

Quality Control of Ayurveda Formulations

Dr. Palash Bandhekar¹ , Dr. Sneha Kubde²

1. PG Scholar, From the Department of Rasashastra and Bhaishajya kalpana.
2. HOD & Professor, Department of Rasashastra & Bhaishajya Kalpana.

Bhauasaheb Mulak Ayurved Mahavidyalaya ,Nagpur.

ABSTRACT:

Ayurveda, Indian traditional system of medicine as well as oldest Holistic system of healing, in relies on herbal and well as metallic formulations for maintaining health and treating diseases. The drug or substance that will be injected into a human body should be safe and shouldn't have any side effects once it has been taken so with the increasing global interest and popularity in Ayurveda, ensuring the quality and safety of Ayurvedic formulations is very crucial. This research article presents an extensive review of the current quality control practices in Ayurveda by integrating modern analytical techniques with classical Ayurvedic principles derived from various ayurveda Samhitas. Here we are going to discuss various aspects of quality control, including authenticity, identity, purity, potency, and safety, providing a valuable resource for researchers, practitioners, and regulatory authorities involved in Ayurveda.

KEY WORDS:- Churna, Kwatha, Sneha, Avleha

Corresponding Details:

Dr. Palash Bandhekar

Plot No. 128 B, pande Layout,
Near Vyankatesh Hospital, Nagpur

Mobile No. 9503358080

E-Mail: palashbandhekar1995@gmail.com



How to cite article:

Palash Bandhekar, Sneha Kubde, Quality Control of Ayurveda Formulations, Sanjeevani Darshan- National Journal of Ayurveda & Yoga 2023; 1(2): 108-120 :<http://doi.org/10.55552/SDNJAY.2023.1212>

INTRODUCTION

The comprehensive medical system known as Ayurveda, which has its roots in ancient India, promotes a holistic approach to health and wellness. In India and Nepal, where almost 80% of people claim to use it, it is widely practiced¹. In many regions of Asia, ayurvedic medicine is a well-organized system of traditional medical treatment that is used for both curative and preventive purposes. With its origins possibly dating back up to 3,000 years in India, Ayurveda has a rich historical background². Ayurvedic remedies made from plant-based substances and some metallic formulations are essential for therapeutic and preventative treatments. To ensure their safety, effectiveness, and reproducibility, Ayurvedic formulation quality is crucial not only for consumers but for practitioners too. The WHO also stresses the necessity to use up-to-date control methods and appropriate standards to ensure the quality of medicinal plant products. The status of a medicine can be described as its quality, which is either established by the manufacturing process or by factors such as identity, purity, content, and other chemical, physical, or biological features.³

CLASSICAL CONCEPT

Ayurvedic formulators have included all the directions required to create a high-quality product, and they have considered both qualitative and quantitative elements. Numerous places in the classics indicate their deep understanding of the needs for quality, treatment regimens, and formulation shelf life. The strict guidelines set by the medication, paramedics, and physicians is one of them. According to Charaka, an ideal medication should be widely available (Bahuta), qualified for use as medicine (Yogyatvam), come in a variety of forms (Aneka vidha kalpana), and possess every quality (Sampat).⁴ The seer goes on to stress the significance of drug quality, stating that excellent drugs should be plentiful in exhibited rasa and virya (potency), free of wounds, unaffected by wind, temperature, etc., and devoid of infections. They should also be harvested during the appropriate season.⁵

The collected raw material needs to be kept in appropriate storage containers that are protected from rodents and other four-legged creatures and are devoid of contaminants including water, smoke, dust, and pollen.⁶ Before being administered, all medications should be thoroughly examined to ascertain their nature (prakriti), qualities (guna), particular acts (prabhava), cultivation location (desha), gathering location (grahana), preservation technique (nihita), processing method (upaskrita), therapeutic dosage (matra), etc.⁷ Charaka asserts that both the use of a potent poison as medicine and the reverse are feasible. As a result, great caution must be used when handling the drugs. Nevertheless, treatment regimens have also been suggested for these diseases in the event that disobedience with the therapy's code of conduct results in adverse effects.⁸

Sharangadhara further states that in therapeutics, plants growing on anthills (valmika), dirty areas (kutsita), marshy land (anupa), graveyards (smashana), salty soil (ushara), highways (margaja), infested with microorganisms (jantu), and adversely affected by temperature changes (vahni and hima) should be avoided as they will not produce the desired effect.⁹

The quality of a drug was defined by Sushruta as follows: it must be born in fertile land (prashasta desha sambhootam), properly collected (prashastechodhrutam), used in the right dosage (yuktamatram), pleasant to the mind (manaskantam), have a pleasing characteristic

smell, color, and taste (Gandha varna rasanvitam), be able to calm the aggravated doshas (doshaghnam), and not have any negative effects (aglanikaram, avikari). These qualities make the medication more potent, therefore it's important to utilize it as prescribed and in compliance with recognized protocols.¹⁰

	Kalpana	Parameter	Presumptive Explanation
1	Churna	Sukshma tantava pata chyutam	The powder needs to get through the delicate fabric fibers.
2	Kwatha	Gatarasata	The basic substance ought to lose its flavor.
3	Avleha	Tantumattvam	Bringing the threads together
		Apsumajjanam	settling down in a secure
		Sthiratvam	Stable character
		Pidite	The way fingerprints appear on paste
		Gandha varna rasotpatti	The appearance of pleasant qualities such as color, taste, and odor
4	Sneha	Vartivat snehakalka	Paste with a wick-like look
		Shabda hino agni nikshipta	Lack of fire crackling noises
		Phenodgama or Phena shanti	The presence or absence of foam
		Gandha varna rasotpatti	The appearance of pleasant qualities such as color, taste, and odor

MODERN CONCEPT-

In the past, doctors created medications on a huge scale and distributed them around the world. As a result, in the current era of commercialization, ayurvedic pharmaceuticals must meet quality assurance and standardization requirements. According to modern science, quality control and standardization of raw materials and Ayurvedic medications are becoming more important for the worldwide acceptability of Ayurvedic treatments. Modern techniques state that the following conditions have to be satisfied in order to determine the quality of a product:

1. Identity and Authenticity
2. Honesty
3. Potency
4. Security

The fundamental components of ayurvedic medicines are certified raw materials or herbs. Every stage of the production process, from harvesting and gathering raw materials to the final formulation quality, is subject to change, hence quality control techniques must be incorporated into every stage.

1.1 Macroscopic and Microscopic Analysis

- Analyzing the morphology of plant material in comparison to a standard reference material, including form, size, color, texture, surface features, fracture characteristics,

odor, taste, and other organoleptic aspects.¹¹

- Microscopic analysis to determine if particular anatomical characteristics are present. Microscopy is used to determine the structural, cellular, and internal tissue features of botanicals. Usually, it's employed to identify and separate related herbals.

1.2 Molecular Techniques and DNA Barcoding

DNA barcoding is used to confirm the existence of particular plant species.

- Identifying species through the use of molecular methods like polymerase chain reaction (PCR).
- DNA barcoding is a useful technique for identifying herbal remedies. Single or several loci may be used to identify most plants; these loci have been used extensively and have yielded satisfactory results. Despite being the main method of molecular identification at the moment, it has certain shortcomings.¹²

1.3 Chemical Constituent Comparative Profiling

- Comparing chemical profiles to ascertain the legitimacy of a product using modern analytical methods including spectroscopy, TLC, and chromatography.

2. Purity

2.1 Heavy Metal Content Analysis

- Characterizing heavy metals using contemporary experimental methods like inductively coupled plasma mass spectrometry or atomic absorption spectroscopy.
- Respect for the allowed limits set by regulatory bodies.

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2.2 Microbial Contamination Testing

- To evaluate the microbial burden, tests for yeast, mold, and certain harmful bacteria are performed, along with a total plate count.
- Adherence to microbiological specifications for safety and shelf life assessments.

2.3 Pesticide Residue Analysis

- Use of liquid or gas chromatography-mass spectrometry for the detection of pesticide residue.
- Admitted constraints must be adhered to in order to guarantee consumer safety.

3. Potency

3.1 Bioactive Markers or Marker Compounds Quantification

- spectrophotometric or high-performance liquid chromatography (HPLC) techniques for quantifying bioactive components.
- Selecting marker chemicals to evaluate consistency between batches.

3.2 Active Ingredient Content Analysis

- To ascertain the concentration of active substances, use titration techniques or gravimetric analysis.
- Adherence to specified parameters to guarantee therapeutic effectiveness.

3.3 Stability Studies

- Accelerated stability studies to assess the formulation's shelf-life under various storage conditions.
- Monitoring degradation and changes in chemical composition over time.

4. Safety

4.1 Toxicity Evaluation

- In vitro experiments to evaluate the possible toxicity of Ayurvedic remedies, such as cell-based cytotoxicity testing.
- in vivo research that look at acute and longterm toxicity utilizing animal models.

4.2 Drug-Herb Interactions and Adverse Effects

- Evaluation of possible interactions with prescription medications using in vivo and in vitro research.
- Tracking side effects using post-market surveillance and observational research.

4.3 Long-Term Safety Studies

- An examination of the long-term safety profile of Ayurvedic medicines.
- Taking long-term ramifications and cumulative impacts into account.

Government Regulate it in following way:

The regulation and quality control of Ayurvedic medicines are covered exclusively under

- the Drugs & Cosmetics Act of 1940
- Constitution of Ayurvedic Pharmacopoeial Committee (APC) on 20th September 1962 and
- the Drugs and Cosmetics Rules of 1945.

The federal government either drafts or amends the rules governing the use of ayurvedic medicines, while state governments are in charge of licensing and quality control. Good manufacturing techniques and quality requirements for the production of Ayurvedic drugs are provided by the Drugs and Cosmetics Rules, 1945, the Ayurvedic Pharmacopoeia, and the authoritative publications listed in Schedule I of the Drugs & Cosmetics Act, 1940. The pharmacopoeia's standards for identification, purity, and strength are applied when evaluating a medication's legitimacy. The Central Government created the Pharmacopoeial Laboratory of Indian Medicine in Ghaziabad, Uttar Pradesh, specifically for this purpose.¹³ let discuss about Ayurvedic Pharmacopoeia

THE AYURVEDIC PHARMACOPEIA

- The Greek word pharmacopoeia is composed of three words. When put together, the phrases verb-stem poi (meaning "make"), abstract noun ending ia , and pharmakon (meaning "a drug") mean "drug-mak-ing."
- A pharmacopoeia's monographs are listings of each particular drug or preparation that makes up the collection.
- In addition to a variety of other ayurvedic pharmaceutical formulations, they are the only legally recognized source of knowledge on the specifications for the quality standards of pharmaceutical products, both natural and manufactured.

Ayurveda Pharmacopoeia committee

- The Department of Ayush's first operating unit was the APC. On September 20, 1962, the Indian government ratified the establishment of the APC.
- Creating Drug Standardization Pharmaceutical Research In April 2006, it was reorganized under the Central Council for Research in Ayurveda and Siddha.
- In 1964, the Indian government modified the Drug and Cosmetics Act 1940 to limit the usage of Ayurvedic, Siddha, and Unani remedies.
- APC considered the collection of formulas as an introduction and acknowledged the importance of the issue. The first volume of API, approved for publication by the APC in 1969, has 444 formulae.
- There is no utility for a formulary without any standards.
- The creation of three Drug Standardization Research Project (DSRP) centers—in Jamnagar, Chennai, and Varanasi—led to the first standards for Ayurvedic formulations being developed.
- In 1976, a book titled "Pharmacopoeia Standards for Ayurvedic Formulations" was published, which compiled dates from various units and included standards for 415 formulations (a revised edition with 431 formulations was produced in 1987).

OFFICIAL AND ESSENTIAL PUBLICATIONS OF APC :

- Ayurvedic Formulary of India
- Ayurvedic Pharmacopoeia of India

- Atlas of Ayurvedic Pharmacopoeia Drugs

OTHER OFFICIAL MONOGRAPHS:

- German Commission E Monographs
- European Scientific Cooperative for phytotherapy (ESCOP)
- The American Herbal Pharmacopoeia
- WHO Monographs
- USP Monographs

APC-Functions

- To establish working standards for compound Ayurvedic formulations, including testing for identification, purity, strength, and quality to guarantee consistency of the final formulations;
- To compile the Indian Ayurvedic Pharmacopoeia of single and compound medications;
- Identifying work techniques, procedures, and plans that would allow for the publication of the standards and formulary for all widely used medications to be released gradually while keeping in mind the time constraints
- To produce the remaining components of the official compound preparation formulary from the classical literature, including the standardized composition of a reputable institution.
- To establish and standardize processing methods, dosage forms, and toxicity profiles.
- To provide safety, effectiveness, and quality criteria for intermediates, such as Ayurvedic raw medicine extracts.
- To create the safety, efficacy, and quality requirements for various plant components; moreover, to incorporate novel plants as Ayurvedic medicines.
- Any other issue concerning identity, shelf life, new formulas, quality requirements, etc.

Targets, Focus of the Committee

- To develop Ayurvedic formulations and single-drug standards in line with official literature
- To create draft Standard Operating Procedures (SOPs) for India's Ayurvedic Formularies using classical texts and other reliable sources.

CONTRIBUTING LABORATORIES & INSTITUTIONS

- University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh
- National Institute Pharmaceutical Education and Research (NIPER), Mohali
- Captain Srinivasa Murthy Drug Research Institute Ayurveda (CSMDRIA), Chennai
- DB. V. Patel, Pharmaceutical Education, & Research Development (PERD) Centre, Ahmadabad

- National Botanical Research Institute, (Council of Scientific & Industrial Research), Lucknow
- Ram Narayan Ruia College, Matunga, Mumbai

Central Council for Research in Ayurveda and Sidda (CCRAS)

- Founded in 1978
- To do study in Sidda and Ayurveda
- Dedicated to creating affordable, suitable, safe, and efficient formulations for priority illnesses
- Funding for basic research initiatives at 35 laboratories across industries and institutions

PROJECTS UNDER APC

- Creation of pharmacopeial standards for individual medications and their combinations
- Isolation of therapeutic plant marker chemicals - Comparative phytochemical screening of bark and roots vs aerial parts
- Creation of the API's Hindi version
- Research on the biological activity of plant extracts
- India's Extra Ayurvedic Pharmacopoeia
- To determine the processes and guidelines for publishing standards for all frequently used AFI formulas.
- Details on Ayurvedic Remedies pertaining to
 - Distinguishing characters
 - Method of preparation and dosage
 - Method of administration with Anupana
 - Toxicity
- To create quality standards, identify products, extend shelf life, and create new formulations that use plant extracts with intermediate safety and efficacy;
- To carry out all other tasks as specified in the APC's functions

Ayurvedic Pharmacopoeia Committee & PLIM

- In 2010-Pharmacopoeia Laboratory for Indigenous Medicines (PLIM)
- Autonomous body for Indian Medicine (Ayurveda, sidda, & Unani) to evolve the standards under the guidance of APC

PLIM - Objectives

- Establishing and verifying drug(s) standards
- Establishing standard;
- Educating drug inspectors and analyzers;
- Offering assistance to APC
- Thus, the first volume of API, 1986, comprising eighty monographs

Ayurvedic Pharmacopoeia of India

The monographs that provide requirements for Ayurvedic single pharmaceuticals of plant origin that are included in one or more formulations accepted into the Ayurvedic Formularies of India include Part I of the Ayurvedic Pharmacopoeia of India, Vols. I through VIII.

Official standards for fifty compound compositions included in the Ayurvedic Formulary are contained in Part II of the Ayurvedic Pharmacopoeia.

Volume	Year of publishing	Number of monograph
I	1986	80
II	1999	78
III	2001	100
IV	2004	68
V	2006	92
VI	2008	101
VII	2008	21 (minerals & metals)
VIII	2011	60 (Aq. & Hydroalcoholic extracts)

Ayurvedic Pharmacopoeia of India – Publications

AYURVEDIC PHARMACOPOEIA OF INDIA – PART 2 (FORMULATIONS)

VOLUME	Year of publication	Number of monographs
I	2008	50
II	2009	51
III	2010	51

TLC Atlas of Ayurvedic pharmacopoeial drugs - Part 1

I	2009	80
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Microscopy & Macroscopy Atlas of API Drugs – Part 1

I	2011	80
V	2009	92

KALPANA	VOL 1 (50)	VOL 2	VOL 3
Arka	-	-	12
Avleha	12	4	3
Churna	11	4	1
Ghrita	12	4	1
Guggulu	1	13	3
Vati	1		11
Asav & Arishta		24	
Taila	1	1	20
Ksharsutra		1	

Kshara(5) & Lavana (1)	6	-	-
Lepa (darvi malahara)	1	-	-

A Typical Monograph of Ayurvedic Pharmacopoeia of India

- Title
- Name of the Drugs
- Synonyms
- Description (Macroscopic & Microscopic)
- Identity, Purity and Strength
- 1. Foreign matter
- 2. Total Ash
- 3. Acid-insoluble ash
- 4. Alcohol-soluble extractive
- 5. Water-soluble extractive
- Assays and Tests
- Constituents
- Properties and action
- Important formulations
- Therapeutic uses
- Dose

Appendix -1. Apparatus for tests and assays

Appendix 3 - Physical tests and determination

Appendix - 2. Tests and Determination

1. Determination of quantitative data

2. Limit tests

3. Microbial Limit tests

4. Pesticide residue

5. Test for aflatoxins

6. Gas chromatography

Appendix - 4. Reagents and Solution

Appendix - 5. Chemical Tests and Assays Appendix - 6. Ayurvedic Definition and Methods

Appendix -7. Weights and Measures

Appendix - 8. Classical Ayurvedic References

Appendix - 9. List of Single Drugs used in Formulation

Appendix - 10. Bibliography

General Structure of API (Formulations)**Title****Definition****Method of Preparation****Description****Identification – TLC****Physico-chemical parameters****Storage****Therapeutic uses****Dose****THE AYURVEDIC FORMULARY OF INDIA**

In this approach, fragmented data on different formulas from traditional ayurveda literature was gathered.

Based on the names that occur in the formulations, a list of individual medications with animal, mineral, and plant origins has been created. For ease of identification, their full names and English counterparts are included.

The list of plant medications has been updated to reflect the botanical names of the plants used in the formulations. This is done for the benefit of users, pharmacists, and those who are not well-versed in Ayurvedic language.

Part	Year of Publishing	Number of Monographs
I	1976	444
II	2000	192
III	2011	350

Formulations	Part I	Part II	Part III
Asava & Arishta	37	3	17
Arka	4	2	14
Avleha	32	7	20
Kwath choorna	9	25	30
Guggulu	12	2	7
Ghrita	44	4	-
Choorna	40	6	69

Taila	62	18	26
Dravaka	1	-	-
Lavan & kshara	13	-	2
Lepa	12	5	23
Vati & Gutika	35	14	26
Varti ,netrabindu , Anjana	8	2	2
Satva	1	-	-
Kupipakva rasayana	10	-	-
Parpati	5	2	1
Pishti	4	2	1
Bhasma	20	5	-
Mandura	2	3	4
Rasayoga	55	69	96
Louha	12	9	11
Dhupa	-	-	1

APPENDICES

Appendix -I

- I. Samanya Paribhasha
- II. Kalpana Paribhasha
- III. Puta Paribhasha
- IV. Yantra Paribhasha

Appendix -II

1. Shodhana
2. Ashta samskara of Parada

Appendix - III

- Therapeutic Indices (Formula & Disease wise)

Appendix – IV

- Diseases/Technical terms and english equivalents

CONCLUSION

Maintaining the formulas' purity has become more important as more people embrace Ayurveda's age-old wisdom for overall wellness. A strong quality control system evolves to protect this delicate balance when modernity and tradition clash. Respecting millennia of knowledge and the quest of wellbeing is what quality control is all about. It's more than just a technical task. In order to increase the validity of formulations, Ayurveda's guardians are combining cutting-edge contemporary technology with age-old expertise to navigate challenges like as adulteration and variances in source. Outside of labs, this collaborative effort reflects a sense of obligation to researchers and respect for customs. It highlights how

the pillars of treatment are the safety and efficacy of Ayurvedic remedies. Quality control remains the compass as Ayurveda spreads internationally, ensuring authenticity prevails and fostering a world that is healthier and more peaceful.

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Source of Support : None Declared

Conflict of Interest : Nil