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STANDARDIZATION OF EERULLI ENNAI FOR SUZHI MAANTHAM (CHILDHOOD ASTHMA) IN CHILDREN

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ABSTRACT

Siddha System of Medicine is a unique system among Indian medical system. Eerulli ennai is an herbal drug which is mentioned in Siddha Literature at Balavagadam. All the Ingredients of the trail medicine are pure herbs. Standardization is one point of safety and efficacy of the drug. The Present study deals with analyzing the physics chemical characterization, Phytochemicals, Heavy metal analysis, Specific pathogen test, Aflatoxin and Pesticide residue of Eerulli ennai to establish standard quality parameters. This study showed Refractive index determining the identity and purity, higher Saponification value improves absorption rate to the intestine, lesser free fatty acid make them less rancidity and having healthy benefits. The implication of the present findings such as Microbial contamination, Specific pathogen, Aflatoxin, Pesticide residues and heavy metal analysis may be taken into consideration of the experimental formulation may be safe.

KEYWORDS: Physicochemical, Siddha, Eerulli ennai and Standardization.

INTRODUCTION

Siddha system of medicine is the most primitive medical system. This system was formulated and established about more than 25000 years back by the eminent power called Siddhar's and hence the name siddha medicine. The Siddha medicine were prepared by the various research work done by the Siddhar's on herbs, metals, minerals and animal products.

The father of siddha medicine is the primordial guru Agasthiyar. There are also 18 Prime Siddhar's who the followers of the primordial guru and they had contributed their valuable knowledge and experience in this field.

Siddha medical system doesn't consider treatment and prevention separately. The main aim of this system is prevention of diseases, and it is well said that "Prevention is better than cure". Siddha system emphasizes not only a healthy body but a peaceful mind and pure soul. Hence it is unique when compared to any other medical system.

Suzhi maantham has been described in the siddha literature as one of the subtypes of maantham, a disease frequently occurring in children. According to the siddha text Balavagadam it is characterized by intermittent fever, wheezing, insomnia, Hiccough, Lack of appetite, dyspnoea. It can be nearly correlated with childhood asthma in modern medicine.

Asthma has been regarded as a complex syndrome occurring in the airway, which shows various disorders such as airflow obstruction acute (or) chronic inflammation, airway hyper responsiveness & structural remodeling. Pediatric respiratory problems are prevalent all over the world and it is closely related to food habits, socio-economic status and plays a major role in the school regularly.

Asthma is the one of the most common chronic disorder in childhood, currently in India among an estimated 7.1 million children under 18yrs of age about 4.1 million children suffered from asthma attack in 2011.

Childhood asthma is the major problem in our country. There are many drugs available for childhood asthma but along with some complication such as tremor and drug intolerance. So, there is a need to develop a safe herbal formulation for this disease.

All Ingredients of the trial medicine are pure herbs. The ingredient of the trial drug exhibits Anti-Inflammatory, Expectorant and Laxative actions. So, the investigator believes that it might be safe and will have efficacy in treating children with childhood asthma.

Standardization of drug means confirmation of its identity and determination of its quality and purity and biological observations. Standardization of medicine starts from collection of raw material upto their clinical application and efficacy.

MATERIAL AND METHODS

Vengayam (Allium cepa), Vellindu (Acacia pennata), Aamanakku nei (Ricinus communis) are used as an ingredient for the preparation of Eerulli ennai.

Collection of Raw Drugs

The drugs were purchased from authorized country raw drug store in Chennai. Classical parameters were taken for the evaluation.

Identification and Authentication of The Drug

All the drugs were identified and authenticated by the Botanist, Department of Gunapadam, National Institute of Siddha, Tambaram Sanatorium, Chennai.

Purification and Preparation of The Ingredients

All the drugs mentioned here were purified as per the Siddha literature.

Vengayam – Peel off the outer skin and washed in water and then juice was extracted.

Vellindu – Purify the plant in water and then juice was extracted.

Castor oil – Filled in a bottle and kept with the bottom partially immersed in sand & Kept under sunlight and filtered.

Table 1: Formulation Composition of Eerulli Ennai.

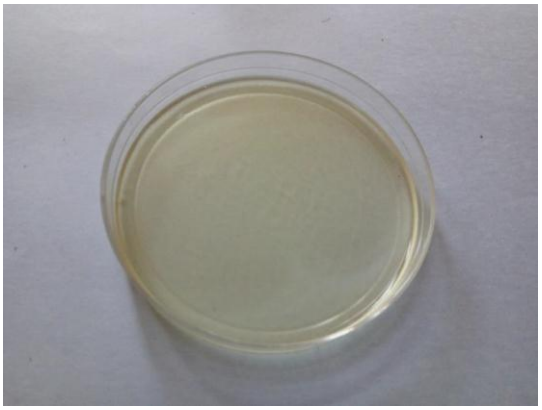
S.NO	INGREDIENTS	WEIGHT IN GRAMS
1	Vengayam (Allium cepa)	1 caer (320 grams)
2	Vellindu (Acacia pennata)	1 caer (320 grams)
3	Aamanakku nei (Ricinus communis)	1 caer (320 grams)

Ingredients of Eerulli Ennai

Acacia Pennata

Allium Cepa

Ricinus Communis



Eerulli Ennai

Method of Preparation
All the above ingredients were purified. The juice of vellindu, vengayam was extracted and mixed with castor oil and heated until it attained a waxy consistency.

1. Physicochemical Analysis Of Eerulli Ennai
Percentage Loss on Drying
10gm of test drug (weight equivalent to oil) was accurately weighed in evaporating dish. The sample was dried at 105oC for 5 hours and then weighed.

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

Determination of Total Ash
3 g of test drug (weight equivalent to oil) was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC 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

Determination of pH
Sample being oily in nature the direct litmus evaluation method was adopted to check the pH of the sample.

Determination of Iodine value
About 20 gm of oil was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about 25 ml of Wiji‟s solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for an hour.T About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value
About 2 gm (weight equivalent to oil) of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeatthe same procedure with out taking the sample for blank titration. Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

2. Phytocomponents Evaluation of Eerulli Ennai
Sample Preparation
Eerulli oil (EO) was extracted with ethanol and the extract was subjected to the following analysis

Test for Alkaloid- Mayer's reagent
To the test drug about 2ml of Mayer's reagent was added and was observed for the presence of alkaloids..

Test for flavonoid
To 0.1ml of the test sample about 5 ml of dilute ammonia solution have been added followed by addition of few drops of conc. Sulfuric acid. 45

Test for Glycosides - Borntrager’s Test
Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it.

Test for Triterpenoids
To the test solution 2ml chloroform was added with few drops of conc. Sulphuric acid (3ml) at the side of the test tube.

Test for Steroids - Salkowski test
To the test solution 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence.

Test for Carbohydrates - Benedict's test
To 0.5 ml of test drug about 0.5 ml of Benedic‟s reagent is added. The mixture is heated on a boiling water bath for 2 minutes.

Test – Phenol- Lead acetate test
The test sample is dissolved in of distilled water and to this 3 ml of 10% lead acetate solution is added..

Test for tannins
About 0.5ml of test sample is boiled in 20 mL of distilled water in a test tube and then filtered. The filtration method used here is the normal method, which includes a conical flask and filter paper. The 0.1% FeCl3 is added to the filtered samples.

Test for Saponins
The test drugs were shaken with water vigorously for 10 mins.

Test for Proteins (Biuret Test)
Biuret test: Equal volume of 5% solution of sodium hydroxide and 1% copper sulphate were added.

Test of Coumarins
1 ml of extract, 1 ml of 10% sodium hydroxide was added.

Test for Quinones
The test samples were treated separately with Alc. KOH solution.

Test for Anthocyanin
About 0.2 ml of the extract was weighed in separate test tube, 1ml of 2N Sodium Hydroxide was added, and heated for 5 minutes at 100 ± 2°C.

Test for Betacyanin
To 2 ml of the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 1000C.

3. Quantitative Estimation of phytoconstituents of eerulli
Ennai
Determination of total Phenol content
The total phenol content was determined using Folin–Ciocalteu reagents with analytical grade Gallic acid as the standard. 1 ml of sample was added to deionized water (10 ml) and Folin–Ciocalteu phenol reagents (1ml). After 5 minutes, 20% sodium carbonate (2 ml) was added to the mixture. After being kept in total darkness for 1 hr, the absorbance was measured at 750 nm using a spectrophotometer. Amounts of total Phenol was calculated using Gallic acid calibration curve. The results were expressed as Gallic acid equivalents (GAE) mg/g of dry plant matter.

Total Flavanoid
Total flavanoid content in the drug EO was determined using aluminum chloride method. In this method Quercetin was used as standard and flavonoid contents were measured as quercetin equivalent. For this purpose, the calibration curve of quercetin was drawn. 1ml of standard or sample EO was taken into 10ml volumetric flask, containing 4ml of distill water. 0.3ml of 5%NaNO2 added to the flask. After 5min, 0.3ml 10%AlCl3 was added to the mixture. At the 6th min add 2ml of 1M NaOH was added and volume made up to 10ml with distilled water. The absorbance was noted at 510nm using UV-Visible spectrophotometer.

Estimation of Alkaloid
EO weight equivalent to 5 gm was weighed into a 250 ml beaker and 200 ml of 10% acetic acid in ethanol was added and covered and allowed to stand for 4 hr. This was filtered and the extract was concentrated on a water bath to one-quarter of the original volume. Concentrated ammonium hydroxide was added drop wise to the extract until the precipitation was complete. The whole solution was allowed to settle and the precipitated was collected and washed with dilute ammonium hydroxide and then filtered. The residue is the alkaloid, which was dried and weighed.

Estimation of Tannin
The tannin content was determined using Folin Ciocalteu assay. Sample EO of 100 µL was added to 750 µL of distilled water, 500 µL Folin-Ciocateu reagent and 1000 µL of 35 % sodium carbonate (Na2CO3). The mixture was shaken vigorously after diluting to 10 mL of distilled water. The mixture was incubated for 30 min at room temperature and read at 725 nm. Distilled water was used as blank. Tannic acid standard solutions were prepared and standard calibration curve was plotted with varying concentration. The total tannins content were expressed as Tannic acid mg/gm, as calculated from the prepared standard curve.

1. Physico Chemical Analysis of Eerulli Ennai.
Table 2:

S.No	Parameter	Observation
1	Color	Creamy white
2	Smell	Characteristic
3	Touch	Oily
4	Appearance	Clear

Table 3:

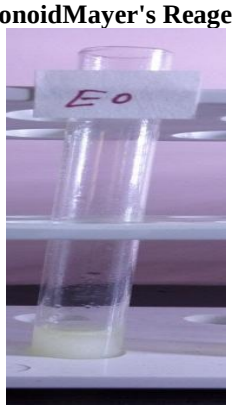
S.No	Parameter	Mean (n=3) SD
1	Loss on Drying at 105 °C (%)	3.83 ± 0.20
2	Total Ash (%)	0.822 ± 0.11

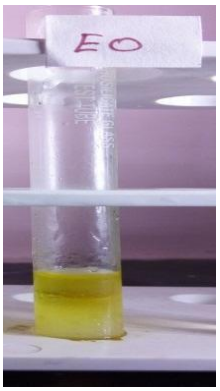
Table 4:

S.No	Specific Test	EO
1	pH	6
2	Refractive index	1.44
3	Iodoine value (mg I2/g)	122
4	Saponification Value (mg of KOH to saponify 1gm of fat)	Clear

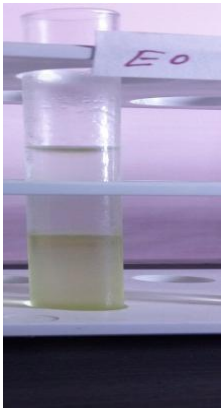
2.Phytocomponents of Eerulli Ennai

Test For Alkaloid- Test For FlavonoidMayer's Reagent

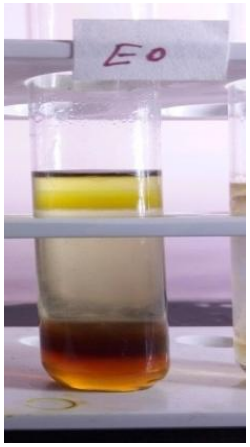


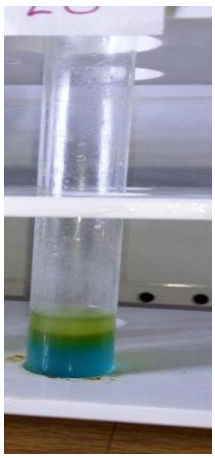


Test For Glycosides – Test For TriterepnoidsBorntrager's Test

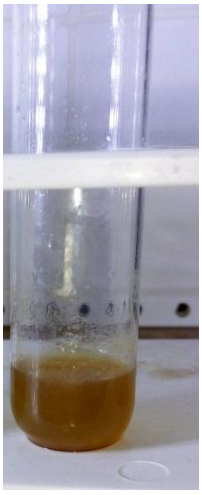


Test For Steroids - Test For Corbhohydrates

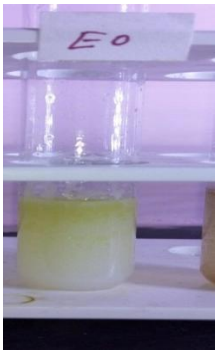
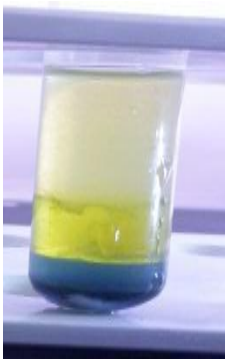




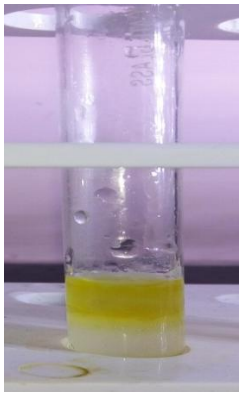
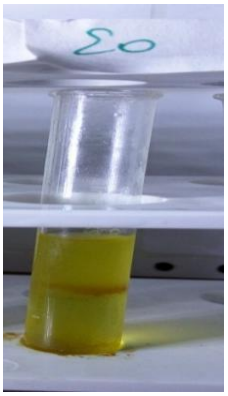
Enedict"S Test Salkowski Test

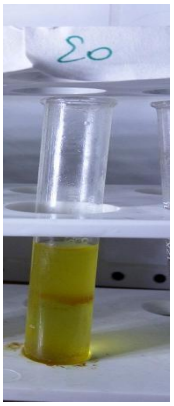
Test – Phenol- Test For TanninsLead Acetate Test

Test For Saponins **Test For Proteins (Biuret Test)**

Test Of Coumarins **Test For Quinones**

Test For Anthocyanin **Test For Betacyanin**

Table 5:

PHYTOCOMPONENTS	EO
ALKALOIDS	+
FLAVONOIDS	+
GLYCOSIDES	+
STEROIDS	+
SUGAR	-
TRITEREPNOIDS	-
COUMARINS	+
PHENOLS	+
TANNINS	+
SAPONINS	+
PROTEINS	+
ANTHOCYANIN	-
BETACYANIN	-
QUINONES	-

\+ Indicates positive
\- Indicates Negative

1. Quantitative estimation of phytoconstituents of Eerulli ennai

Table 6:

Phyto- constituents	**EO**
Total phenols (GAE mg/gm)	0.620 ± 0.04
Total flavonoids (Quercetin mg/gm)	0.21 ± 0.05
Total alkaloids(mg/gm)	0.69 ± 0.01
Total tannins(mg/gm) (Tannic acid mg/gm)	0.44 ± 0.08

Mean with 3 replicates ± SD.

Interpretation

The acidic radicals test shows the presence of Chloride, Fluoride & Oxalate.

Table 10: Results of basic radicals studies.

S.NO	PARAMETER	OBSERVATION	RESULTS
1	Test for Lead	--	Negative
2	Test for Copper	-	Negative
3	Test for Aluminium	-	Negative
4	Test for Iron	-	Negative
5	Test for Zinc	-	Negative
6	Test for Calcium	-	Negative
7	Test for Magnesium	-	Negative
8	Test for Ammonium	-	Negative
9	Test for Potassium	-	Negative
10	Test for Sodium	-	Negative
11	Test for Mercury	-	Negative
12	Test for Arsenic	-	Negative

Interpretation

The basic radicals test shows the absence of heavy metals such as lead, arsenic and mercury.

Table 11: Miscellaneous.

S.NO	PARAMETER	OBSERVATION	RESULTS
1	Test for Starch	--	Negative
2	Test for Reducing sugars	-	Negative
3	Test for Alkaloids	Yellow colour developed	Positive
4	Test for Tannic acid	-	Negative
5	Test for Unsaturated compounds	-	Negative

6	Test for Amino acid	-	Negative
7	Test for Type of compounds	-	Negative

Interpretation
The Miscellaneous test shows the presence of Alkaloids.

Test Report Of Heavy Metals, Pesticide Residue Organochlorine, Organophosphorus, Pyrethroids
Table 12: Heavy Metals.

S.No	Test Parameters	Units of Measurement	Result	Method of Testing
1	Cadmium	mg/kg	ND(DL-0.01)	BVCPSCH/NS/SOP/053 by ICP OES
2	Lead	mg/kg	ND(DL-0.01)	
3	Mercury	mg/kg	ND(DL-0.01)	
4	Arsenic	mg/kg	ND(DL-0.01)	

Organochlorine

1	Aldrin(Aldrin and dieldrin combined expressed asdieldrin)	mg/kg	BLQ(LOQ-0.01)	ERUL Method by GC MSMS/LC MSMS
2	Chlordane (cis & trans)	mg/kg	BLQ(LOQ-0.01)	
3	Chlorothalonil	mg/kg	BLQ(LOQ-0.01)	
4	DDT (all Isomers)	mg/kg	BLQ(LOQ-0.01)	
5	Dicofol (sum of p,p‟ and o,p‟ Isomers)	mg/kg	BLQ(LOQ-0.01)	
6	Dieldrin (see Aldrin)	mg/kg	BLQ(LOQ-0.01)	
7	Endosulphan (all Isomers)	mg/kg	BLQ(LOQ-0.01)	
8	Endrin	mg/kg	BLQ(LOQ-0.01)	
9	HCH (sum of isomers,except the gamma isomers)	mg/kg	BLQ(LOQ-0.01)	
10	Heptachlor (sum ofheptachlor and heptachlorepoxide expressed as heptachlor)	mg/kg	BLQ(LOQ-0.01)	
11	Lindane (gamma-HCH)	mg/kg	BLQ(LOQ-0.01)	
S.No	Test Parameter	Unite of Measur ement	Result	Method of Testing
12	4- bromo-2- chlorophenol (metabolite of profenophos)	mg/kg	BLQ(LOQ-0.01)	ERUL Method by Gc MSMS/LC MSMS
13	Acephate	mg/kg	BLQ(LOQ-0.01)	
14	Chlorfenvinphos	mg/kg	BLQ(LOQ-0.01)	
15	Chlopyrifos	mg/kg	BLQ(LOQ-0.01)	
16	Chlopyrifos methyl	mg/kg	BLQ(LOQ-0.01)	
17	Diazinon	mg/kg	BLQ(LOQ-0.01)	
18	Dichlorvos	mg/kg	BLQ(LOQ-0.01)	
19	Dimethoate (including Omethoate)	mg/kg	BLQ(LOQ-0.01)	
20	Edifenphos	mg/kg	BLQ(LOQ-0.01)	
21	Ethion	mg/kg	BLQ(LOQ-0.01)	
22	Etrimphos	mg/kg	BLQ(LOQ-0.01)	
23	Fenitrothion	mg/kg	BLQ(LOQ-0.01)	
24	Fenthion	mg/kg	BLQ(LOQ-0.01)	
25	Iprobenphos	mg/kg	BLQ(LOQ-0.01)	
26	Malathion (sum of malathion and malaoxon expressed as malathion)	mg/kg	BLQ(LOQ-0.01)	
27	Methamidophos	mg/kg	BLQ(LOQ-0.01)	
28	Monocrotophos	mg/kg	BLQ(LOQ-0.01)	
29	Omethoate (refer to Dimethoate)	mg/kg	BLQ(LOQ-0.01)	
30	Oxydemeton- methyl(sum of oxydemeton methyl anddemeton-S-methyl sulfone expressed as oxydemeton –methyl)	mg/kg	BLQ(LOQ-0.01)	
S.No	Test Parameter	Unite of Measurement	Result	Method ofTesting
31	Parathionethyl	mg/kg	BLQ(LOQ-0.01)	

32	Parathion methyl(sum of parathion methyl and paraoxon methyl expressed as parathion methyl)	mg/kg	BLQ(LOQ-0.01)	
33	Phenthoate	mg/kg	BLQ(LOQ-0.01)	
34	Phorate(sum of phorate,itsoxygen analogue and theirsulfones expressed as phorate)	mg/kg	BLQ(LOQ-0.01)	ERUL Methodby Gc MSMS/LC MSMS

1. Organophosphorus

35	Phosalone	mg/kg	BLQ(LOQ-0.01)	ERUL Method by Gc MSMS/LCMSMS
36	Phosphamidon	mg/kg	BLQ(LOQ-0.01)	
37	Pirimiphos methyl	mg/kg	BLQ(LOQ-0.01)	
38	Profenophos	mg/kg	BLQ(LOQ-0.01)	
39	Propetamphos	mg/kg	BLQ(LOQ-0.01)	
40	Quinalphos	mg/kg	BLQ(LOQ-0.01)	
41	Temephos	mg/kg	BLQ(LOQ-0.01)	
42	Thiometon	mg/kg	BLQ(LOQ-0.01)	
43	Triazophos	mg/kg	BLQ(LOQ-0.01)	

2. Synthetic Pyrethroids

44	Allethrin and	mg/kg	BLQ(LOQ-0.01)	
	Bioallerthin			
45	Bifenthrin	mg/kg	BLQ(LOQ-0.01)	
46	Cypermethrin (including	mg/kg	BLQ(LOQ-0.01)	
	other mixture of			
	constituent isomers sum			
	of isomers)			
47	Cypermethrin (including	mg/kg	BLQ(LOQ-0.01)	
	other mixture of			EURL
	constituent isomers sum			Method By
	of isomers)			MSMS /LC
				MSMS
48	Deltamethrin	mg/kg	BLQ(LOQ-0.01)	
49	Ethofenprox	mg/kg	BLQ(LOQ-0.01)	
50	Fenpropathrin	mg/kg	BLQ(LOQ-0.01)	
51	Fenvalerate (sum of RR	mg/kg	BLQ(LOQ-0.01)	
	& SS isomers)			
52	Lambda-cyhalothrin	mg/kg	BLQ(LOQ-0.01)	
53	Permethrin(sum of	mg/kg	BLQ(LOQ-0.01)	
	isomers)			
54	tau-Fluvalinate	mg/kg	BLQ(LOQ-0.01)	
55	Transfluthrin	mg/kg	BLQ(LOQ-0.01)	

ND- Not Detected /DL-Detection Limit/BLQ: Below Limit of Quantification /LOQ-Limit of Quantification.

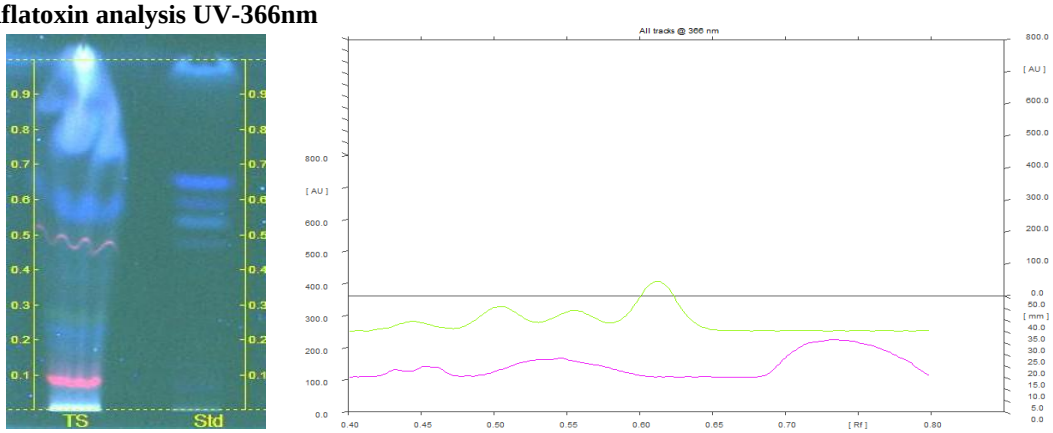
Inference

- Heavy metal –Not detected.
- Organochlorine – Below limit of quantification.
- Organophosphorus - Below limit of quantification.
- Synthetic Pyrethroids-- Below limit of quantification.

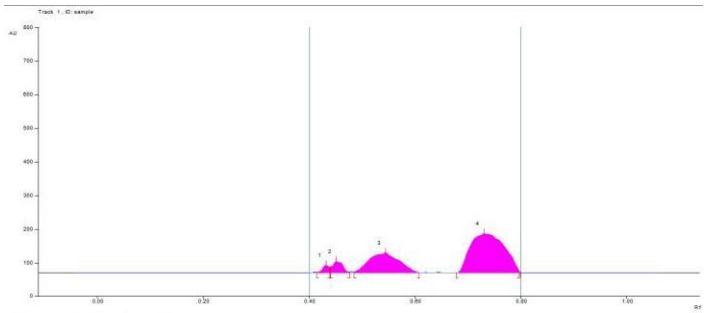
Table 13 7: Analysis of Microbial Load.

S. No.	Parameters	Reference Limits as perWHO (2007)	Results	Remarks
1	**Total Bacterial Count (TBC)**	10^5CFU/gm	Less than 1 cfu/ml	Within permissible limits
2	**Total Fungal Count (TFC)**	10^3CFU/gm	Less than 1 cfu/ml	
3	**Enterobacteriaceae**	10^3	Absent	
4	***Escherichia coli***	10	Absent	
5	**Salmonella Spp**	Absent	Absent	
6	***Staphylococcus aureus***	Absent	Absent	

Test for Aflatoxin analysis UV-366nm



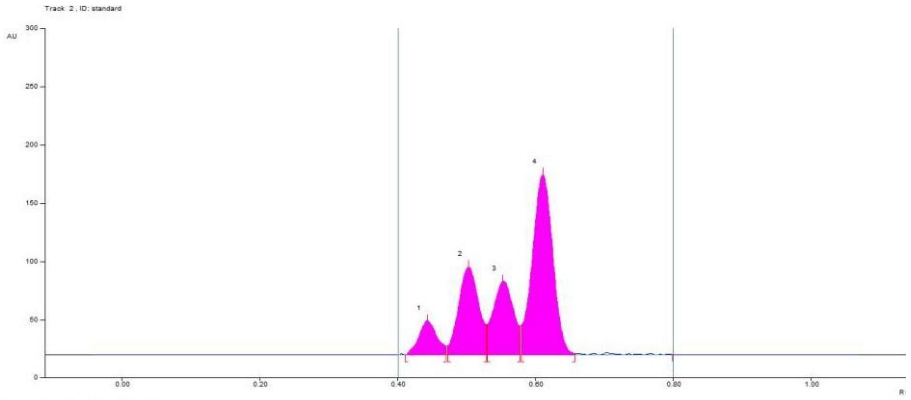
Densitometric chromatogram at UV-366nm; Test sample; Standard – G2, G1, B2 &B1



HPTLC finger print of Test sample at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.42 Rf	1.5 AU	0.43 Rf	22.4 AU	9.64 %	0.44 Rf	17.6 AU	235.4 AU	2.37 %
2	0.44 Rf	18.2 AU	0.45 Rf	33.7 AU	14.55 %	0.48 Rf	2.7 AU	543.5 AU	5.47 %
3	0.49 Rf	2.9 AU	0.55 Rf	59.4 AU	25.61 %	0.61 Rf	0.5 AU	2819.8 AU	28.38 %
4	0.68 Rf	0.0 AU	0.73 Rf	116.3 AU	50.20 %	0.80 Rf	4.2 AU	6338.9 AU	63.79 %

Rf value of Test sample at 366nm



HPTLC finger print of Standard at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.41 Rf	0.0 AU	0.44 Rf	29.3 AU	9.07 %	0.47 Rf	7.3 AU	649.1 AU	8.18 %
2	0.47 Rf	7.6 AU	0.50 Rf	75.7 AU	23.43 %	0.53 Rf	26.2 AU	1870.4 AU	23.58 %
3	0.53 Rf	26.5 AU	0.55 Rf	63.2 AU	19.56 %	0.58 Rf	24.7 AU	1560.2 AU	19.67 %
4	0.58 Rf	25.1 AU	0.61 Rf	154.8 AU	47.95 %	0.66 Rf	0.9 AU	3851.5 AU	48.56 %

Rf value of Standard at 366nm

Note: Similar Rf values were seen in the standard and test sample, upon derivatization with isopropyl alcohol and conc. H_2 SO_4 (9:1), the band colour changed from bluish green to yellow in Track 2 (standard) whereas no

colour change was seen in the Track 1 (TS) which indicated the absence of aflatoxins in the Test sample.

RESULT AND DISCUSSION

The observation of organoleptic, physicochemical and Phytochemical analysis of Eerulli Ennai is mentioned in (Table 2, 3 and 5). The present study dealt with analyzing the physiochemical, Phytochemical characterization, Heavy metal analysis, Microbial contamination and Pesticide residue of Eerulli Ennai to establish standard quality parameters.

In quantitative analysis, the trial medicine Eerulli ennai had alkaloids, flavonoids, glycosides, steroids, coumarins, phenol, tannins, saponins, proteins.

Physicochemical analysis was done as a preliminary evalution of the trial drug Eerulli Ennai. . Loss on drying (LOD) is a method of measuring the amount of water and volatile matters in a sample when the sample is dried. Low moisture content is always desirable for higher stability of drugs. In Eerulli Ennai, the loss on drying at 105^{o}C was found to be 3.83±0.20. So the determination of moisture content shows the good stability of the drug Eerulli Ennai.

The total Ash values are helpful in determining the quality and purity of drugs, especially in powder form. The total Ash value in Eerulli Ennai found to be 0.822±0.11. The minimal level of total ash shows the less inorganic residue and purity of the drug Eerulli Ennai.

Strongly Acidic nature of the drug can cause the harmful effects to the body, so the screening for the pH is important for drugs. It represents the chemical nature of the drug and the site of absorption of non-polar drug. The pH of Eerulli Ennai is found to be 6, that is weekly acidic and safe in pH. The weekly acidic drugs are rapidly absorbed from stomach. So the drug Eerulli Ennai can act rapidly on oral administration.

The refractive index is a measure of purity of a sample. It is a ratio of velocity of light in vacuum. If any adulteration is present in the sample the refractive index will increase or decrease, which is very helpful in determination of unsaturation. Refractive index increases with increase in unsaturation. Since the refractive index is 1.44 it interprets that there is no adulteration in the sample and degree of unsaturation is low.

Iodine value, Saponification value is used to measure the relative degree of unsaturated fatty acid in the sample. Smaller the molar weight of the fat higher the saponification value. The saponification value indicates the mean molecular weight of fatty acid of triglycerides comprising of fat. Lower the saponification value larger the molecular weight of fatty acids and triglyceride vice versa. Since the Iodine value (mg I2/g) is 122 & saponification value (mg of KOH to saponify 1gm of fat) is 241. The observation shows medium chain fatty acid or triglycerides as the main component. Medium chain triglycerides passively diffuse from the GI Tract to the portal system. It facilitate easily absorbed and metabolization of the trial drug.

The test reveals there the absence of heavy metals and micro- organism, Below limit of quantification of pesticides and aflatoxin.The trial drug is also free from microbial contamination, Aflatoxin and Pesticide residues. So it is safe to be administrated in children. There is no adverse effect produced by the trial drug Eerulli Ennai during the entire course of treatment.

CONCLUSION

Paediatric respiratory problems are prevalent all over the world and it is closely related to food habits, socio-economic status and plays a major role in the school regularly.

The trial medicine is a composition of pure herbs. The ingredient of the trial drug exhibits Anti-inflammatory, Expectorant and Laxative action. The management of Suzhimantham with Eerulli ennai has showed good response with no adverse effect. It is very effective and in the management of suzhi maantham and easily palatable in administration. In this study, results were found to be good in 86% of patients.

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