Int J Ayu Pharm Chem
ISSN 2350-0204
www.ijapc.com

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Modern Analytical Techniques in the Standardization and Quality Parameters of AYUSH/Herbal Products

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ABSTRACT

There has been escalating wakefulness and universal adequacy of the utilization of ayurvedic medicines in today's medical and alternative profession. Renaissance of public awareness in traditional medicine is escalating in all the countries. This augmentation in the use of ayurvedic drugs has also given rise to a variety of abuse and adulteration of the ayurvedic drugs important to consumers and manufacturers leading to the lethal penalty. Quality evaluation of ayurvedic drugs is a significant tool in the preparation of high quality AYUSH/Herbal drugs. The present work seeks to enlighten the stakeholders in AYUSH products on necessitate to ascertain the quality consideration with the help of higher analytical tools and well defined standardization methods. In this article a study has been made to fix the parameters including Macroscopic analysis, Microscopic analysis, Quantitative analysis, Qualitative analysis, Limit Tests, Microbial Limit Tests, Pesticide Residue, Test for Aflatoxins etc and Biological evaluation (Pharmacological evaluation, Toxicological studies in order to ensure the use of only genuine ayurvedic remedies. The obtained values/ranges can be used as standards for quality control of the AYUSH/Herbal products.

Key Words AYUSH/*Herbal products, Standardization, Analytical techniques*

Received 09th April 23 Accepted 31st May 23 Published 10th July 2023

INTRODUCTION

Standardization of different herbal formulation is essential in order to check the quality of any drugs, based on the pharmacognositical evaluation (Macroscopic analysis, Microscopic analysis, Quantitative analysis, Qualitative analysis, Limit Tests, Microbial Limit Tests, Pesticide Residue, Test for Aflatoxins etc.), Biological evaluation (Pharmacological evaluation, Toxicological studies).[1] There has been escalating wakefulness and universal adequacy of the utilization of AYUSH products in today's medical and alternative profession. Renaissance of public awareness in herbal products is escalating in both the developing and developed countries. This augmentation in the use of AYUSH products has also given rise to a variety of abuse and adulteration of the herbal

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products important to consumers and manufacturers leading to the lethal penalty. Objective of this article is to enlighten the stakeholders in AYUSH/Herbal products on necessitate to ascertain the quality consideration with the help of modern analytical tools and well defined standardization parameters.

Methodology/ Observations: The processes of quality assurance and standardization of AYUSH products is assured by using Macroscopy, Microscopy, Chromatography, Spectroscopy, Electrophoresis and other analytical parameters.[2] Therefore standardization of AYUSH/Herbal remedies can be ensured by using these various analytical techniques.[3]

Standardization of AYUSH/Herbal remedies by using various quality parameters of ayush/herbal products:[4, 5, 6, 7]

- **Macroscopic Examination (Organoleptic)**
- **Microscopic Examination**
- **Determination of Quantitative data**
  - Determination of foreign matter
  - Determination of Moisture Content (Loss on Drying)
  - Determination of Ash value
  - Determination of Extractive value
  - Thin- Layer Chromatography (TLC)
- **Determination of Heavy Metals by Atomic Absorption Spectorphotometry**
- **Determination of Microbial contaminents and test for Aflatoxin**
- **Biological evaluation**

Macroscopic Examination-

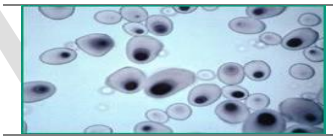
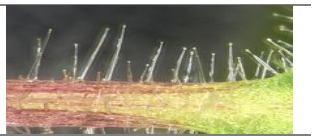
- shape, size, colour, surface characteristics, texture, and appearance
- Observing it with a naked eye or with the aid of a magnifying lens.



Cinnamon **Saffron** **Nux vomica**

Microscopic examination-[8, 9, 10, 11, 12]

- Depend on the nature of the material i.e., entire, cut or powdered.
- Transverse and longitudinal sections are made (Leave, stem, bark, root) and powdered drugs samples are cleared by clearing agents, mostly chloral-hydrate solution, before mounting on the slide.
- It includes study of stomata number, index, vein islet number, types of trichomes, starch grains, calcium oxalate crystals.

Starch grains Trichomes of Nux vomic

Determination of Quantitative data-

Determination of foreign matter-

The drugs should be free from mould and other foreign matters.

Determination: Weigh 100–500g of the drug sample and spread it out in a thin layer. Inspection with the unaided eye or by the use of a lens (6x). Separate and weigh it and calculate the percentage present.

Determination of Moisture Content-

Determination: Place about 10 g of powdered drug in a tared evaporating dish. Dry at 105º F

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for 5 hours, and weigh. Continue the drying and weighing at one hour interval until difference between two successive weightings. Constant weight is reached when two consecutive weighings after drying for 30 minutes and cooling for 30 minutes in a desiccator, show not more than 0.01 g difference.

Determination of Ash value-

Total Ash

Weigh the empty crucible and then after adding 2 to 3 g of drug, incinerate it. Temperature set at 450º for 4 hrs. After self-cooling, calculate the percentage of ash

Acid insoluble ash

Boil the ash obtained in total ash for 5 minutes with 25 ml of dilute hydrochloric acid. Collect the insoluble matter through an ash less filter paper and then placed in a crucible and incinerate it. After self-cooling, calculate the percentage of acid-insoluble ash.

Water insoluble ash

Boil the ash obtained in total ash for 5 minutes with 25 ml of water. Collect the insoluble matter through an ash less filter paper and then placed in a crucible and incinerate it. After self cooling, calculate the percentage of water-insoluble ash.

Determination of Extractive value-

For Determination of Alcohol Soluble Extractive

At first macerate 5 g of the coarsely powdered drug with 100 ml of Alcohol in a closed flask for 24 hours, shaking frequently during 6 hours and allowing to stand for 18 hours. Then filter it and 25 ml of the filtrate taken in a tared flat bottomed shallow dish, and dry at 105º, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

For Determination of Water-Soluble Extractive

At first macerate 5 g of the coarsely powdered drug with 100 ml of water in a closed flask for 24 hours, shaking frequently during 6 hours and allowing to stand for 18 hours. Then filter it and 25 ml of the filtrate taken in a tared flat bottomed shallow dish, and dry at 105º, to constant weight and weigh. Calculate the percentage of water-soluble extractive.

Chromatography Techniques-

Thin Layer Chromatography

Prepare the silica gel plate and Circular spotting was done of solvent on plate then allow to stand at room temp. Visualization of spots (bands) under UV light 254 nm and 365 nm. Measure and record the distance of each spot from the point of its application and calculate the R_f. value by dividing the distance travelled by the spots by the distance travelled by the front of the mobile phase.

Gas Chromatography[13-14]

The apparatus consists of an injector, a chromatographic column contained in an oven. Gas flows through the column at a controll10ed rate or pressure and then through the detector. Equilibrate the column, the injector and the detector at the temperatures and the gas flows until a stable baseline is achieved. Prepare the test solution (s) and the reference solutions (s). Criteria for assessing the suitability of the system on Chromatographic separation techniques.

High Performance Liquid Chromatography

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High performance liquid chromatography (HPLC) is a method of chromatographic separation in which the mobile phase is pumped into a column containing stationary phase by a high-pressure pump system. The test solution injected is carried into the column by the mobile phase. All the components are separated in the column and pass through the detector sequentially. The recorder, integrator or data acquisition system thus records the chromatographic signals

Determination of Heavy Metals-

Take 5gm of drug powder [dried at 150℃]. Incinerate the drug. To the ash add con. H_2SO_4. Incinerate at 6oo℃ for 2-3 hour ash obtained. Dissolve the ash in 100 ml of 5% HCL subjected to atomic absorption spectroscopy.

Determination of microbial contaminants and aflatoxin-

Microbial contamination –

- Test for E.coli
- Test for Salmonella
- Test for pseudomonas
- Test for staphylococcus aureus

Aflatoxin -

- Extract of drug with methylene chloride is evaporated
- Residue is taken in column
- MP is chloroform : Acetone
- Elite of column is subjected to evaporation and TLC is performed
- Mobile phase – Chloroform: Acetone: Isopropanol
- Detector: UV

Biological Evaluation- [15, 16, 17]

- Some drugs have specific biological and pharmacological activity which is utilized for their evaluation.
- Actually this activity is due to specific type of constituents present in the plant extract.
- For evaluation the experiments were carried out on both intact and isolation organs of living animals.
- With the help of bioassays, strength of drug in its preparation can be evaluated.

RESULTS AND DISCUSSION

The research arena of quality control of AYUSH/Herbal products is truly an interdisciplinary research. It requires crossover of chemistry, Physics, Ayurvedic Pharmacology-pharmaceutics and even statistics to provide a platform for the quality evaluation of AYUSH products and further to find out the novel remedies composed of multiple Physico-chemical compounds. By using these various analytical parameters, the obtained values/ranges can be used as standards for quality control of the AYUSH/Herbal products.

CONCLUSION

The quantitative determination of constituents has been made easy by recent developments in analytical instruments. The results from these sophisticated techniques provide the nature of chemicals or impurities present in herbal drugs.

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