International Journal of Pharmaceutical Science Invention
ISSN (Online): 2319 – 6718, ISSN (Print): 2319 – 670X
www.ijpsi.org || Volume 4 Issue 6 || June 2015 || PP. 33-37

Standardization of Poly Herbal Siddha Medicine Eladhi Chooranam

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ABSTRACT: *Most of the traditional systems of medicine are effective but they lack standardization. So there is a need to develop standardization technique. AYUSH has given preliminary guidelines for standardization of the conventionally used formulations. Standardization of herbal formulations is essential in order to assess the quality of drugs, based on the concentration of their active principles, physical and chemical standards. This study reports on standardization parameters of Eladhi Chooranam a polyherbal Siddha formulation used as anti-ulcer siddha drug. Samples were collected from local market and were subjected to standardization on the basis of organoleptic properties, physical characteristics, and physico-chemical evaluation. Microscopic characterization was compared with authentic ingredients as a reference. It was observed that commercial sample from market matched exactly with that of authentic standards after performing the standardization. The set parameters were found to be sufficient to evaluate the studied formulation and this can be used as reference standard for the quality control/assurance purpose.*

KEY WORDS: *Standardization, Polyherbal formulation, Siddha medicine, Eladhi Chooranam.*

I. INTRODUCTION:

The traditional systems of medicine have become significantly more popular all over the globe because of the curative property, less toxic and minimal side effects. It is more widely used for the human ailments from time immemorial. It has been estimated that 70-80% of world's population relies on traditional healthcare. The mode of preparation and plant used in traditional medicine varies from place to place. In addition acceptance of traditional medicines, especially herbal medicines in the developed world is sharply increasing[1,2,3]. According to World Health Organization, medicinal plants are the best source to obtain a variety of newer herbal drugs. About 80% of individuals from developed countries use traditional medicine, which has compounds derived from medicinal plants. Therefore, such plants should be investigated to understand their properties, safety and efficacy [4]. In ASU systems plants, minerals, and animal products are used as main drugs to cure various ailments [5] .

Herbal medicine also called botanical medicine or phytomedicine refers to the use of plant's seeds, berries, roots, leaves, bark, or flowers for medicinal purposes. Herbalism has a long tradition of use outside of conventional medicine. It is becoming more mainstream as improvements in analysis and quality control along with advances in clinical research show the value of herbal medicine in treating and preventing disease [6].

Siddha is the oldest healing system of medicine and it has fundamental aspects for drug formulation. Major formulations used in Siddha are based on herbs. The medicinal herbs are used as decoctions, infusions, tinctures, and powders[7].There is a global resurgence in the use of these medicines along with a growing scientific interest in them as a source of new drugs [8].There has been a boom in the usage of ASU drugs and export is appreciably high in the last two decades [9].There has been an increase in science based research in ASU drugs for the purpose of globalization. One of the most critical issues involved in any research study is the quality of the test material.

Standardization of herbal formulations is an essential factor in order to assess the quality, purity, safety and efficacy of drugs based on the concentration of their active principles. It is very important to establish a system of standardization for every plant medicine in the market, since the scope for variation in different batches of medicine is enormous [10].Plant material when used in bulk quantity may vary in its chemical content and therefore, in its therapeutic effect very according to different batches of collection e.g. collection in different seasons and/or collection from sites with different environmental surroundings or geographical locations. The increasing demand of the population and the chronic shortage of authentic raw materials have made it incumbent, so there should be some sort of uniformity in the manufacture of herbal or Ayurvedic medicines so as to ensure quality control and quality assurance .[11]

The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety and efficacy [12]. In the present research work, an attempt was made to standardize Eladhi Chooranam a polyherbal siddha formulation [13,14] (Table 1).

II. MATERIAL AND METHODS:

Physico-chemical studies like total ash, water soluble ash, acid insoluble ash, water and alcohol soluble extract, loss on drying at 105°C, microbial contamination and heavy metals analysis were carried out as per the WHO guide lines [12] and Indian Pharmacopoeia.[15] Preliminary phytochemical tests were performed as per the standard methods.

***Plant Material*:**

The samples were collected from physician and manufacturers of SKM Siddha and Ayurvedha Company (India) Limited, Erode, Tamilnadu (Formulation code EC1) which is being used as Anti-ulcer Siddha drug [16]. For in house preparation, the ingredients were purchased from local raw material traders, Chennai (Formulation code EC2) and used as control. Polyherbal formulation consists of twelve ingredients (Table 1).

Preparation of Polyherbal Formulation:

All the ingredients (Table 1) were collected, dried and powdered separately, passed through 100 # sieve and then mixed together in specified proportions in geometrical manner to get uniform mixture.

Standardization Parameters:

The various standardization parameters studied were organoleptic properties, microscopical studies, physico-chemical investigations, preliminary phytochemical analysis, Heavy metal analysis, microbial evaluation and analysis of aflatoxins.

Organoleptic Evaluation: *[17,18]*

The organoleptic characters of the samples were evaluated based on the method described by Siddiqui et al. Organoleptic evaluation refers to evaluation of the formulation by colour, odour, taste and texture etc (Table 2).

Physico-chemical investigations: *[15,19]*

Physico-chemical investigations of formulations were carried out were the determination of extractive values and ash values (Table-3).

Preliminary Phytochemical Analysis : *[20]*

Preliminary qualitative phytochemical analysis of all the extracts was carried out on methanolic extract by employing standard conventional protocols (Table 4).

Heavy Metal Analysis: *[21] (Table-5)*

Preparation of Samples by Acid Digestion Method:

Accurately weighed 2 g of sample was taken in Kjeldah flask. Acid mixture of HNO3: HClO4 (4:1) was added in the flask and heated continuously till the solution is colorless. The sample was then transferred in a 25 ml volumetric flask and the volume was made-up with distilled water. Reagent blank was synchronously prepared according to the above procedure. The standards of Lead (Pb), cadmium (Cd), arsenic (As) and mercury (Hg) were prepared as per the protocol in the manual and the calibration curve was developed for each of them.

***Detection*:**

Then samples were analyzed for the presence of Pb, Cd, As and Hg using Atomic Absorbance Spectrophotometer (AAS).

Microbial Analysis: *[15]*

Microbial analysis was carried for determination of microbial contamination as per procedures of Indian pharmacopoeia [15] 2010 and WHO Guideline [12] . The test included total bacterial count, total fungal count,identification of specified organisms such as Escherichia coli, Salmonella sp., Staphylococcus aureus and Enterobacteriaceae, (Table 6).

***RESULTS AND CONCLUSION**:*

As a part of standardization procedure, both the samples (Formulation code EC1 and EC2) were tested for relevant physical and chemical parameters, and also subjected to microbial screening through quality control measures. Botanical parameters revealed that light sandal in colour, with a aromatic odour, sweet taste and fine texture (Table 2).

Results of quantitative analysis for Total ash, Acid insoluble ash, Alcohol soluble extractives, Water soluble extractive, Loss on drying at 105º C were analysed and results were shown (Table-3). Ash value is useful in determining authenticity and purity of drug and also these values are important quantitative standards. Percent weight loss on drying or moisture content was found to be 5.4% w/w. The less value of moisture content could prevent bacterial, fungal or yeast growth.

Phytochemical analysis revealed the presence of glycosides, alkaloid, amino acid, coumarin, phenol, steroid, triterpenoid and tannins (Table 4).

For detection of such microorganisms, colonies obtained on specific media were subjected to suitable microbial tests along with pure strains to detect their presence or absence. The results obtained (Table 6) revealed the absence of these microorganisms thereby confirming the non toxic nature of the formulations.

Heavy metals may be present in crude drugs through atmospheric pollution and through the soil. Moreover minerals and metals are also used in preparing Ayurvedic formulations. However, heavy metals have been associated with various adverse effects [22] including status epilepticus, fatal infant encephalopathy, hepatotoxicity, congenital paralysis and deafness, and developmental delay. Many case studies have reported serious adverse conditions due to heavy metals in Ayurvedic and other herbal drugs [23].

Hence, heavy metals need to be detected in such preparations. In this study, all the samples tested negative for the presence of heavy metals (Table 5), thereby further confirming the non toxic nature of the preparation. Hence, Eladhi Chooranam is a safe polyherbal formulation and is free from any toxic materials. The results obtained in this study may be considered as tool for assistance to the regulatory authorities, scientific organization and manufacturers for developing standards.

Table-1: Ingredients of Eladhi Chooranam:

Botanical Name	*Siddha Name*	*English Name*	*Family*	*Quantity*
Eletteria cardamomum	*Elam*	*Cardamom seeds*	Zingiberaceae	*9.09%*
Cuminum cyminum	*Seeragam*	*Cumin seeds*	Apiaceae	*9.09%*
Syzygium aromaticum	*Kirambu*	*Cloves*	Myrtaceae	*9.09%*
Glycyrrhiza glabra	*Adhimadhuram*	*Indian liquorice*	Fabaceae	*9.09%*
Emblica officinalis	*Nellivattral*	*Indian Gooseberry*	Euphorbiaceae	*9.09%*
Cinnamomum tamala	*Lavangapathiri*	*Cinnamum Leaves*	Lauraceae	*9.09%*
Cinnamomum verum	*Sirunagapoo*	*Ceylon iorn wood*	Lauraceae	*9.09%*
Murraya koenigii	*Karuveppilai*	*Curry leaf*		*9.09%*
Santalum album	*Sandhanam*	*Sandal wood*	Santalaceae	*9.09%*
Nardostachys jatamansi	*Sadamanjil*	*Valerian root*	Valerianaceae	*9.09%*
Foeniculam vulgare	*Sombu*	*Anise seeds*	Apiaceae	*9.09%*
Saccharum officinarum	*Karkandu*	*Sugarcane*	Poaceae	*Q.S*

Table-2: Organoleptic character of Eladhi Chooranam:

Organoleptic characters	*Formulation code*	
	EC-1	*EC-2*
Colour	*Light sandal*	*Light Sandal*
Odour	*Aromatic*	*Aromatic*
Taste	*Sweet*	*Sweet*

Table-3: Physico- chemical Evaluation of Eladhi Chooranam:

S.No	*Parameter*	*Results*	
		EC-1	*EC-2*
1.	*Loss on drying at 105^0C*	*5.43%*	*5.01%*
2.	*Ash Values* *a. Total Ash* *b. Acid Insoluble Ash*	 *2.41%* *0.25%*	 *2.31%* *0.18%*
3.	*Extract Values* *a. Alcohol* *b. Water*	 *2.98%* *58.72%*	 *2.76%* *54.64%*

Table-4: Phytochemical Screening of Eladhi Chooranam:

S.No	*Parameters*	*Formulation code*	
		EC-1	*EC-2*
1	*Alkaloid*	*Positive*	*Positive*
2	*Amino acid*	*Positive*	*Positive*
3	*Coumarin*	*Positive*	*Positive*
4	*Flavonoid*	*Negative*	*Negative*
5	*Glycoside/ Sugar*	*Positive*	*Positive*
6	*Phenol*	*Positive*	*Negative*
7	*Quinone*	*Negative*	*Negative*
8	*Steroid*	*Positive*	*Positive*
9	*Tannin*	*Negative*	*Negative*
10	*Tritepenoid*	*Positive*	*Positive*
11	*Saponin*	*Negative*	*Positive*
12	*Lignin*	*Negative*	*Negative*
13	*Carboxylic acid*	*Negative*	*Negative*

Table – 5: Heavy Metal Analysis of Eladhi Chooranam :

S.No	*Heavy Metals*	*Formulation code*		*Permissible Limit*
		EC-1	*EC-2*	
1	*Lead*	*0.0197ppm*	*0.012ppm*	*10ppm(WHO)*
2	*Cadmium*	*Not Detected*	*Not Detected*	*0.3ppm (WHO)*
3	*Mercury*	*Not Detected*	*Not Detected*	*1ppm(API,2008)*
4	*Arsenic*	*Not Detected*	*Not Detected*	*3ppm(API,2008)*

Table – 6: Screening for Micro – organisms in Eladhi Chooranam:

S.No	*Parameters*	*Formulation code*		*Permissible limit for Internal use*
		EC-1	*EC-2*	
1	*Total Bacterial Count (TBC)*	*7×10^4CFU/gm*	*8×10^4 CFU/gm*	*10^5 CFU/gm*
2	*Total Fungal Count(TFC)*	*6×10^2 CFU/gm*	*6×10^2CFU/gm*	*10^3CFU/gm*
3	*Enterobacteriaceae*	*Absent*	*Absent*	*10^3 CFU/gm*
4	*Escherichia coli*	*Absent*	*Absent*	*10 CFU/gm*
5	*Salmonella Spp*	*Absent*	*Absent*	*Absent*
6	*Staphylococcus aureus*	*Absent*	*Absent*	*Absent*

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