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Standardization and Comparative Analysis of Metalloid Based Novel Siddha Preparation Thurusu

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Abstract

Siddha system of medicine is a pioneering practice among the Indian system of traditional medicine. Siddha is a traditional art of healing which provided therapeutic benefits to the mankind since several centuries. Siddhars are considerably an ancient siddha physicians systematically formulated the siddha formulation with the added medicaments from herbs, minerals, metals and even with ores. Due to increase need of globalization and with other regulatory necessities it is now a days becomes highly mandate that the drug should proves its standard, genunity and safety before prescribing the same to the humans. Hence the main aim of the present investigation is to systematically standardize and make a comparative evaluation of unpurified thurusu (UPT) and purified thurusu (PT) a metalloid based novel siddha preparation. The results obtained from the physicochemical evaluation reveals that the loss on drying value of UPT and PT was found to be 28.23 and 3.56%w/w. The total ash value of UPT and PT was 47.51 and 22.89%w/w. In which the acid insoluble ash value of UPT (0.0961 % w/w), PT (0.2174% w/w). The water soluble ash value of UPT and PT was 22.54 and 1.708%w/w respectively. The results of water soluble extractive of UPT were 71.45% w/w and for PT it was 22.49%w/w. Similarly the alcohol soluble extractive value of UPT and PT was found to be 1.673% and 22.52%w/w. The percentage of copper present in UPT was 23.36%w/w and for PT it was 12.67%w/w, whereas the total percentage of sulphur present in UPT was 13.57%w/w and for PT it was 4.403%w/w. It was concluded from the results of the present investigation that there is significant change in the physicochemical data's of unpurified and purified form of thurusu with respect to significant decrease in the values obtained from LOD, total ash, extractive value and also with total percentage of copper and sulphur. Hence it as concluded that the purified thurusu complies with the prescribed standard and further the standardization values of PT are within the limit to confirm the genunity of the preparation.

Keywords: Siddha, Standardization,Thurusu, LOD, Total ash, Extractive value, Copper, Sulphur

1. Introduction

Globalization prevails across the world as a measure of increasing the standards and to improve the benchmark quality of the exports in particular with formulation pertains to Indian medicine. In recent days there is an increasing interest among the health care sectors on routing the therapy towards siddha medicines. The major reason behind the conversion from conventional therapy toward siddha is it's devoid of potential adverse effects and further it works behind the principle of rejuvenation.

Standardization and quality assurance of formulations from metalloid origin is a major problem. There is again a chance of variation as the minerals and metals present in the formulation varying in their concentration due to difference in the purification procedures. Hence there is need to have establish and regularize the standard protocol for developing methods for purifying the preparations from metal and other mineral origin. Several modern analytical techniques recently adopted by several formulators with respect to quality assurance of the preparation's such as X-RD, SEM, FT-IR etc in accordance with pharmacopoeial limit for that particular preparation.

Formulations such as thurusu needs to be purified according to the standard vedic literature and to be ascertained for quality and genunity before clinical usage. When formulation is of metalloid base chemical characterization and profiling to ensure the standard becomes mandatory. Siddha system of medicine has a well-established purifying methodologies to convert the concentration with in well tolerated range. This can be undertaken through finger printing (FP). Chemical FP through FTIR, XRD, Chromatographic techniques such as High performance Liquid Chromatography (HPLC) and High performance Thin Layer Chromatography (HPTLC) is commonly used for standardization and is obtained in terms of one or more marker compounds which may be the active component and frequently when no active marker is known analytical markers without known clinical relevance are used as surrogates [1-2].

The present investigation aimed at systematical standardization and make a comparative evaluation of unpurified thurusu (UPT) and purified thurusu (PT) a metalloid based novel siddha preparation.

2. Materials and Methods

2.1. Source and authentication of raw drugs

The required ingredient is procured from a well reputed indigenous traditional Indian medicine drug shop from Chennai, Tamil Nadu, India and were authenticated by the concerned authorities before use.

2.2. Ingredients

- Thurusu - 500 gm
- Honey – 250 gm
- Ghee – 250 gm
- Whey water (Decanted milk water) – 800 ml (from 1000 ml of milk)

2.3.Purification Procedure [3]

Thurusu is triturated with honey and ghee and boiled in a crucible. Then soaked in decanted milk water for 3 days and dried.

2.4.Physicochemical Evaluation [4-5]

2.4.1.Percentage Loss on Drying

10gm of test drug was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

2.4.2.Determination of Total Ash

3 g of test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ^{o}C until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

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

2.4.3.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 crucible 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

2.4.4.Determination of Water Soluble Ash

The ash obtained by total ash test will be boiled with 25 ml of water for 5 mins. The insoluble matter is collected in crucible and will be washed with hot water, and ignite for 15mins at a temperature not exceeding 450ºC. Weight of the insoluble matter will be subtracted from the weight of the ash; the difference in weight represents the water soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.

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

2.4.5.Determination of Alcohol Soluble Extractive

About 5 g of test sample will be 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

2.4.6.Determination of Water Soluble Extractive

About 5 g of the test sample will be 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

2.4.7.Determination of pH

About 5 g of test sample will be dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and the subjected to pH evaluation

2.4.8.Determination of Bulk density [6]

A weighed quantity of 15g (m) of sample powder was gently introduced in to a 50ml dry graduated cylinder without compacting. Carefully the powder was leveled up without compacting, and the unsettled apparent volume (V0) to the nearest graduated unit was read. The bulk density was calculated in (g/ml) using the formula m/V0.

2.4.9.Determination of Tap density

15 g of sample powder was filled in 50 ml of dry graduated measuring cylinder. It was then placed on a mechanical tapper apparatus which operates for a fixed number of tap (approximately 100) until the powder has reached to its minimum level. Volume was measured to determine its tapped density.

3. Results

3.1. Physicochemical Evaluation of Un-Purified and Purified Thurusu

Result's on organoleptic evaluation of UPT and PT signifies the presence of characteristic blue coloured fine powder reveals the quality and authenticity of the preparation. The results obtained from the physicochemical evaluation revels that the loss on drying value of UPT and PT was found to be 28.23 and 3.56%w/w. The total ash value of UPT and PT was 47.51 and 22.89%w/w. In which the acid insoluble ash value of UPT (0.0961 % w/w), PT (0.2174% w/w). The water soluble ash value of UPT and PT was 22.54 and 1.708%w/w respectively. The results of water soluble extractive of UPT were 71.45% w/w and for PT it was 22.49%w/w. Similarly the alcohol soluble extractive value of UPT and PT was found to be 1.673% and 22.52%w/w. The percentage of copper present in UPT was 23.36%w/w and for PT it was 12.67%w/w, whereas the total percentage of sulphur present in UPT was 13.57%w/w and for PT it was 4.403%w/w.pH plays a vital role in drug disintegration and absorption further the pH of the formulation UPT and PT was found to be 3.71 and 4.89.The results were tabulated in Table 01.

Table 1: Physicochemical Analysis of UPT and PT

S.No	Parameters	Unpurified Thurusu	Purified Thurusu	Permissible Range
1	Appearance	Blue coloured fine Powder	Black coloured fine powder	_
2	Solubility (NS)	Soluble in water Insoluble in alcohol Soluble in Acid	Partially soluble in water Partially soluble in alcohol Partially soluble in Acid	_
3	pH (1%w/w suspension)	3.71	4.89	4 – 14
4	Loss on drying at 105^{o}C	28.23%w/w	3.562%w/w	1-20 % w/w
5	Total Ash	47.51%w/w	22.89%w/w	1–25 %w/w
6	Acid Insoluble ash	0.0961% w/w	0.2174% w/w	1–25 % w/w
7	Water Soluble ash (NS)	22.54% w/w	1.708%w/w	1–25 % w/w
8	Water Soluble Extractive (WSE)	71.45% w/w	22.49%w/w	4–85 % w/w
9	Alcohol Soluble Extractive (ASE)	1.673% w/w	22.52%w/w	4–85 % w/w
13	Copper	23.36%w/w	12.67%w/w	_
14	Sulphur	13.57%w/w	4.403%w/w	_

3.2. Density Parametric result analysis of Un-Purified and Purified Thurusu

Density evaluation is one of the critical parameters which provides the basic understanding the packing volume, shape and surface morphology of the prepared formulation. Bulk density and tap density are the two important parameters that signifies the flow property of the formulation. The results of the study projects that bulk density value of UPT and PT were 0.6015g/mland 0.6052g/mlthe corresponding tap density value is 0.9715 g /ml and0.7349g/ml. The results were tabulated in Table 02.

Table 2: Density parametric analysis of UPT and PT

S No	Parameters	UPT	PT
1.	Bulk density	0.6015g/ml	0.6052g/ml
2.	Tap density	0.9715g/ml	0.7349g/ml

4. Discussion

Therapeutic ailments of natural origin gains greater attention and were used extensively throughout the world, at least in 70% of drugs available in the global market. However, there is a great threat to biodiversity [7] due to overharvesting raw materials for herbal/ mineral based medicines and health care products. An ancient system of traditional Indian medicine '*Siddha'* uses metals, metalloids and minerals [8] that comprises elements such as copper, lead, mercury and arsenic. This raises the public concerns and alarms the large population on consumption of these traditional medicines [9-12]. The issues related to public concerns should be settled down scientifically by pinpointing its physicochemical properties and its biological interactions [13-14]. As a measure of developing monograph of the metalloid based preparation such as Thurusu in this present investigation we have developed a standards for future researcher to work on metal based siddha preparations.

Elements have both a curative and a preventative role in combating diseases. Trace elements, for example the metals selenium, zinc and copper, are essential to maintain the metabolism of the human body. Elements, in one form or another play an important role in the field of medicine, including the trace elements present in traditional medicines. The consumption of such medicines contributes to the intake of both essential and non-essential trace elements by the human body [15]. The results obtained from the physicochemical evaluation reveals that the loss on drying value of UPT and PT was found to be 28.23 and 3.56%w/w. The total ash value of UPT and PT was 47.51 and 22.89%w/w. In which the acid insoluble ash value of UPT (0.0961 % w/w), PT (0.2174% w/w). The water soluble ash value of UPT and PT was 22.54 and 1.708%w/w respectively. The results of water soluble extractive of UPT were 71.45% w/w and for PT it was 22.49%w/w. Similarly the alcohol soluble extractive value of UPT and PT was found to be 1.673% and 22.52%w/w. The percentage of copper present in UPT was 23.36%w/w and for PT it was 12.67%w/w, whereas the total percentage of sulphur present in UPT was 13.57%w/w and for PT it was 4.403%w/w.Search of alternate therapy from the natural origin is a never ending process in these view herbs and elemental preparations have become the predominant source for the supply of valuable therapeutic leads with multiple components and may render versatile pharmacological action against several diseases in recent times.

5. Conclusion

Development of monographs and standard for metalloid preparations has greater importance for the research pertains to biological significance of metals and its impact on the human health. However, modernization of traditional medicine should not be simply westernization it could definitely pave a way to stream line the global regulations pertains to quality , safety and genunity of the product by which it actually intended to be. From the results obtained from the present investigation it was evident that the siddha preparation purified Thurusucomplies with the standard prescribed by the board of AYUSH. Further usage of this medicine as an ailment for diseases may be recommendable and trust worthy source.

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