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A Study on Standardization and Parameters for Standardization of Crude Drugs

Deepa Rangari[1]*, Dr. Naveen kumar Singhal[2]

[1] Research Scholar, Shyam University Dausa Rajasthan

[2] Supervisor's Department of Pharmacy, Shyam University Dausa Rajasthan

Abstract - Raw pharmaceuticals are any naturally occurring, unprocessed material produced from organic or inorganic sources such as plant products, animal products and microbes for use in human or other animal diagnosis, treatment, mitigation or prevention of sickness. Research in pharmacognosy relies heavily on the discovery of crude drugs utilising their organoleptic characteristics. In light of this, the present study focuses on Crude Drug Standardization and Standardization Parameters in light of this fact.

Keywords - Crude drug, Standardization, Parameters

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1. INTRODUCTION

Crude medications are natural chemicals that have simply been gathered and dried from plants or animals. The phrase "natural substances" refers to substances that have not been tampered with by humans. For example, Senna and Cinchona are used both internally and topically to cure sickness in people and animals.

[1–2] To assess the quality of medicines, the amount of the active principle as well as physical, chemical, physcio-chemical standardisation of herbal formulations must be standardised. For the vast majority of our medicines, we've used natural components. Infinitely complex and unusual chemical compounds may be synthesised, which would otherwise be beyond human comprehension. Pharmaceutical quality and standardisation are necessary for phytopharmaceutical use to be accepted as a legitimate alternative medicine. A combination of quantitative and qualitative methods is recommended by WHO for sample classification, biomarker or chemical indicator measurement, and fingerprint profiling. If the principal active element of a compound can be identified, it makes sense to quantify the compound. It is important to standardise compounds in botanical preparations that are known to have therapeutic benefits; when the active components of botanical plants are unknown, a unique marker material is utilised for analysis [2, 3].

2. METHODS OF STANDARDIZATION

Pharmaceuticals derived from plants are often available as liquids, powders, or aqueous solutions. It is possible to make them, for example, by macerating or distilling (volatile oils). Fluid extracts may be made using ethanol, water, or a combination of ethanol and water. Several phytotherapeutic compounds are heavily concentrated in order to improve their medicinal efficacy.

Herbal medicines are tested using pharmacopoeias to ensure their purity and identification. The Pharmacopoeia sets standards for the analytical, physical, and structural properties of herbal medicines. A list of important criteria is included in the pharmacopoeia shown in Fig. 1. Crude medicines must be identified and tested in herbal formulation processes due to their greater variety and changes in their chemical makeup or qualities.

Figure 1: Schematic for the Standardization and Evaluation of Herbal Drugs

In terms of herbal medicines' stability, these elements are: When determining the physical properties of a substance such as colour, odour, viscosity, pH, disintegration time, fractility and hardness, flowability and flocculation, sedimentation, and settling rate, it is important to take into account the following [4] Chromatography may be used to analyse herbals in a variety of ways.

3. PHYSICAL EVALUATION

Additionally, each book provides macroscopic descriptions as well as detailed drawings and pictures that provide visual evidence of accurately classified material. As a preliminary step in screening for impurities, a microscopic inspection verifies the material's legitimacy.

3.1 Determination of ash

Ash in three forms: acid-insoluble ashes, water-soluble ashes, and the total of these three are used to determine how much ash remains after medicinal plant components have been burnt. In the aftermath of a fire, there are a variety of ways to determine how much material is left in the charred item. Non-physiological ash is the residue of foreign chemicals adhered to the plant's surface as well as "physiological" ash, which is produced from the plant tissue itself.

3.2 Determination of Foreign Matter

One way of determining if medicinal plant components have produced any ash is to burn them, and two other ways are to use acids and water to dissolve the acid. The total ash technique is used to determine how much material is left behind after it has been burnt. Physiological ash as well as the residue of foreign substances adhering to the plant's surface are included in this category. Insoluble acid-insoluble ash is the residue that remains after the insoluble material is burned and the acid-insoluble ash is boiled with weak hydrochloric acid. Sand and siliceous soil are examples of materials that may be tested for silica content using this approach. When total ash and residue are handled with water, the weight difference between the two is known as water soluble ash [5].

3.3 Chemical Evaluation

The specific chemical components of the majority of drugs dictate their pharmacological and biological effects. Quality and purity of a drug are assessed using a qualitative chemical test. Active chemical compounds are identified, isolated, and purified using chemical procedures of evaluation. Preliminary phytochemical analysis is typically part of a chemical investigation. There are two qualitative chemical assays for assessing crude drugs: the saponification and acid values [6].

3.4 Chromatographic Fingerprinting and Marker Compound Analysis

In order to adequately depict the HM under investigation, the chromatographic profile relies on "sameness" and "differences," or "integrity" and "fuzziness.". Chromatographic fingerprints can be used to authenticate or identify herbal medicines even if different samples of the same HM contain different amounts or concentrations of chemically characteristic components, or that chromatographic fingerprints can demonstrate both the "similarity" and "difference" between various samples of this HM [7].

a) Thin Layer Chromatography (TLC)

In addition to being simple to use, TLC may be utilised for the analysis of a wide range of samples.

Up to 30 samples may be analysed at the same time on a single plate. In the end, the benefits of TLC for the identification of herbal drugs are their adaptability, high rate of analysis and sensitivity, and cheap cost [8].

b) High Performance Liquid Chromatography (HPLC)

An advantage of HPLC is that it is simple to learn and does not rely on the volatility or stability of the sample component to perform its analysis.

c) Gas Chromatography (GC)

There is an excellent fingerprint in the volatile oil's GC, which may be utilised to identify the plant. Extracting volatile oil is simple and conventional, and GC-MS analysis helps to determine its contents. The exceptional sensitivity of GC to

almost all volatile chemical substances is one of its main features.

d) Capillary Electrophoresis (CE)

A sample's purity or complexity may be documented using CE, which can handle almost any link in a charged sample chain. With CE, the active components in herbal remedies may be isolated and analysed.

3.5 Biological evaluation / Biological assays

Pharmacological activity has been used to evaluate and standardise crude medications. Live animals and their entire or isolated organs may be used in research to assess the strength of a drug or its preparation. A number of medicines have specific biological and pharmacological features that might be utilised to evaluate their effectiveness. The plant extract contains an active component that is responsible for this activity. In order to get data, researchers used both whole animals and separated organs. To determine the potency of a pharmaceutical, bioassays may also be utilised throughout the manufacturing process [9].

3.6 Hemolytic activity

Plant materials or saponin-containing preparations may be tested for hemolytic activity by comparing them to saponin, which is a standard hemolytic test material.

3.7 Antibiotic activity

Using Klebsiellapneumoniae and other bacteria, it is also evaluated for antibiotic activity. In order to test particular vitamins, we employ live bacteria, yeast, and moulds. Samples are evaluated using cylinder plate and turbidimetric microbiological assays [10].

3.8 Antifertility activity

Antifertility drugs include, but are not limited to, contraceptives and abortifacients. Abortion pills are used to terminate a pregnancy, whereas contraceptives are meant to prevent it. Herbal drug antispermatogenic and spermicidal action is measured in male rats, whereas antifertility activity, i.e. pregnancy rate, is measured in female rats (anti ovulation and anti-implantation).

3.9 Hypoglycemic activity

An animal model is used to assess the hypoglycemic effects of plant extracts.

4. AUTHENTICATION OF MINERALS

Medicinal uses for minerals and herbals go hand in hand. After being treated with herbal juices, they are calcified or oxided and provided as drugs. Since they are so important, figuring out what they are is just as important as knowing what they are**.**

1. Physicalproperties

Nature, streak, colour, transparency, tenacity and hardness are only few of the physical characteristics that distinguish minerals from one other. The unique physical characteristics of minerals may be used to confirm their validity.

2. Opticalproperties

Polarized light may be rotated in a plane by optically active substances (optical rotation). Measurement of optical rotation is done using a sodium lamp at 25°C. Levorotatory and dexterorotatory optical rotations are the two types of optical rotations (-ve). Certain conditions must be met before this may be determined with a polarising microscope. In order to distinguish between crystalline and transparent materials, optical crystallography is used [11].

5. AUTHENTICATION OF MARINE AND ANIMAL PRODUCTS

1. Chromatographicmethods

a. Gas Chromatography /Mass Spectrometry (GCMS)

GC-MS is a versatile approach for detecting volatile chemicals that combines two analytical processes. The total mass chromatogram (TMC) is the most frequent form of TIC plot, however there are others [12].

b. Liquid Chromatography-Mass Spectrometry (LCMS)

The excellent sensitivity and specificity of LC-MS technology may be useful in a wide range of applications. In most cases, it is used to detect and perhaps identify compounds in the presence of other substances. It is possible to create spectral fingerprints for raw materials like honey and animal fats using this method.

6. STANDARDIZATION FOR CRUDE DRUGS

The standardisation of crude medicines is a tough endeavour because of the many factors that affect the quality and purity of crude pharmaceuticals. An Ayurvedic medicine manufacturing company's standardising techniques are not enough to build a unique standardisation system for crude pharmaceuticals. No other kind of standardisation technique compares to the benefit of firsthand experience with crude medications. Conventional

Ayurvedic drug development relies greatly on the experience of drug collectors and personnel who have worked with crude medicines for a long period of time. In addition, because of their extensive experience in the industry, pharmaceutical businesses can vouch for the purity and potency of the raw materials they use. The quality and purity of a medication cannot be determined solely by this method [13].

There is no other criteria for assuring quality and purity in this people's historical experience than the organoleptic character of crude drugs. For a raw medicine to be effective, it must have active components in sufficient quantity. Crude drug active components are influenced by a mix of environmental and ecological factors. A crude drug's grade and purity can only be determined by conducting an organoleptic evaluation if these features are given the highest importance.

It's not uncommon for the majority of Ayurvedic remedies to have a number of distinct active ingredients. It's impossible to predict the interaction between various chemical components in a drug formulation, and finding out whether a certain component is in the final product is almost impossible. The therapeutic effects of a drug combination are not always specific, but they may also be supportive. There is thus no restriction on who a medicine can help since the effect formed is a total of effects from several formulations due to logical mixing.

To retain the therapeutic efficacy of a formulation, the quality and purity of the components must be maintained. Because of this, standardising medicine begins with the selection of fundamental drugs. There should be a record of every Ayurvedic Pharmaceutical company's collection of standardised raw medicines in order to build an effective standardising system. To assure the quality and purity of crude digs purchased, samples from the market are compared to an industry-maintained reference sample collection.

Ayurveda has been trying for years to create criteria for the quality control of crude remedies, but nothing has come of it. Changes have been made to the law since then, the most recent in 1982, making it unlawful to manufacture or distribute medications that are labelled incorrectly or that include bogus or tainted ingredients. Examples from Ayurveda were used, but as quality control processes are problematic in all three systems, what was said about Ayurvedic pharmaceuticals may equally be applied to Sidha and Unanimedicines[14].

7. SELECTION OF PARAMETERS

Scientific criteria for crude medicines have become imperative. Industry ethics have been disregarded and fake items have been promoted. Making Ayurvedic treatments is becoming a lucrative business for enterprising herbalists like a 'true' or 'currept' enterprising herbalist. For crude drugs, interpreting scientific standards is a pressing need at this time.

To be clear, any crude ingredient may be used in the production of medicines, but the resulting pharmaceutical's quality and efficacy will surely vary. As a consequence, it is vital to detect the unprocessed drugs.

The following causes need raw material or crude medicament standardisation in Ayurveda.

(a) To see whether there has been any adulteration.

(b) To locate the phoney items.

(c) To increase the quality of pharmaceuticals.

(d) To preserve consistency in the goods of various manufacturers.

(e) Establishing standards for various mineral, animal, and plant items.

(f) To indicate their distinguishing characteristics.

In this thesis, the general explanation of the selected crude drugs, findings, and other details will be given.

Many efforts have been made to set standards in this area, but there is still much more work yet to be done. There are several elements to take into account while dealing with crude medications.

(a) Identification of crude medicines.

(b) Availability

(c) The current state of the market for certain crude medications.

(d) Procurement.

(e) Varieties.

(f) Manufacturing Process (Sodhana etc.)

(g) The contents or components included inside it.

(h) Its pharmacological effects on the human body.

(i) Adulterates and substitutes for certain crude medications.

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8. CONCLUSION

As a result, India has the potential to become a prominent participant in the manufacturing of standardised, medically effective Ayurvedic medications. Medicinal plants should be studied in India. As long as standardised methods like UV-visible, TLC, HPLC, HPTLC and GC-MS are used to inspect and study the crude pharmaceutical, this may be achieved.

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Corresponding Author

Deepa Rangari*

Research Scholar, Shyam University Dausa Rajasthan