RESEARCH ARTICLE

Development of quality standard of *Ksheerabala* oil: An *Ayurvedic* Formulation

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ABSTRACT

This contemporary study is intended to standardize the *Ksheerabalatailam* with respect to *Sida cordifolia* root powder processed with sesame oil and milk. The chief objective of this contemporary research work is to assess the various Standardization properties of the *Ksheerabalatailam* like saponification value, Iodine value, Acid value, Peroxide value, Total fat, weight per milliliter, high-performance thin-layer chromatography (HPTLC) and gas chromatography–mass spectrometry (GCMS) analysis. The physicochemical properties like the iodine value, saponification value, acid value, peroxide value, total fat, and HPTLC fingerprinting and GC-MS analysis were established. The results of these studies would be useful for authentication, standardization, and disclosing counterfeit deterioration of the original herbal drug of *Ksheerabalatailam*.

Keyword: *Ayurvedic* oil, Balamul, *Ksheerabalatailam*, *Sida cordifolia, Vata* disorder.

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INTRODUCTION

Ksheerabalatailam (Ksheerabala oil) is meant for Internal and external applications widely prescribed by *Ayurvedic* practitioner for *Vata* disorders. It is also used as Vasthi (enema) and Nasya (nasal administration).[1] In *Ksheerabalatailam*, the powder of the root of *Sida cordifolia* L. (Balamula Churna) is processed with sesame oil and milk. Bala, is an *Ayurvedic* medicinal plant used to treat bronchial asthma, cold, flu, chills, lack of perspiration, headache, nasal congestion, aching joints and bones, cough, wheezing, and edema. The root infusion is given in nervous, urinary blood, and bile related disorder. *S. cordifolia* has been reported to possess analgesic, anti-inflammatory, hypoglycemic activities and hepatoprotective activity. Traditionally the plant *S. cordifolia* has been used for CNS depressant, fat loss, analgesics, anti-inflammatory, hypotensive and hepatoprotective purposes. The presence of ephedrine has highlighted the utility of this plant. Oil preparation of *Bala* is used to cure pain, swelling disorder, and Gritha preparation cures Heart diseases. This plant has great potential to develop a supplement for athletics as nutraceuticals. Ephedrine is known to stimulate the central nervous system (CNS), and as such, can enhance weight loss.[2] *Ksheearbalataila* was first mentioned in Sahasra Yoga, an authentic *Ayurvedic* formulary of Kerala. The similar preparation has been mentioned by almost all ancient *Ayurvedic* texts but with different names. Charaka mentioned as *shatasahasra pakabala taila*, Sushruta mentioned as Shatapakabalataila and Ashtangahridaya mentioned as Shatapaka- sahasrapakabalaTaila.[3-6] An attempt has been made to standardize Ksheerbala oil due to a lack of modern scientific data.

MATERIALS AND METHODS

Ksheerabalatailam was prepared from roots *Sida cordifolia* as per the reference mentioned in *Sahasrayagom tailaprakarana* (5/124)5-7) The plant was identified and authenticated by Survey of Medicinal Plants Unit at Central Research Institute of Unani Medicine, Hyderabad. Herbarium of the plant specimens was prepared and deposited in the herbarium section of the Central research institute of Unani Medicine, Hyderabad, with voucher specimen number SMPU/CRI-Hyd13572. The fine powder of *Bala* (*Sidacordifolia* root) near about 3.125 kg was mixed with 40 liters of cow's milk and 10 liters of sesame oil and boiled on a moderate fire constantly checked the Kalka (Paste by rolling between the fingers). Heating was stopped as the appearance of froth over the oil and the oil alone remained. *Varthi* (thread formed by pressing underneath paste of processing oil) was exposed to flame and confirmed that absence of crackling sound indicating absence of moisture, then the oil was filtered and cooled, packed in tightly closed containers.[7]

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Organoleptic and physiological evaluation

The prepared oil is evaluated for organoleptic as well as physiological evaluation as per standard protocol.[8]

HPTLC screening

Thin-layer chromatography of oil was developed using solvent system toluene: ethyl acetate (9:1), which was saturated for 45 minutes in CAMAG twin trough chamber. The extract was applied manually on TLC Silica gel 60 F_{254} Aluminum coated plate and run up to 8 cm. Plates were observed under daylight, ultraviolet light at 366nm, and subsequently derivatized with Iodine vapor and anisaldehyde-sulphuric acid. Developed band colors and retention factor (R_f) were recorded.[9]

GC-MS analysis

GC-MS analysis was carried out at VIT-SIF Lab, SAS, Chemistry Division for NMR, Vellore, Tamil Nadu, India, Perkin Elmer system Clarus 680 GC was used in the analysis employed a fused silica column, packed with Elite-5MS (5% biphenyl 95% dimethylpolysiloxane, 30 m × 0.25 mm ID × 250µm df) and the components were separated using Helium as carrier gas at a constant flow of 1 mL/min. The injector temperature was set at 260°C during the chromatographic run. The 1 µL of extract sample injected into the instrument the oven temperature was as follows: 60°C (2 min); followed by 300°C at the rate of 10°C for 1 min; and 300 °C, where it was held for 6 minutes. The mass detector conditions were: transfer line temperature 240°C; ion source temperature 240°C; and ionization mode electron impact at 70 eV, scan time 0.2 sec and scan interval of 0.1 second. The fragments were from 40 to 600 Da. The spectrums of the components were compared with the database of a spectrum of known components stored in the GC-MS NIST (2008) library.[10]

RESULTS

The organoleptic and physicochemical parameter is depicted in Table 1 (Figure 1) and Table 2, respectively.

Oil shows four major spots under UV 366nm at Rf values 0.39, 0.49 , 0.60 and 0.83.

The phytochemical constituents present in the chloroform extract of the *Ksheerabalatailam* are reported in Table 3. The GC-MS analysis of the oil extract revealed the presence of three chemical constituents that could contribute to the medicinal properties of the *Ksheerabalatailam*. The identification of the active principles present in the tailam extract was confirmed based on the peak area, retention time, molecular formula, molecular weight, and peak area in percentage were shown in Table 3 and Figure-3. The first compound identified with less retention time 18.47 min was N-Hexadecanoic acid, molecular weight of 256, molecular formula of $C_{16}H_{32}O_2$ and its peak area percentage was 9.95 %, and the second compound identified with retention time 19.74 min was 17-Octadecynoic acid,

Figure 1: Step of Preparation of *Ksheerabalatailam*

Table 1: Organoleptic characters for oil

Parameter	*Observation*
Color	Brown
Odor	Pleasant
Touch	Oily
Taste	Characteristic

Table 2: Physiochemical properties of oil

Parameter	*Value*
Weight per milliliter	0.8421g/mL
Saponification value	137.4
Iodine value	116
Acid value	6.0
Peroxide value	6.4
Total fat	94%

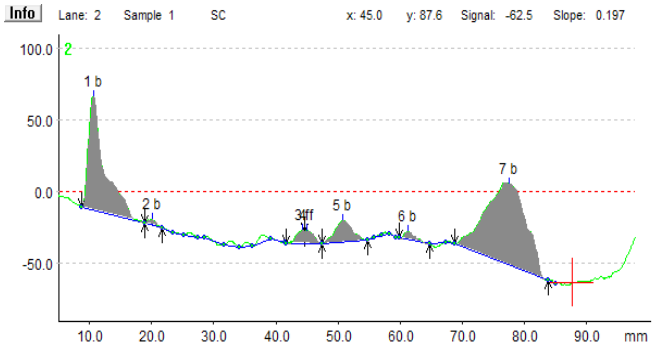

Figure 2: Overlay Densitogram of SC Oil at UV 366nm

Table 3: GC-MS spectral analysis of chloroform extract of *Ksheerabalatailam*

S.NO	*RT (Min)*	*Name of the compound*	*Molecular weight*	*Molecular formula*	*Peak area %*
1	18.47	N-Hexadecanoic acid	256	$C_{16}H_{32}O_2$	9.95
2	19.74	17-Octadecynoic acid	280	$C_{18}H_{32}O_2$	85.97
3	28.04	1,3-Benzodioxole, 5,5'-(Tetrahydro-1H,3H-furo[3,4-c]furan-1,4-Diyl) bis	354	$C_{20}H_{18}O_6$	4.07

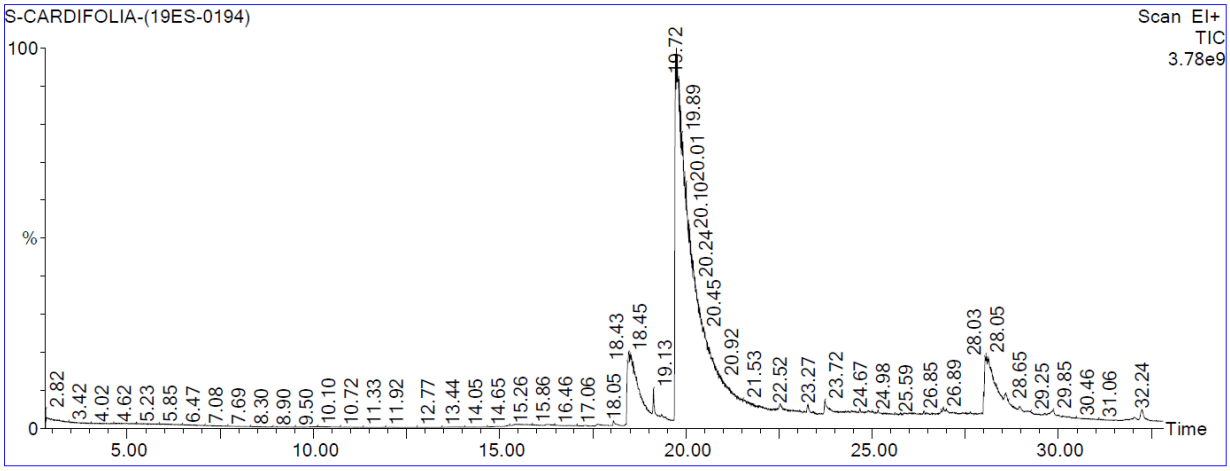

Figure 3: GC-MS chromatogram of chloroform extract of *Ksheerabalatailam*

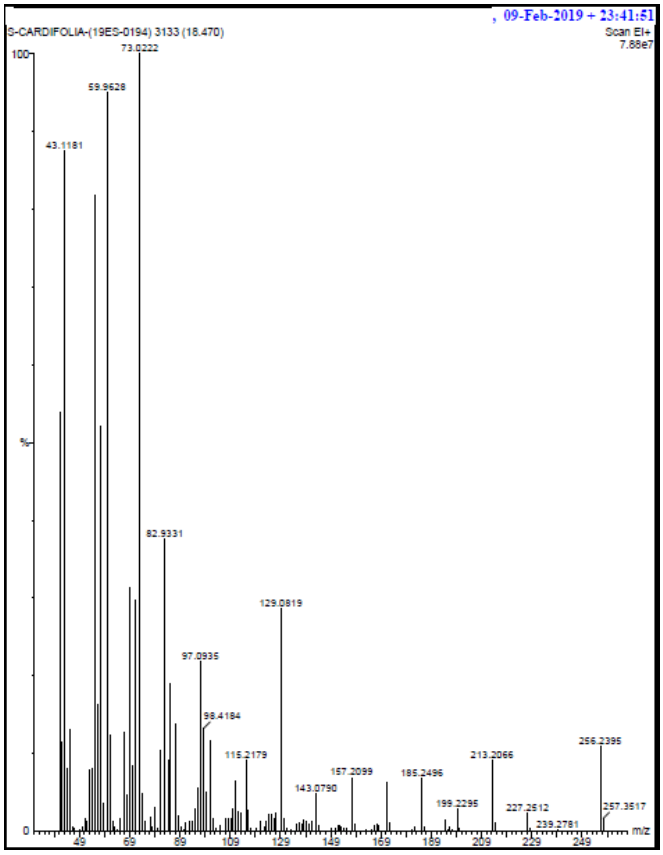

Figure-4: Fragmentation patterns of Hexadecanoic acid

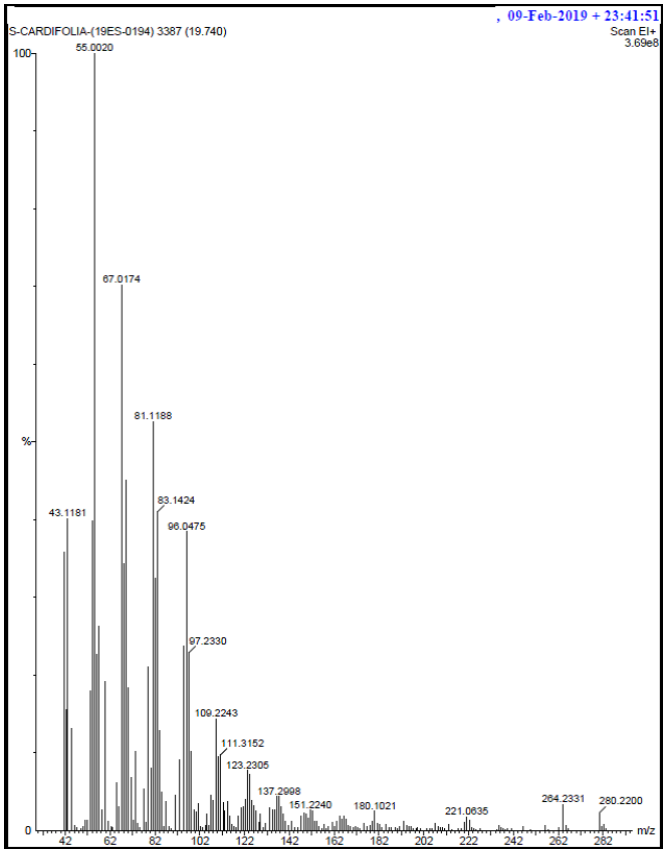

Figure 5: Fragmentation patterns of compound 17-Octadecynoic acid

molecular weight of 280, molecular formula of $C_{18}H_{32}O_2$ and its peak area percentage was 85.97 %. The third compound identified which took longest retention time 28.04 min to identify was 1,3-Benzodioxole, 5,5'-(Tetrahydro-1H,3H-furo[3,4-c]furan-1,4-Diyl) bis, molecular weight of 354, molecular formula of $C_{20}H_{18}O_6$ and its peak area percentage was 4.07 %.[11-13]

DISCUSSION

Now a day's many herbal raw drugs were adulterated in the market. To confirm the identity of a sample, standardization became a must. Repeated standardization studies on a particular drug and particular part of the drug provide the authenticity in fixing the referral values for future identification and utility. In this regard, *Sida cordifolia* L. root powder, a very useful drug of *Ayurvedic* system of medicine, was studied for organoleptic characters and subjected to physicochemical analysis to standardize for further clinical studies and utility. The results are further useful for the scholars working in the field of medicinal plants, as referral values of standardization. The developed HPTLC fingerprints of the drug are also useful

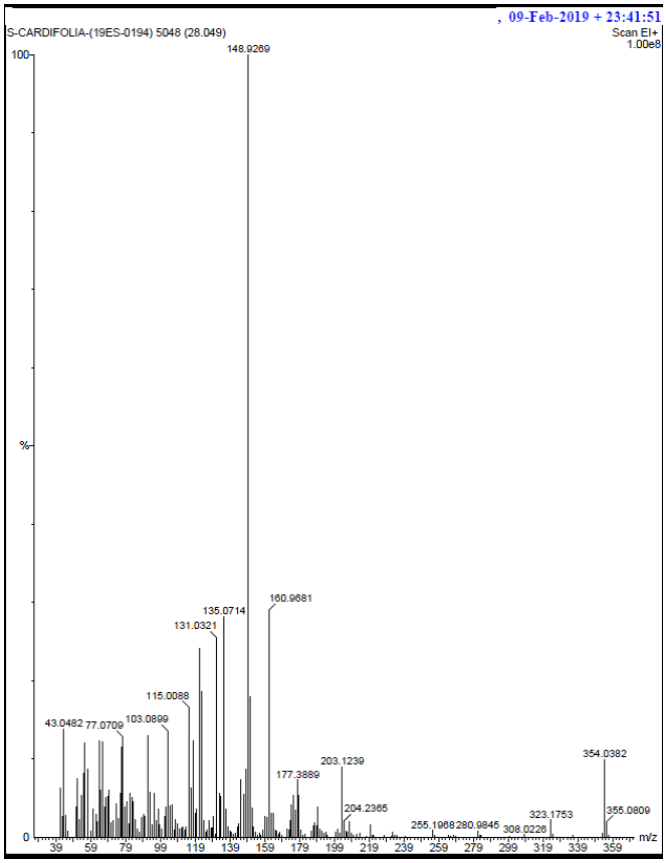

Figure 6: Fragmentation patterns of 1,3-Benzodioxole, 5,5'-(Tetrahydro-1H,3H-furo[3,4-c]furan-1,4-Diyl)bis

in identifying the drug. The limit tests of arsenic and lead were found below the normal level, and this result is needed to conduct a clinical trial. The oil *Ksheerabalatailam* was prepared from *Sida cordifolia* for clinical study as per the reference of Sahasrayogam and the physiochemical properties of this oil was slight different with that of AFI may be due to the various procedures. In AFI, *Ksheerabalatailam* was prepared to take *Kashaya* (decoction), but as per the Sahasrayogam, this oil was prepared by taking *Kalkam* (paste) mixing with cow's milk. Physicochemical studies of oil viz. weight for ml, iodine value, saponification value, acid value, peroxide value, and total fat are certain parameters selected to establish the standards of the oil. The developed HPTLC fingerprints of the oil may be also useful for verification and comparison in future studies. By comparing the HPTLC of root powder and oil, we found that the components which are present in the powder also found in the oil so that the active principle present in the root powder found in the oil which is useful for a clinical trial on osteoarthritis. The study will be considered useful to the scientific fraternity as referral tool in identifying and testifying the drug. The phytochemical screening studies have been carried out by GC-MS analysis and identified the chemical constituents present in the *Ksheerabalatailam*. The gas chromatogram shows the relative concentrations of various compounds getting eluted as a function of retention time. The heights of peak indicate the relative concentrations of the components present in the tailam extract. The mass spectrometer analyzes the compounds eluted at different times to identify the nature and structure of the compounds. The mass spectra are finger print of that compound which was identified from NIST library databases. The compounds which was identified by GC-MS analysis were N-Hexadecanoic acid, 17-Octadecynoic acid and 1,3-Benzodioxole, 5,5'-(Tetrahydro-1H,3H-furo[3,4-c]furan-1,4-Diyl)bis.

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