Journal of Advances and Scholarly Researches in Allied Education
Vol. 16, Issue No. 11, November-2019, ISSN 2230-7540

Standardization in the Pharmaceutical Manufacturing of Crude Drugs (Kampillaka)

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Abstract - It is the goal of this research to investigate the production process, quality control, and criteria of standardisation of Kampillaka in Pharmaceutical Companies. Geological Survey of India, Parshva Chemicals, Mumbai (Maharashtra), Institute of Chemical Technology, Mumbai (Maharashtra), and VJTI Chemistry Lab and Department, Mumbai (Maharashtra), all in Mumbai (Maharashtra), all participated in the current investigation. Most pharmacological methods are based on A.F.I., I. & II in this research. As you can see, the samples came from a variety of sources. Sodhana and other pharmaceutical processes were used to process these samples. Sodhana of crude pharmaceuticals and Marana of sodhita (purified) samples make up the bulk of the pharmaceutical procedure for the selected-crude drug Kampillaka.

Keywords - Crude drugs, Kampillaka, Standardization

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1. INTRODUCTION

It is challenging to standardise crude medications since so many variables impact their quality and purity. Many Ayurvedic medication manufacturing businesses now employ standardisation procedures that fall short of creating a unique standardisation system for crude pharmaceuticals. It is significantly more important to have a working knowledge of crude pharmaceuticals than any other standardisation method. Drug collectors and personnel having a lengthy history of working with crude pharmaceuticals are extensively relied upon by most Ayurvedic pharmaceutical manufacturing firms that produce conventional goods. As a result of their extensive knowledge in the industry, several drug manufacturing enterprises can verify the quality of crude pharmaceuticals for specific people or businesses. This, however, does not provide a full picture of the quality and purity of the medicine (1).

Almost all Ayurvedic medications are composed of a variety of raw substances. Because they are natural products, drugs include a wide range of chemical components in various amounts. Consequently, we have no idea how these chemical components of a complex medicine formulation will interrelate with one another. Checking for a particular component in the final product is practically difficult, as stated above. Although a medicine combination's therapeutic impact isn't always specific, it may be helpful. It is because of this that a drug's therapeutic impact is not confined to a certain group, since the total of its effects is the product of the rational combination (2-4).

In-depth research on the number of pharmaceuticals and the criteria needed, in addition to the amount of time and effort needed in the field. In Ayurvedic formulations, for example, there are roughly 500 unique medications of natural origin. The research only included a few different medicines.

The effectiveness of a medication combination is determined by its purity, chemical composition, potency, absorption rate, metabolic transformation, and excretion. In order to retain purity, increase potency, and facilitate the metabolic transformation and excretion of varied doses, several pre and therapeutic processing methods are recommended (5-7).

Vata, pitta, and kapha are the triidosas from which the body is produced, and Ayurveda aims to bring them into harmony. To sustain regular bodily functions, tridosas are needed.

2. REVIEW OF LITERATURE

Siddiqui, M. R., et al., (2017) Human health was revolutionised by the introduction of drugs. In order to be effective, these medications must be free of contaminants and supplied in the correct dosage. Various chemical and instrumental procedures involved in drug assessment have been created on

a regular basis to make medications fulfil their purpose. In order to ensure that these medications are safe to use, they must be tested for contaminants at several points in their production and distribution. Analytical equipment and procedures play a significant influence in this. Analysis instruments and methodologies play a critical role in determining the quality of pharmaceutical products. As a result of this study, a wide range of analytical techniques and procedures for the examination of pharmaceuticals are discussed, such as titrimetric analysis as well as chromatographic, spectroscopic, electrophoretic, and electrochemical methods (10).

Ahmed, S., &Hasan, M. M. (2015) Code of behaviour and need dictate that crude medications be standardised. In today's world, substitution and adulteration are so commonplace that the worldwide crude drug industry is no longer safe for the millions of people who rely on it. There are several elements that impact the bio-efficacy and repeatability of therapeutic effects, making the assessment of crude drugs difficult. The wide range of standardisation ensures the intended therapeutic benefits are achieved by using the proper material in the precise dosage. It also outlines all of the precautions that have been followed throughout the process of collecting, producing, and distributing the medicine for clinical use. For crude medication standardisation, writers have attempted to cover specific instruments in a recent review (11).

Gupta et al. (2014) publications data was used to identify the most productive pharmaceutical companies in India. The study found that research institutions, INIs (Institutes of National Importance), and universities' approach of financing for research is superior in terms of both quantity and quality. Pharmacy schools and colleges, engineering colleges, medical colleges, and industrial businesses tend to have poorer models of finance than other types of educational institutions. Indian pharmaceutical research has to be monitored, coordinated, and managed by an adequate institutional system. Setting up research facilities that are shared by scientists and teachers from different organisations, allocating funds for priority national research and promoting creativity among young scholars, and determining the critical support needed for setting up specialised research facilities should be addressed appropriately (12).

3. METHODOLOGY

3.1 Field study

As part of the study, the Kampillaka survey is critical.

Sample collection: The following three Kampillaka samples were collected for scientific study.

Sample – I

Kampillaka has a reddish hue. Some of the particles are grey in hue. It was purchased at a Maharashtrian raw medicine shop.

Sample – 2

As the name suggests, kampillaka is a reddish-brown powder with flecks of grey. In Maharashtra, I bought it from a Raw pharmacy.

Sample – 3

*Kampillaka*is a reddish-orange fruit with a small, delicate flavour. At many locations, including Devi Ram Sagar, BhattaBondia and KichhaUdam Singh Nagar, it was collected.

3.2 Pharmaceutical study

Ayurvedic pharmaceutics places a premium on the purity of the raw ingredients used in the formulation of the final product.

The ancient Ayurvedic scholars recognised the general toxicity of mineral, animal, and plant objects while supporting their usage for medical reasons. People have not suggested taking these drugs in their natural form internally. They are also very toxic and difficult to absorb in their raw state, which makes them dangerous. Micronized lower dosages of these drugs can only be absorbed by live organisms and have therapeutic effects. According to our old Ayurvedic Scholars, there are particular techniques that may help remove impurities and toxins from raw materials and change them into pharmaceutical form, such as sodhana or marana. Pharmacological protocols for sodhana and marana of different drugs were described in Ayurvedic classics.

These days, finding and evaluating the quality of diverse crude medicines has become an increasingly difficult problem for Ayurvedic drug manufacturers. When crude pharmaceuticals are utilised in the production of medicines, their importance is emphasised even more. It is possible to see changes in various pharmaceutical samples during the course of the manufacturing process.

SodhanaSamskara and other techniques will be used to identify the optimal grade of crude drugs, i.e. by documenting different findings for each sample.

3.3 Materials and methods

The drugs, references, prior experiences, and expert assessments all influence the materials used, the processes followed, and the modifications performed.

A.F.I., I., and II.are the primary pharmacological mechanisms used in this study.

All of the samples were taken from different sources. Sodhana and other pharmaceutical techniques were used to process these samples.

It is possible to divide the drug production process for the crude medicines under consideration into the two parts outlined below:

1. Sodhana of crude drugs.

2. Marana of sodhita (purified) samples.

3.4 Sodhana of kampillaka

Kampillaka Samples: There were three samples of Kampillaka acquired for the study, two from the market and one from a source.

Sodhana Process

Ingredients and equipments required:

(1) Kampillaka – Sample - 1, Sample - 2, Sample - 3,500 gm. of each.

(2) Water – Q.S.

(3) Containers – 3

(4) Cloth – 3 Pieces

(5) KhalvaYantra – 3

Table 1: Kampillaka Samples

(6) Nimburasa – q.s.

(7) Ardraka Rasa – q.s.

Procedure: 500 grammes of Kampillaka (Sample-1) are combined with water in a container and well mixed by hand. Afterwards, the contents are left alone for around 15 minutes to cool down. Genuine Kampillaka floats on top of the water, whilst the alien stuff sinks to the bottom owing to its little weight. The Kampillaka that floats to the surface is then scooped up, filtered, and dried. In addition to Nimburasa, Ardrak Rasa, and bhavana, which is supplied daily for one prahara, bhavana is also offered for three days each with each drava (total six days). Once Kampillaka is collected, it is preserved in a safe place. Both Samples 2 and 3 [97,23] follow the same procedure.

4. PHYSICO-CHEMICAL ANALYTICAL STUDY

Studying raw medicines and purified samples, as well as bhasma's from various markets and obtained samples is the goal of this study in the field of physics, chemistry, and analytical methods.

The end objective of this study is to create crude medications of greater quality. Market and sample analysis, both qualitative and quantitative, are the foundations of modern research.

In order to identify various crude pharmaceuticals for quality control, it is necessary to use the following two components:

1. Ayurvedic quality evaluation based on Ayurvedic characteristics.

2. Evaluation of quality using contemporary quality control measures.

Ayurvedic-approved kampillaka characteristics have been investigated. A Standard Monograph is required to investigate and assess the quality of these unprocessed medications. There has been an effort to create a standard monograph for the three drugs mentioned. This might make it simpler to identify foreign substances and substitutes, as well as possible ways of adulteration.

Geological Survey of India, Parshva Chemicals, Institute of Chemical Technology, Mumbai, Maharashtra, and VJTI Chemistry Lab and Department, all in Mumbai, Maharashtra, undertook the current analytical investigation.

4.1 Materials and methods

Samples of rock or mineral are crushed into very thin chips and then mounted on a glass plate using canadabalsam before being covered in a transparent layer of coating.

Afterwards, the slide is studied using a petrological microscope. Color, shape, and location of mineral grains are used to identify minerals, and these characteristics are also used to define how the rock looks. Names are given to rocks depending on their mineral composition and origin.

Determination of Foreign Matter

A thin coating of the chemical to be tested was spread over a contrasting backdrop, weighing between 100 and 500 grammes. The foreign material was discovered during a visual examination without the use of a hand lens or magnifying glass (6x). The foreign material was isolated and weighed. Foreign matter was determined by calculating the percentage.

Determination of Total Ash

An properly weighed powdered medicine was burned at 450°C 5oC in a tared platinum or silica crucible until it was clean of all organic matter, then cooled down and weighed. As a standard, the air-dried drug is used to calculate the ash content.

Determination of Acid - Insoluble Ash

Ashes should be heated for 5 minutes in 25 mL of weak hydrochloric acid, then collected and washed with hot water before being ignited until the weight is constant; ashless filter paper should be used. Air-dried medicine may be used to measure the acid-insoluble content.

Determination of Water-Soluble Ash

For 15 minutes at 450°C, ignite the weighted ash in 25 mL of hot water after it has been boiled for 5 minutes. The insoluble material may be collected in a Gooch crucible or an ashless filter paper and washed with hot water. To determine the amount of water-soluble ash, subtract the weight of the insoluble material from the weight of the ash. Using the air-dried drug as a guide, figure out what percentage of the medication is water-soluble ash.

Determination of Water - Soluble Extractive

Macerate for twenty-four hours in a closed flask 5g of coarsely powdered air dried medicine in 100m1 chloroform water, stirring every six hours for the first six hours and letting to stand for eighteen hours for the first 18. Immediately remove the solvent by fast filtering, evaporate 25m1 of the filtrate to dryness, and dry at 105° to a constant weight in a flat bottomed shallow dish, and weigh. Calculate the proportion of water-soluble extractive using the air-dried medicine as a guide.

Determination of Moisture Content (Loss on Drying)

Place 10 grammes of crude medication, accurately weighed, in a tared evaporating plate (without first drying it). Dry for 5 hours at 10.5oC after adding the above-mentioned amount of medication to the tared evaporating dish, and then weigh. Weigh every hour or so until the difference between two consecutive readings is less than 0.25 percent. In a desiccator, the weight is considered to be constant if it fluctuates by no more than 0.012 after drying for 30 minutes and chilling for 30 minutes.

Limit Test for Iron

Dissolve 0.01726gm of Ferric Ammonium Sulphate in 10ml (0.1 N) of sulfuric acid to create 1000ml of standard solution. Fe concentration is 0.02 g/mL in this solution.

Method

Transfer 10 ml of the solution to a Nessler cylinder, or dissolve the necessary quantity of the sample in 40 nil of water. Using an iron-free ammonia solution, dilute 2 mL of an iron-free Citric acid solution with 0.1 mL of Thioglycollic acid to 50 mL and leave aside for 5 minutes. The new colour isn't much brighter than the original.

Standard colour: Dilute 2 mL of standard iron solution with 40 mL of water in a Nessler cylinder. 2 ml iron-free citric acid (20% w/v) and 0.1 m1 thioglycollic acid are combined in a 50 m1 water solution, which is then alkalized with an iron-free ammonia solution and allowed to stand for five minutes before being diluted again.

Determination of pH Values

Testing the pH was done using a pH metre that had a glass electrode sensitive to hydrogenation and a calomel reference electrode. The test is carried out at a temperature of 25.2°C.

Method

Immerse the electrodes in the test solution and take a pH reading at the same temperature as the standard solutions [109].

Partial analysis of Calcium Carbonate

Varatika shell samples were pulverised to a mesh size of (-80). The carbonate content of the powdered samples was determined using a traditional wet chemical quantitative technique.

Calcium Estimation: In around 150 ml of water, dissolve a reasonable amount of calcium salt (about 0.05gm Ca). 4 mL 8 N potassium hydroxides, 0.2 gramme Patton and Reeder's indicator (containing ascorbic acid). Titrate to a pure blue end-point with 0.05 M. EDTA.

Table 2: Physico-Chemical Characters of different Kampillaka (Crude form) Samples

S. No.	Name of the test	Sample No.1	Sample No.2	Sample No.3
01.	Colour	Red (Some Grey Colour Particles)	Red (Some Grey Colour Particles)	Red
02.	Appearance	Powder	Powder	Powder
03.	Rubbing Over White Paper	Yellow Colour Mark	Yellow Colour Mark	Yellow Colour Mark
04.	Moisture content	2.42% w/w	2.76% w/w	2.30% w/w
05.	Total Ash	33.88% w/w	23.61% w/w	6.49% w/w
06.	Water soluble extractive	3.18% w/w	3.83% w/w	2.83% w/w
07.	Dilute Acid soluble extractive	7.55% w/w	8.11%.w/w	7.055% w/w
08.	Identification of Iron	+Ve	+Ve	– Ve
09.	Foreign Matter	3.02% w/w	1.98% w/w	1.49% w/w
10.	Acid Insoluble Matter	92.45% w/w	91.89% w/w	92.95% w/w

Table 3: Physico-Chemical Characters of different SuddhaKampillaka Samples

S. No.	Name of the test	Sample No.1	Sample No.2	Sample No.3
01.	Colour	Dark Red	Redish Grey	Red
02.	Appearance	Powder form	Powder form	Powder form
03.	Moisture Content	8.048% w/w	12.79% w/w	4.72% w/w
04.	Total Ash	14.13%	22.07%	6.87%
		w/w	w/w	w/w
05.	Water Soluble Extractive	16.34% w/w	3.99% w/w	4.1% w/w
06.	Dilute Acid Soluble	17.33% w/w	9.91% w/w	10.20% w/w
07.	Foreign Matter	0.035% w/w	3.52% w/w	1.99% w/w
08.	Acid Insoluble Matter	82.67% w/w	90.09% w/w	89.80% w/w

5. CONCLUSION

Numerous ways for authenticating raw pharmaceuticals have been discussed in this article. Organoleptic properties can be used to authenticate certain medications, although the presence of adulterants and similarity in the chemical ingredients may need more advanced methods. It is also essential to use the most up-to-date and proven approaches while doing research using chemical methods and other analytical equipment. Before beginning any evaluation, it is critical to identify the sort of raw material or composition being examined. The microbiological contamination, pesticide residue, and heavy metal analyses should still be evaluated before the raw material is processed for medication manufacture, notwithstanding all of these considerations. This is a question about medication safety. Botanicals need to be authenticated using this sort of examination since the presence of extraneous pollutants might have detrimental physiological consequences. To sum up, more fundamental research should be conducted, and more people should be taught in these authentication approaches in order to overcome this problem that is prevalent in crude medications.

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Table 1: Kampillaka Samples

No. of the Sample	For Making Cakrika - Dravadravya Used	Desired Temp. in O°C	Time to reach the desired temp.	Duration of Maintenance of desired temp.	Observations 1st After Puta	Observations 2nd After Puta	Observations 3rd After Puta	Wt. Loss in %	Possible Reason for the Loss	Precautions
01.	Ghrtakumari	700°C	3Hr.	1 Hr.	Varatika is found brittle and gray in colour. Wt. before puta. 200 gms. Wt. after puta.148 gms.	Powder is slightly white colour wt. after 2nd pup 127 gms.	Powder is white colour, somewhat fine particles wt. after 3rdputa 120 gms.	40%	Loss is due to burning of organic substances during incineration process	The sealed crucibl should be dried properly.
02.	Ghrtakumari	700°C	3Hr.	1 Hr.	Varatika is found little hard and slightly white in colour wt. before puta 160 gms. Wt. after puta 150 gms.	Powder is white colour and fine wt. after 2ndpula 142 gms.	Powder obtained is having bhasmalakshna wt. after 3rdputa 138 gms	31%		The cakrikas also should be dried properly.

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03.	Ghrtakumari	700°C	3Hr.	1 Hr.	Varatika is found very hard & greyish black in colour. Wt. before puta. 200 gms. Wt. after puta. 140 gms.	Powder is whitish black wt. after 2nd puta 120 gms.	Powder is slightly greyish white colour wt. after 3rd p up 112 gms.	44%		The temp. should be raised gradually

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