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ANALYTICAL PROFILING OF KUPIPAKVA RASAYANA – A REVIEW

Radhakrishna Reddy D[1], Surekha Medikeri[2]

[1]Ph.D. Scholar, Dept of PG and Ph.D. studies in Rasashastra & Bhaishajya Kalpana, Govt. Ayurvedic Medical College and Hospital, Dhanvantari Road, Bengaluru, Karnataka, India and
Assistant Professor, Dept of Rasashastra & Bhaishajya Kalpana, SJG Ayurvedic Medical College and Hospital, Gavimath campus, Koppal, Karnataka, India
[2]Principal, Professor & HOD
Dept of PG and PhD studies in Rasashastra & Bhaishajya Kalpana, Govt. Ayurvedic Medical College and Hospital, Dhanvantari Road, Bengaluru, Karnataka, India

Corresponding Author: drrkreddy19@gmail.com

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ABSTRACT

Introduction: Though the Ayurvedic formulations are time tested for their promising and reliable therapeutic efficacy, there is a need for standardisation of the same in the current era to meet the global standards followed by global acceptance. A formulation must pass all the analytical tests before it enters the market, regardless of the system of medicine and dosage form, for the safe use of the drug. Analytical profiling in *Kupipakva Rasayana* (herbo-mineral preparations cooked in glass flasks under controlled heat) is essential for ensuring the safety, efficacy, and quality of these potent formulations used in Ayurveda, particularly *Rasashastra*. The complex processes and materials involved in *Kupipakva Rasayana* require a robust analytical assessment to validate their therapeutic use. **Aim and Objectives:** The study's main aim is to emphasise the importance of Analytical profiling in *Kupipakva Rasayana*. **Materials and Methods:** Concept of Kupipakva Rasayana, Instrumentation and SOP of each Analytical test for *Kupipakva Rasayana*, Impact of Analytical profiling in safety aspects, Need of Analytical profiling for *Kupipakva Rasayana*. **Discussion:** Though designing a formulation is the prime step in developing pharmaceutics, the analytical standardisation of the designed formulation encourages further product movement.

Conclusion: Analytical profiling of *Kupipakva Rasayana* is essential because it decides the Pharmacodynamics and pharmacokinetics of the Drug thereby playing a significant role in therapeutic applications

Keywords: *Kupipakva Rasayana*, Pharmacodynamics, Pharmacokinetics.

INTRODUCTION

Rasaushadhi, a category of traditional Ayurvedic medicines, is derived primarily from minerals, metals, and precious gems. These formulations, often called *"Rasa"* preparations, combine the wisdom of ancient Indian alchemy (*Rasashastra*) with therapeutic practices aimed at achieving holistic health benefits. These medicines are believed to possess potent pharmacological properties and are used for various conditions, ranging from rejuvenation to treatment of diseases. However, due to their unique composition, particularly involving heavy metals like mercury (*Rasa*), lead (*Vanga*), and gold (*Swarna*), their safety, efficacy, and quality must be rigorously tested through modern **analytical profiling** techniques to ensure they meet contemporary standards of quality, safety, and therapeutic reliability. Analytical chemistry is a tool to gain information about the qualitative and quantitative composition of substances and chemical species, i.e., to determine what a substance is composed of and exactly how much.

AIMS AND OBJECTIVES:

- To emphasise the need for Drug analysis in Ayurvedic dosage forms with particular reference to *Kupipakva Rasayanas*.
- To review Different Analytical parameters for *Kupipakva Rasayanas.*
- To ensure the Role of Analytical Profiling in Drug standardisation.

MATERIALS AND METHODS:

- Concept of standardisation.
- Need for Analytical profiling.
- Different Analytical parameters of *Kupipakva Rasayanas.*
- Regulatory Guidelines and Standards

CONCEPT OF STANDARDIZATION:

Rasaushadhis, or ***Rasashastra*** formulations, represent a critical branch of **Ayurvedic medicine** that utilises metals, minerals, precious stones, and herbs to create powerful therapeutic remedies. Often complex in composition and preparation, these formulations are designed to deliver potent effects for various health conditions, from rejuvenation (*Rasayana*) to disease treatment (*Chikitsa*). However, due to the involvement of **metals and minerals**, there are inherent challenges in ensuring their safety, efficacy, and quality. **Standardisation** is crucial in addressing these challenges, ensuring that ***Rasaushadhis*** are consistently produced, safe for consumption, and therapeutically effective.

What is Standardization?

Standardisation refers to the process of establishing **specific quality benchmarks** for a product. For ***Rasaushadhis***, this means ensuring that each formulation consistently meets particular criteria, including:

- **Correct chemical composition** (active ingredients, herbal and mineral components).
- **Proper dosages** of metals and minerals, ensuring safety and efficacy.
- **Consistency in physical characteristics** such as appearance, texture, and form.
- **Reproducibility** of therapeutic effects across different batches.

This process is essential for integrating traditional Ayurvedic practices with modern pharmaceutical standards. It ensures that the formulations maintain their therapeutic benefits while minimising risks, such as heavy metal toxicity.

NEED OF ANALYTICAL PROFILING

The complexity and diversity of *Rasaushadhi* formulations, often composed of organic (plant-based) and inorganic (mineral-based) components, necessitate a detailed analysis. The primary goals of analytical profiling in the context of *Rasaushadhi*, **with particular reference to** *Kupipakva Rasayanas*, are:

1. **Ensuring Safety**: Some metals and minerals used in *Rasaushadhi*, like mercury and lead, can be toxic if not processed correctly. Analytical profiling helps identify potential toxicological risks and ensures that the formulations meet regulatory safety standards.
2. **Verifying Efficacy**: Analytical profiling ensures that the therapeutic properties mentioned in the texts are present and effective when consumed. Proper analysis can help confirm whether the intended bioactive components are present in significant amounts.
3. **Quality Control**: *Rasaushadhi* formulations are complex, and consistency in their preparation and composition is critical to ensuring each batch performs reliably. Analytical profiling can help standardise formulations to avoid variability.
4. **Regulatory Compliance**: In today's global pharmaceutical environment, Ayurvedic medicines—including *Rasaushadhis*—must comply with regulatory frameworks for herbal and traditional medicines established by the **FDA** (U.S. Food and Drug Administration) or **WHO** (World Health Organization). Analytical profiling ensures *Rasaushadhi* formulations comply with these regulations, particularly those concerning heavy metals and other toxic substances.

ANALYTICAL PARAMETERS FOR KUPIPAKVA RASAYANAS

Kupipakva Rasayana is a traditional Ayurvedic alchemical formulation prepared through the *Kupipakva* (sealed bottle) process. It contains both organic (herbal) and inorganic (metallic) components. A series of analytical tests must be performed to ensure the safety, efficacy, and quality of these formulations. These tests are necessary to determine the Ramayana's chemical composition, purity, toxicity, stability, bioactivity, and other vital characteristics.

The analytical profiling of ***Kupipakva Rasayana*** is a comprehensive process that includes **chemical**, **toxicological**, **physicochemical**, and **biological** tests to ensure its quality, safety, and efficacy. Combining traditional Ayurvedic knowledge with modern scientific techniques can validate these formulations for use in contemporary therapeutic practices. Each test contributes to the overall goal of ensuring that *Kupipakva Rasayanas* meet rigorous safety standards, are effective, and are consistent for use in human health.

Critical Components of Analytical Profiling

1. Organoleptic tests:

Description, Colour, Odour, Taste, Touch, Appearance

2. Physical tests [2, 3, 4, 5, 6, 7, 8]

a. Determination of pH value
b. Determination of Ash value
c. Determination of Acid insoluble ash
d. Determination of Water-soluble ash
e. Determination of Loss on drying at 110°C
f. Determination of Acid insoluble ash
g. Determination of Water-soluble ash
h. Particle Size Analysis (Zeta potential Analyzer)

3. Chemical Composition and Identification of Ingredients [9, 10, 11]

a. X-Ray Fluorescence (XRF)
b. SEM-EDX: energy-dispersive x-ray spectroscopy analysis conducted using scanning electron microscopy
c. Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
d. Atomic Absorption Spectroscopy (AAS)
e. High-Performance Liquid Chromatography (HPLC)
f. Gas Chromatography (GC)
g. Fourier Transform Infrared Spectroscopy (FTIR)

4. Toxicological Profiling

a. Heavy Metal Testing
b. Total Organic Carbon (TOC) Analysis.
c. Toxicity Studies (In vitro and In vivo)

5. Physicochemical Characterization [6, 12, 13, 14]

a. Particle Size Distribution (PSD)
b. Thermal Analysis (TGA & DSC)
c. X-ray diffraction (XRD)
d. Dissolution Testing

6. Stability testing

a. Accelerated Stability Testing
b. Long-term Stability Testing

7. Other requirements:

a. Microbial contamination

- Total bacterial count
- Total fungal count

b. Test for specific pathogens

- E coli
- Salmonella spp.
- S. aureus
- Pseudomonaaeruginosa

c. Pesticide residue

- Organochlorine pesticides
- Organophosphorus pesticides
- Pyrethroids

d. Test for Aflatoxins (B1, B2, G1, G2)

OVERVIEW OF SALIENT ANALYTICAL PARAMETERS OF *KUPIPAKVA RASAYANAS*

Here's an overview of the **various analytical tests** typically performed on *Kupipakva Rasayana*:

1. Chemical Composition and Identification of Ingredients

The chemical composition of *Kupipakva Rasayana* is essential to ensure that the formulation contains the correct proportions of both herbal ingredients and metals. Analytical tests for this purpose include:

A. X-Ray Fluorescence (XRF)

Purpose: To identify and quantify metallic elements in the *Rasayana*, including mercury (*Rasa*), gold (*Swarna*), silver (*Rajata*), and others.

Details: XRF is a non-destructive technique that uses the characteristic fluorescent X-rays emitted from the sample when exposed to high-energy radiation to identify the elements present.

B. Inductively Coupled Plasma Mass Spectrometry (ICP-MS)

Purpose: To measure the concentration of metals and trace elements, including toxic heavy metals such as arsenic, cadmium, lead, and mercury.

Details: ICP-MS is a sensitive and exact method used for elemental analysis, particularly for detecting toxic metals at deficient concentrations.

C. Atomic Absorption Spectroscopy (AAS)

Purpose: To quantify the presence of metals like lead, mercury, arsenic, and cadmium in the *Rasayana*.

Details: AAS measures the light absorption by metal atoms in a sample when vaporised in a flame or graphite furnace.

D. High-Performance Liquid Chromatography (HPLC)

Purpose: To identify and quantify organic compounds and active constituents from the herbal ingredients used in the *Rasayana.*

Details: HPLC is a separation technique that uses a liquid mobile phase to pass the sample through a column, separating different components based on their chemical properties.

E. Gas Chromatography (GC)

Purpose: Used to analyse volatile compounds (e.g., essential oils) that might be present in the herbal ingredients of the *Rasayana*.

Details: GC separates mixtures by volatilising the compounds and passing them through a column. The compounds are divided based on their interaction with the stationary phase.

F. Fourier Transform Infrared Spectroscopy (FTIR)

Purpose: To detect the functional groups, present in the organic and inorganic components of the *Rasayana*.

Details: FTIR provides a spectrum of absorption or transmission of infrared light by the sample, helping identify specific chemical bonds and functional groups (e.g., alcohols, carbonyl groups, etc.).

2. Toxicological Profiling

If not processed correctly, Kupipakva Rasayana often involves toxic metals. Therefore, toxicological testing is crucial to ensure its safety.

A. Heavy Metal Testing

Purpose: To ensure the formulation does not contain toxic levels of heavy metals such as lead, mercury, arsenic, and cadmium.

Methods: ICP-MS, AAS, and GFAAS (graphite furnace atomic absorption spectroscopy) are used to detect these toxic metals precisely at trace levels.

B. Total Organic Carbon (TOC) Analysis

Purpose: To check for organic contaminants or degradation products that might form during preparation.

Details: TOC analysis measures the amount of carbon in organic compounds within the sample. Excessive organic carbon may indicate contamination or incomplete detoxification.

C. Toxicity Studies (In vitro and In vivo)

Purpose: To evaluate Rasayana's potential cytotoxicity or harmful effects on biological systems.

Methods: MTT assays, LDH release assays, and cell viability assays can be used for in vitro studies, while animal models may be used for in vivo testing.

3. Physicochemical Characterization

Physicochemical tests evaluate Rasayana's physical and chemical properties to assess its quality, stability, and bioavailability.

A. Particle Size Distribution (PSD)

Purpose: To assess the particle size and distribution in the *Rasayana* formulation. Smaller particle sizes may lead to better absorption and bioavailability.

Methods: Laser Diffraction, Dynamic Light Scattering (DLS), and Microscopy are commonly used for this analysis.

B. Thermal Analysis (TGA & DSC)

Purpose: To assess the thermal stability of the *Rasayana* and determine any potential decomposition or moisture content.

Methods: Thermogravimetric Analysis (TGA) measures weight loss due to heating, while Differential Scanning Calorimetry (DSC) provides data on the sample's heat flow and melting point.

C. X-ray diffraction (XRD)

Purpose: To identify the crystal structure and polymorphs in the *Rasayana*, particularly in mineral components.

Details: XRD helps understand the crystalline nature of minerals and salts, which can affect the drug's dissolution rate and bioavailability.

D. Dissolution Testing

Purpose: To evaluate how well the *Rasayana* dissolves in simulated gastric fluids or other solvents, which is crucial for understanding its bioavailability.

Details: Dissolution testing measures the rate and extent of drug dissolution, which affects how quickly and efficiently the body absorbs active ingredients.

4. Stability Testing

Stability testing is essential to understand how the *Rasayana* formulation changes over time and under different environmental conditions.

A. Accelerated Stability Testing

Purpose: To predict the shelf life and stability of the *Rasayana* under various environmental conditions such as temperature, humidity, and light exposure.

Details: The *Rasayana* is stored under accelerated conditions (e.g., high temperature and humidity) to simulate long-term storage and assess degradation over time.

B. Long-term Stability Testing

Purpose: To monitor the formulation over a prolonged period to assess how its potency, physical properties, and chemical composition change.

Details: Samples are stored under standard conditions and tested periodically for stability parameters such as chemical integrity, bioactivity, and appearance.

5. Bioavailability Studies

Purpose: To assess the bioavailability of the *Rasayana* and determine how much of the active ingredients are absorbed and utilised by the body.

Methods: Techniques like LC-MS/MS (Liquid Chromatography–Mass Spectrometry) measure drug concentrations in plasma, urine, and other biological fluids.

REGULATORY GUIDELINES AND STANDARDS

Given the increasing popularity of traditional medicines and *Rasashastra* formulations, regulatory bodies require rigorous testing to ensure their safety and efficacy. The following frameworks are relevant:

Indian Pharmacopeia (IP): This pharmacopoeia provides standards for the preparation and quality control of Ayurvedic formulations, including those based on metals.

WHO Guidelines for Quality Control of Herbal Medicines: Ensure that herbal medicines, including *Rasayanas*, meet international safety and quality standards.

Good Manufacturing Practices (GMP): Guidelines ensure that *Kupipakva Rasayanas* are produced con-

sistently and with proper documentation and safety measures.

DISCUSSION

Though designing a formulation is the prime step in developing pharmaceutics, the analytical standardisation of the designed formulation encourages further product movement. Various categories of Analysis of *Kupipakva Rasayana,* such as **Chemical Composition,** which makes identification of bioactive compounds such as alkaloids, flavonoids, terpenes, and essential oils using techniques like HPLC, GC-MS, or LC-MS. **Trace Elements** Analysis for trace minerals and heavy metals to ensure safety and efficacy. **Physicochemical Properties** like **pH, Solubility, and Density** can impact the bioavailability and absorption of rasayana. **Moisture Content** is Important for shelf-life and stability. **Microbial Analysis** ensures the preparation is free from pathogenic microorganisms through microbiological testing (e.g., total viable count, specific pathogens). **Toxicological Assessment** evaluates safety through acute and chronic toxicity studies to determine any adverse effects. Hence, analytical profiling is crucial in proving that formulation is safe, effective, and reliable for therapeutic use.

CONCLUSION

The **analytical profiling of *Rasaushadhi*** is critical for ensuring the safety, efficacy, and quality of these traditional Ayurvedic medicines. With the increasing demand for integrating traditional medicine into modern healthcare, robust analytical techniques provide the scientific basis for these complex formulations' safety and therapeutic potential. Analytical profiling, including the assessment of chemical composition, toxicological safety, and bioactivity, helps bridge the gap between ancient Ayurvedic knowledge and contemporary pharmaceutical science, ensuring that these time-tested formulations are safe, effective, and reliable to meet the global standards for global acceptance.

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