4.89
Specific gravity	0.9173	0.9185	0.923

As seen in Table 1, both Brands of the *Thalangai ennai* had similar organoleptic properties except for the colour of the each oil compared with Sesame oil. The results showed that, the specific gravity and pH value for *Thalangai ennai* DUT were found to be

0.9185 and 4.61; in case of MFT these were found to be 0.9173 and 4.97 at room temperature (29°C) respectively. The pH and specific gravity of these brands were showed not remarkable difference between them.

Table 2: Organoleptic properties of the water and dichloromethane extracts of the of *Thalangai ennai* MFT & DUT

Parameter	MFT		DUT	
	Water extract	Dichloromethane extract	Water extract	Dichloromethane extract
Appearance	Liquid	Liquid	Liquid	Liquid
Touch	Liquid	Liquid	Liquid	Liquid
Colour	Colourless	Colourless	Pale yellow	Light yellow
Clarity	Clear	Clear	Clear	Clear
Odour	Characteristic	Characteristic	Characteristic	Characteristic

As seen in Table 2, both extracts of the each *Thalangai ennai* had similar organoleptic properties except for the colour of the water and dichloromethane extracts of oils.

Thin Layer Chromatography (TLC) fingerprint analysis

The numbers of different solvent systems were employed to generate fingerprint profiles for these oils. The TLC finger print of both the formulations were comparable and revealed dichloromethane extract of the oil samples showed twelve spots with Rf values ranging from 0.02 to 0.97 in the hexane: dichloromethane: 1% methanol in dichloromethane (1: 4: 5 v/v) solvent system for both brands and fifteen spots with Rf values ranging

from 0.03 to 0.96 (MFT) and 0.03 to 0.97 (DUT) in the pure dichloromethane solvent system.

Although the separation of the oil extracts occurred in the solvent system comprised of hexane: dichloromethane: 1% methanol in dichloromethane (1:4:5 v/v) as the mobile phase, the best separation of the oil extracts occurred in the solvent system comprised of pure dichloromethane (v) as the mobile phase. In dichloromethane extract of different brands of *Thalangai ennai* (MFT and DUT) analyzed by TLC, the number of spots with the Rf values were observed not remarkable differences in between these both oil.

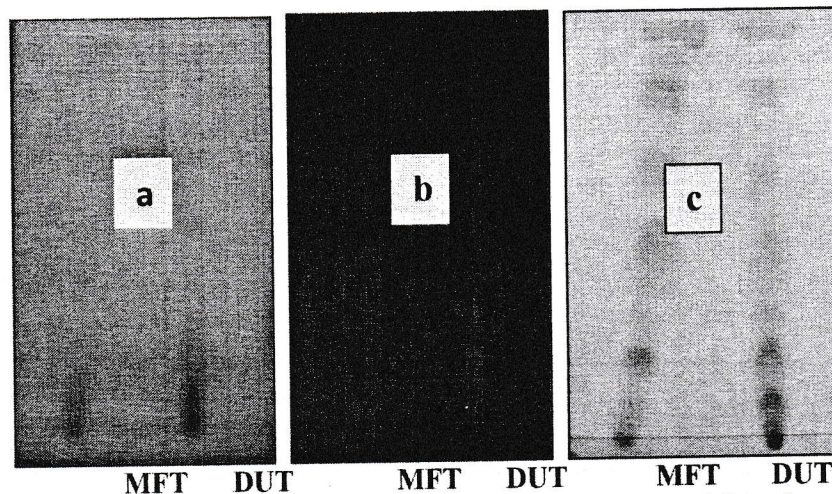


Figure 1: TLC fingerprints of oil extract a) 254 nm, b) 366 nm and c) visible after spray in the Solvent system of Hexane: Dichloromethane: 1% Methanol in Dichloromethane (1: 4: 5 v/ v) mixture

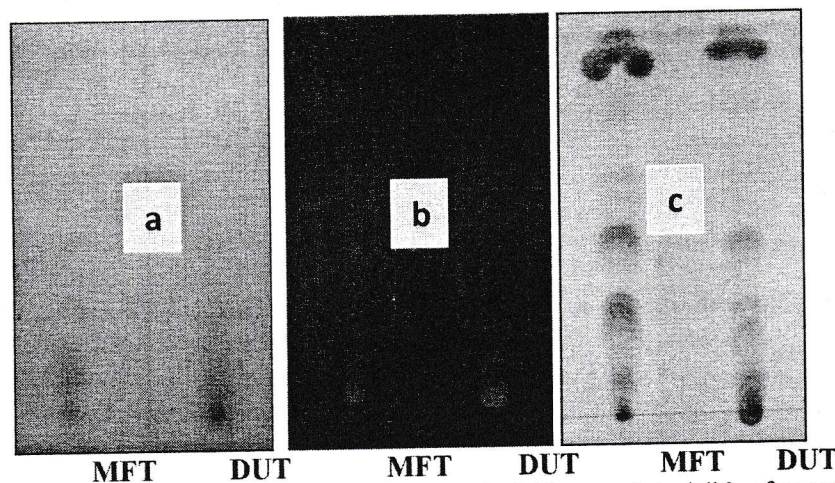


Figure 2: TLC fingerprints of oil extract a) 254 nm, b) 366 nm and c) visible after spray in the Solvent system pure Dichloromethane

Conclusion

The results obtained with the both brands of *Thalangai ennai* (MFT and DUT) were found to be comparable and variations were not remarkable. These set of parameters presented in this paper can be used as reference standards for the quality assurance of *Thalangai ennai*. Though the analytical values can be as preliminary reference

standards, these values mostly related to the purity of the sesame oil, the qualitative and quantitative estimation of each single ingredient of *Thalangai ennai* requires further research work in future.

Acknowledgement : The financial support provided by the Higher Education Twenty-first Century

(HETC) Project, Ministry of Higher Education, Nugegoda, Sri Lanka (Reference No - JFN/ Sidda/ N1), and the guidance given by Dr (Mrs.) Menuka Arawwawala, Industrial Technology Institute (ITI), Colombo 07, to conduct the physicochemical and TLC finger print studies are gratefully acknowledged. This work is a part of the research carried for postgraduate programme (PhD) at faculty of Graduate Studies, University of Jaffna.

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