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Standardization of Siddha drug Thalagam by Comparative Physiochemical evaluation in accordance with regulatory guidelines

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Abstract

Traditional medicine is the knowledge, skills and practices of holistic healthcare, recognized and accepted for its role in the maintenance of health and the treatment of diseases. It is based on indigenous theories, beliefs and experiences that are passed on from generation to generation. Siddha system of medicine emerged from the southern zone of Tamil Nadu, India. Siddha medicine has certain unique formulation with metal, minerals and metalloids in its counterpart. Stringent regulation necessitates the level of heavy metals in siddha preparation that are about to expose clinically. Ancient siddha system has well optimized purification procedures which always limits the level of metals and minerals and also promotes the activity. The main aim of the present study is to compare the elemental composition of thalagam (unpurified and purified arsenic trisulphide) using modern instrumental techniques. Results of the physiochemical evaluation of the purified and unpurified samples shows the appearance of the drug changed to pasty, consistency after purification. The total ash value was change from 0.1/% (Unpurified Lingam) 3.7% (Purified Lingam). The acid insoluble ash was change from <1% to 0.6%. The water soluble ash was change from <1% to 0.7%. The water soluble extract was change from 17.2% to 63.8%. The Alcohol soluble extraction was change from 0.2% to 62.4%. The moisture content was change from 0.11% to 11.51%.It was concluded from the results that the purification process attempted were successful with justification of change in organoleptic characters of un purified and purified form of thalagam further there is a significant change were observed with respect to total ash, loss on drying and extractive value of unpurified and purified thalagam.

Keywords: Traditional medicine, Thalagam, Siddha medicine, Physiochemical evaluation, Ash value, Extractive value.

1. Introduction

Natural products are used extensively throughout the world, at least in 70% of drugs available in the global market. However, there is a great threat to biodiversity [1] due to overharvesting raw materials for herbal medicines and health care products. Since many medicinal plants are also in the endangered list, it is better to adapt mineral-based medicine practiced traditionally in India. An ancient system of traditional Indian medicine '*Siddha'* uses metals, metalloids and minerals [2] that comprises toxic and heavy elements such as lead, mercury and arsenic. This raises the public concerns and alarms the large population on consumption of these traditional medicines [3-5].

These international developments are of particular significance for India that has a pluralistic medical culture with a well-documented history and practice of alternative medicinal forms namely—Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy–now jointly referred to as AYUSH [6,7]. As integral part of Indian culture, Indian System of Medicine (ISM) comprising of Ayurveda, Yoga, Unani and Siddha was practiced even before formal health system took shape.

The WHO has conducted a number of surveys about regulatory issues regarding natural products [8]. A global survey in 2005 has taken into account the regulatory findings of 141 countries indicating that many countries have started establishing regulatory authorities for the assessment of safety and efficacy of herbal medicines [9]. The WHO has also specified guidelines for improving consumer information, pharmacovigilance and good agriculture and collection practices for herbal medicines [10].

Siddha system of traditional medicine has well optimized procedure onpurification of several metals and herbomineral preparation, but still now the validation of identifying the change in elemental composition through purification process is not much documented, Hence the main aim of the present study is to compare the elemental composition of thalagam (unpurified and purified arsenic trisulphide) using modern instrumental techniques.

2. Materials and Methods

2.1. Organoleptic Analysis

Both unpurified and purified Thalagam were subjected to the organoleptic analysis with respect to the Colour, Odour, Taste, Nature and Glittering capacity level in accordance with standard PLIM guideline

2. 2. Physicochemical Evaluation [11,12]

2.2.1. Percentage Loss on Drying

10gm of NC was accurately weighed in anevaporating dish and was air dried at 105^{o}C for 5 hours and then weighed.

2.2.2. Determination of Total Ash

3 g of test drug NC was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates theabsence of carbon. Percentage of total ash will be calculated with reference to the weight of theair-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

2.2.3. Determination of Acid Insoluble Ash

The ash obtained by total ash test will be boiled with 25 ml of dilute hydrochloric acid for 6mins. Then the insoluble matter is collected in acrucible and will be washed with hot water and ignited to constant weight. Percentage of acid insoluble ash will be calculated with reference to the weight of air-dried ash.

Acid-insoluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

2.2.4. Determination of Alcohol Soluble Extractive

Test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

Alcohol sol extract = Weight of Extract/ Wt of the Sample taken X 100

2.2.5. Determination of Water Soluble Extractive

Test sample was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand and for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

Water soluble extract = Weight of Extract/ Wt of the Sample taken X 100

2.2.6. Determination of pH

Test sample was dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and the subjected to pH evaluation.

2.3. Qualitative Phytochemical Analysis [13-16]

2.3.1. Test for alkaloids

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

2.3.2. Proteins (Biuret Test) – Amino acids

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

2.3.3. Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

2.3.4. Test for Starch

The aqueous extract 5ml was treated with the reagent of the starch (iodine). Any shift to blue violet indicates the presence of starch.

2.3.5. Test for Tannic acid,Oxyquinole, epinephrine, Pyrocatechol

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

3. Results

3.1. Results of Organoleptic Evaluation of Un-purified and Purified Thalagam

Organoleptic Character of T1, T2 and T3 described in Table 1. The study reveals the color of the drug came back to dull brick red to bright brick red and also the nature of the drug was changed to pasty consistency from the powder. The pH was change from 6.79 (unpurified Thalagam) to 3.78 (Purified Thalagam). As shown in Table 1.

Table 1: Organoleptic evaluation of Unpurified Thalagam (T1) and Purified Thalagam (T2, T3)

S.no	Parameters	T1 (Un purified)	T2 (Purified)	T3 (Purified)	Method of Testing
1	Colour	Golden Yellow	Yellowish orange	Pinkis brown Yellow	By visual
2	Odour	Rotten Egg Smell	Mild Smell of Rotten Egg	Odour less	Olfactory examination
3	Taste	Taste less	Taste less	Taste less	Olfactory examination
4	Nature	Hard	Hard	Brittle	By breaking
5	pH	6.5	7.7	6.3	APHA 4500H+A,B
6	Glittering capacity level	Positive (High)	Positive(High)	Positive (moderate)	By visual

3.2. Results of Physicochemical Analysis

Physico chemical evaluation of T1, T2 and T3 described in Table 2. This study shows the appearance of the drug changed to pasty, consistency after purification. The total ash value was change from 0.1/% (Unpurified Lingam) 3.7% (Purified Lingam). The acid insoluble ash was change from <1% to 0.6%. The water soluble ash was change from <1% to 0.7%. The water soluble extract was change from 17.2% to 63.8%. The Alcohol soluble extraction was change from 0.2% to 62.4%. The moisture content was change from 0.11% to 11.51%. As shown Table 2.

Table 2: physicochemical evaluation of Unpurified Thalagam (T1) and Purified Thalagam (T2, T3)

S.No	Physico Chemical Parameters	T1 % in w/w (mg/g)	T2 % in w/w (mg/g)	T3 % in w/w (mg/g)
1.	Appearance	Hard Yellow	Light Yellow	Canary Yellow
2	Total ash value	3.77%	5.25%	0.25%
3	Acid insoluble ash	9.9%	5.43%	7.17%
4.	Water soluble extraction	0.72%	1.36%	0.8%
5.	Alcohol soluble extraction	1.99%	0.78%	2.089%
6.	Moisture content	0.07%	0.15%	0.39%
7.	Sulphated Ash Value	4.91%	7.12%	0.15%
8.	Melting point	131^{o}C	133^{o}C	134^{o}C
9.	Boiling point	285-289^{o}C	288-292^{o}C	287-289^{o}C
10.	Protien Estimation	70 µg	190µg	210 µg
11.	Alkaloid Estimation	Absent	Absent	Absent

3.3. Phytochemical Investigation Unpurified Thalagam (T1) and Purified Thalagam (T2, T3)

Phytochemical investigation report justifies the presence of starch in both the forms and also absence of alkaloids, amino acids. tannic acid, reducing sugar, oxyquinole, epinephrine, and pyrocatechol.

Table 3: physicochemical evaluation of Unpurified Thalagam (T1) and Purified Thalagam (T2, T3)

S.no	Phytocomponents	T1 (Un purified)	T2 (Purified)	T3 (Purified)
1.	Test for Starch	+	-	+
2.	Test for Reducing sugar	-	-	-
3.	Test for Alkaloids	-	-	-
4.	Test for Amino acids	-	-	-
5.	Test for Tannic acids	-	-	-
6.	Test for Oxyquinole, epinephrine, Pyrocatechol	-	-	-

"+" Present, "-"absent

4. Discussion

Standardization is a process which maintains consistency in the claimed efficacy of a product and its batch-to-batch reproducibility. The major challenges in terms of scientific standardization to adhere to industry norms are variation in the source, lack of safety evaluations and difficulty in quality control [17]. In the present study Purification process converts the drugs from hard to brittle consistency, also from rotten egg smell to odorless, Color turns from golden yellow to pinkish brown.

Standardization of traditional products can be divided into two categories: first, an active constituent extract, where biochemical principles are known and have therapeutic values, and second, a marker extract, where the active principle is not known and a characteristic compound is used as a marker to assess the presence of other therapeutic biochemical compounds [18].From the results of the present study it was shown that the appearance of the drug changed to pasty, consistency after purification. The total ash value was change from 0.1/% (Unpurified Lingam) 3.7% (Purified Lingam). The acid insoluble ash was change from <1% to 0.6%. The water soluble ash was change from <1% to 0.7%. The water soluble extract was change from 17.2% to 63.8%. The Alcohol soluble extraction was change from 0.2% to 62.4%. The moisture content was change from 0.11% to 11.51%.The Pharmaceutical Research and Development Committee report of Ministry of Chemicals, Government of India also underscores the importance of traditional knowledge [19]. The increasing use of traditional therapies demands more scientifically sound evidence for the principles behind therapies and for effectiveness of medicines.

5. Conclusion

Globally, there have been concerted efforts to monitor quality and regulate the growing business of herbal drugs and traditional medicine. Health authorities and governments of various nations have taken an active interest in providing standardized botanical medications. Nevertheless, recently the inorganic arsenic is accepted as the first line chemotherapeutic agent against certain hematopoietic cancers in the western medicine.

The issues related to public concerns should be settled down scientifically by pinpointing its physicochemical properties and its biological interactions. It was concluded from the results that the purification process attempted were successful with justification of change in organoleptic characters of un purified and purified form of thalagam further there is a significant change were observed with respect to total ash, loss on drying and extractive value of unpurified and purified thalagam.

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