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REVIEW ARTICLE

Advanced Manufacturing Techniques in the Ayurvedic Pharmaceutical Industry: A Synthesis of Regulatory, Analytical and Engineering Perspectives

Ravi Sharma^{1*} Avadesh Kumar Bhatt²

1 Ph.D Scholar MMM Govt. Ayurved college PG Department of Rasa shastra and Bhaishajya Kalpana & Resident Medical Officer, Dr. S R Rajasthan Ayurved University, Jodhpur

2 Prof and HOD, PG department of Rasa shastra and Bhaishajya Kalpana, MMM Govt. Ayurved college, Udaipur

Corresponding Author: Ravi Sharma; Email: drravisharma4194@gmail.com

Abstract

The Ayurvedic pharmaceutical sector has moved from a craft-based tradition towards an industrial discipline, driven by rising global demand for herbal medicines and by mounting expectations of batch-to-batch consistency, traceability and evidence of quality. This review examines how advanced manufacturing techniques are being integrated into the production of Ayurvedic medicines, and how regulatory, analytical and engineering developments interact to support that transition. The regulatory spine formed by statutory good manufacturing practice requirements, World Health Organization guidance and the monograph standards of the Ayurvedic Pharmacopoeia of India is discussed as the foundation on which modern process design rests. The review then considers intensified extraction platforms, including supercritical fluid extraction, ultrasound-assisted extraction and allied green techniques, that improve yield and selectivity while reducing solvent burden. The nanotechnological dimension of classical incinerated preparations (*Bhasma*) is examined, since modern characterisation has shown that these medicines contain engineered-scale particulate matter whose physicochemical identity varies with the manufacturing process. Process analytical technology, quality by design and chemometric fingerprinting are presented as the connective tissue that links raw-material variability to a controlled finished product, followed by a discussion of automation, continuous processing and the principal barriers to adoption. The review concludes that the credibility of Ayurvedic manufacturing will depend less on any single technology than on the systematic coupling of fit-for-purpose process control, transparent pharmacopoeial standards and reproducible analytical evidence.

Keywords: Pranayama; Hypertension; Blood Pressure; Yoga; Autonomic Regulation; Heart-Rate Variability; Complementary Medicine

Introduction

Ayurveda, the classical medical system of the Indian subcontinent, has been practised continuously for well over two millennia and remains a living therapeutic tradition rather than a historical curiosity. Over the past two decades it has undergone what several authors describe as a shift from tradition to trend, in which classical knowledge is being reappraised through contemporary pharmacological, analytical and industrial lenses.¹ This reappraisal has been accompanied by a rapid expansion of the herbal products market, both in India and internationally, and by a corresponding growth in the expectations placed on manufacturers. Consumers, prescribers and regulators increasingly demand products whose identity, potency and safety can be demonstrated rather than assumed.²

The scientific credibility of any traditional medicine system ultimately rests on the reproducibility of its

products. Classical Ayurvedic pharmacy was governed by detailed procedural texts that specified raw materials, processing sequences and observable end-points, yet those descriptions were qualitative and depended heavily on the skill of the individual practitioner. Industrial manufacture removes the practitioner from the bench and replaces personal judgement with instrumentation, which makes the explicit codification of quality far more important. The monograph standards compiled in the Ayurvedic Pharmacopoeia of India (API) provide this codification for a growing number of single drugs and formulations, describing identity, purity and strength in terms that can be tested in a laboratory.³

At the same time, Ayurvedic drug development has benefited from integrative research strategies that combine ethnopharmacological leads with modern screening, thereby generating products that are simultaneously rooted in classical practice and defensible

under contemporary regulatory scrutiny.⁴ The present review brings together three strands that are usually discussed separately: the regulatory and pharmacopoeial framework, the engineering of extraction and processing, and the analytical science that verifies the result. Its objective is to show how these strands must be coupled if advanced manufacturing is to deliver consistent Ayurvedic medicines at industrial scale.

The Regulatory and Pharmacopoeial Framework

Manufacturing practice in the Indian systems of medicine is anchored in statutory good manufacturing practice (GMP) requirements, of which the most influential for Ayurvedic, Siddha and Unani medicines is the provision commonly known as Schedule T. Schedule T sets out requirements for factory premises, plant layout, hygiene, personnel, documentation and in-process controls, and its underlying purpose is to compel manufacturers to hold a uniform standard of cleanliness and process discipline across batches.⁵ These national requirements are complemented by international guidance. The World Health Organization has published manufacturing guidance specific to herbal medicines, addressing the particular difficulties created by variable botanical raw materials and by extraction-based processes,⁶ together with a companion volume of quality-control methods that describes practical tests for medicinal plant materials.⁷

Pharmacopoeial standards translate regulatory expectations into measurable specifications. The API is the official compendium for Ayurvedic single drugs and formulations, and its monographs are the reference point against which manufacturers and regulators assess identity, purity and strength.³ A monograph typically combines macroscopic and microscopic description, physicochemical constants, chromatographic identity and limits for contaminants, and the progressive expansion of the compendium has extended this framework from individual herbs to finished multi-ingredient preparations.

Pharmacopoeial testing, however, is largely a batch-release activity: it establishes whether a completed lot conforms to specification, not whether the process that produced it was controlled. Phytochemical standardisation of herbal drugs and polyherbal formulations has therefore developed as a complementary discipline, using marker compounds and

chromatographic fingerprints to characterise the material at successive stages of manufacture.⁸ The regulatory and pharmacopoeial layer thus defines the destination, while process understanding determines whether that destination can be reached repeatedly.

Advanced Extraction and Processing Technologies

Extraction is the operation in which the therapeutic identity of an Ayurvedic medicine is largely determined, and it is also the stage at which conventional manufacture is least efficient. Traditional percolation and maceration consume large volumes of solvent, require long contact times and expose thermolabile constituents to prolonged heating. The search for technologies that improve selectivity and yield while reducing solvent and energy demand has produced a family of intensified platforms, of which supercritical fluid extraction (SFE) is the most thoroughly documented. A widely cited review of SFE for bioactive compounds from botanical matrices sets out the underlying thermodynamics and mass-transfer principles and examines the economic considerations that govern industrial adoption.⁹

The practical viability of SFE at production scale has been demonstrated for several botanicals relevant to Ayurvedic pharmacy. In the extraction of ginger oil from *Zingiber officinale* var. *Amarum*, laboratory optimisation was followed by a fifty-fold scale-up in which the solvent-to-feed ratio was held constant as the principal scaling criterion; the scaled process delivered a higher oil yield while the proportion of the marker constituent 6-gingerol was lower than at laboratory scale.¹⁰ An analogous study on *Phyllanthus niruri*, a plant with a long history of medicinal use, used ethanol–water modified carbon dioxide and reported that the process remained economically favourable at larger scales, with safety of the enriched extract assessed in a zebrafish embryo model.¹¹ Together these studies illustrate both the promise and the caution required: a change of scale can alter the composition of the extract even when the overall yield improves, which makes in-process measurement essential.

Liquid-phase intensification offers a complementary route, particularly for polar constituents that are poorly soluble in carbon dioxide. Ultrasound-assisted extraction

(UAE) exploits cavitation to disrupt cell walls and accelerate mass transfer, and its operating variables are usually optimised statistically rather than empirically. Response surface methodology has been used to optimise UAE of phenolics and antioxidant compounds from the rhizomes of *Rheum moorcroftianum*, a high-altitude Himalayan species, yielding a model that relates solvent composition, temperature and sonication time to recovery.¹² A comparable approach applied to Piper betle leaves established optimal conditions for phenolic recovery and demonstrated the advantage of UAE over conventional maceration for the same raw material.¹³ The common methodological thread in these studies is the use of designed experiments that make the relationship between process parameters and product attributes explicit, which is precisely the information a manufacturer needs in order to control a process rather than merely repeat it.

Table 1. Selected Intensified Extraction Technologies Relevant to Ayurvedic Manufacture

Technology	Principle	Principal advantages	Reported application
Supercritical fluid extraction (CO ₂)	Solubility and transport in a supercritical fluid; polarity tuned with co-solvent	Solvent-free product, low thermal load, selective	Ginger oil scale-up ¹⁰ ; <i>Phyllanthus niruri</i> ¹¹
Ultrasound-assisted extraction	Acoustic cavitation disrupts cell structure	Reduced time and solvent, higher recovery of phenolics	<i>Rheum moorcroftianum</i> ¹² ; Piper betle ¹³
Design-of-experiment process optimisation	Statistical modelling of parameter-response relationships	Identifies interactions and optimum robustly	Applied across the above extraction studies ^{12,13}

The Nanotechnological Dimension of *Bhasma*

Among Ayurvedic dosage forms, the incinerated metallic and mineral preparations known as *Bhasma* present the most striking convergence with modern materials science. *Bhasma* are produced through repeated cycles of trituration with herbal juices or decoctions followed by controlled incineration, and modern analysis has shown that the products consist of particulate matter in the nanometre range.¹⁴ This observation has led several authors to describe *Bhasma* as an ancient form of nanomedicine, since the classical procedures appear to have generated engineered nanoparticles long before the term existed, and transmission electron microscopy has confirmed the presence of globular metallic nanoparticles in well-prepared samples.¹⁵

The significance for manufacturing is that the biological behaviour of these preparations depends on their physicochemical state, which in turn depends on the process. *Rajata Bhasma*, the silver-based preparation, has been characterised to contain silver particles in the nanometre size range and to exhibit measurable antibacterial activity, establishing that particle size is not incidental but central to function.¹⁶ *Svarna Bhasma*, the gold-based preparation, was found in a blood-compatibility study to consist of gold nanoparticles and to be non-haemolytic under the conditions tested, supporting the classical claim of safety while providing a modern toxicological rationale.¹⁷ More recent work has profiled the toxicity of *Svarna Bhasma* in a rat model and assessed behavioural effects in zebrafish, contributing a structured safety dataset to complement the characterisation data.¹⁸

The most important lesson for industrial practice emerges from comparative studies of commercial products. A multi-manufacturer investigation reported that *Svarna Bhasma* samples differed in their physicochemical characteristics and produced different in vivo bioaccumulation profiles, indicating that ostensibly equivalent products are not interchangeable.¹⁹ Independent work comparing incinerated gold particles with chemically synthesised nanoparticles of similar size examined cellular entry and localisation, and showed that the classical material behaves in a manner that must be evaluated on its own terms rather than assumed to match a synthetic analogue.²⁰ For the Ayurvedic pharmaceutical industry the implication is direct: process parameters such as number of incineration cycles, temperature profile and trituration medium are critical quality attributes in all but name, and their control requires particle-level characterisation as a routine release test rather than a research exercise.

Process Analytical Technology and Quality by Design

The conceptual bridge between regulatory expectation and manufacturing reality is the framework of process analytical technology (PAT) and quality by design (QbD). QbD begins with the identification of critical quality attributes and the process parameters that influence them, and proceeds through a design space within which variation is understood rather than merely tolerated.

Table 2. Analytical characterization approaches applied to incinerated Ayurvedic preparations

Parameter	Analytical approach	Illustrative finding
Particle size and morphology	Transmission and scanning electron microscopy	Globular metallic nanoparticles identified in <i>Bhasma</i> ^{15,16}
Elemental /phase identity	Spectroscopic and diffraction methods	Nanometre-range metal particles confirmed in Rajata <i>Bhasma</i> ¹⁶
Biocompatibility	Blood-compatibility and cytotoxicity assays	Swarna <i>Bhasma</i> non-haemolytic in vitro ¹⁷
Safety profile	Animal toxicity and behavioural models	Structured toxicity dataset for <i>Suvarna Bhasma</i> ¹⁸
Batch comparability	Multi-source physicochemical comparison	Inter-manufacturer variation with differing bioaccumulation ¹⁹

A proposal for a comprehensive quality system for herbal products argued that hazard analysis at critical control points should be embedded in the manufacturing process and coupled with PAT, so that quality is built into production instead of being inspected into the finished batch.²³ Reviews of quality-control methods for herbal-derived preparations have reached a similar conclusion, describing an integrated approach that follows the material from raw herb to finished product and relies on multivariate analysis of analytical data ²⁴

The enabling instrumentation for PAT is largely spectroscopic. Near-infrared (NIR) spectroscopy, coupled with multivariate calibration, permits real-time estimation of physical and chemical attributes during processing. A representative study developed NIR calibration models for the real-time prediction of powder density, a property that governs tablet mass, hardness and dissolution behaviour in solid dosage manufacture, and showed that spectra acquired in a continuous manufacturing plant could be related to the calibration set.²¹ The relevance to Ayurvedic manufacture lies in the fact that the physical behaviour of herbal powders which are inherently heterogeneous mixtures of plant tissue, gums, resins and, in some cases, mineral particles- is at least as variable as that of purified pharmaceutical ingredients.

Analytical Standardization and Fingerprinting

Because a herbal preparation is a multi-component mixture rather than a single active substance, its standardization relies on fingerprints and marker compounds rather than on assay of a lone analyte. High-

performance thin-layer chromatography (HPTLC) has become a workhorse for this purpose, offering parallel separation of many constituents with minimal sample preparation. The validation of standardised HPTLC methods for the quality control and stability testing of herbal materials provided an early and influential framework for evaluating the performance of such qualitative and semi-quantitative techniques.²⁵ Subsequent applications have demonstrated the practical reach of the approach. The Ayurvedic formulation *Haridra Khanda*, in which turmeric is the principal ingredient, was standardised using HPTLC–densitometry with fingerprint acquisition at multiple wavelengths and quantification of its marker constituents.²⁶ More recently, an HPTLC method was validated for the simultaneous quantification of several major bioactive compounds in *Mahasudarshan Churna*, a polyherbal preparation containing a large number of ingredients – a case that illustrates how fingerprinting can impose order on a genuinely complex matrix.²⁷

Chromatographic data are now increasingly supplemented by rapid, non-destructive sensing technologies. Electronic nose, electronic tongue and electronic eye instruments, combined with near-infrared spectroscopy and chemometric data fusion, have been used to authenticate and identify closely related botanical species where conventional morphology is insufficiently discriminating²⁸. The value of such multi-sensor fusion lies in its robustness: agreement between independent physical channels is harder to obtain spuriously than a match in a single fingerprint. For Ayurvedic manufacture, where adulteration and substitution of raw materials are persistent quality risks, these methods offer a practical screening capability that can be deployed at goods-receipt.

Automation, Continuous Processing and Scale-Up

The convergence of PAT instrumentation with process equipment makes continuous and automated manufacture feasible in principle. In a continuous line, material moves through unit operations without intermediate hold, and quality is assured by measurement at intervals rather than by testing of discrete lots. The NIR monitoring study cited earlier was conducted in exactly this configuration, relating spectral

data to powder properties within a continuous plant.²¹ The extension of such an approach to herbal products is attractive because it addresses the principal weakness of batch manufacture, namely that a deviation detected at final release has already affected the entire lot.

Scale-up remains a distinct engineering challenge, and the extraction literature shows why. The ginger-oil study maintained a constant solvent-to-feed ratio as its scaling criterion and still observed a compositional shift on scale-up.¹⁰, while the *Phyllanthus* work validated its scale-up criteria through economic analysis and safety testing of the resulting extract.¹¹. The general lesson is that geometric and hydrodynamic similarity cannot be assumed, and that a scale-up protocol must specify which dimensionless or operational quantity is held constant. Automation extends this discipline by recording the value of that quantity continuously, turning scale-up from a one-off experiment into a documented and repeatable transfer.

Regulatory frameworks are broadly compatible with these developments. Schedule T requires documentation and in-process control⁵, and the WHO guidance on GMP for herbal medicines anticipates the particular hazards of botanical processing.⁶ What is required to realise the potential of advanced manufacturing is not a new regulatory philosophy but the operationalisation of existing expectations through instrumentation, defined specifications and trained personnel.

Challenges and Future Directions

Several obstacles constrain the adoption of advanced manufacturing in Ayurvedic pharmacy. The first is raw-material variability. Botanical identity, harvest season, geographic origin and post-harvest handling all influence composition, and no amount of downstream technology can fully compensate for an uncharacterised input. Multi-sensor authentication and fingerprinting at goods-receipt are therefore prerequisites rather than luxuries.²⁸ The second obstacle is the analytical and infrastructural cost of the required instrumentation. Spectroscopic PAT systems, particle-sizing equipment and validated chromatographic methods represent a substantial capital and running expense, and small and medium manufacturers may struggle to absorb it without collective or institutional support. A third obstacle is methodological: the classical literature describes

processes in qualitative terms, so the translation of procedures such as incineration cycles into quantitative process parameters requires research that is only partially complete. The observed inter-manufacturer variation in *Bhasma* products.¹⁹ indicates that this translation is not merely academic; without it, products bearing the same name may not be therapeutically equivalent. A fourth obstacle concerns evidence: process control assures consistency, but clinical and pharmacological evidence is still required to establish benefit, and the integrative research strategies that connect classical practice to modern drug development remain essential to that task. ⁴

Looking ahead, three directions appear most promising. The first is the routine embedding of chemometric fingerprinting and multi-sensor authentication in raw-material control, which directly addresses the largest single source of variability.^{24,28} The second is the wider deployment of PAT in extraction and drying operations, where NIR and allied techniques can monitor critical attributes in real time.²¹ The third is the systematic application of QbD to both formulation and analytical method development, so that robustness is designed into products and methods from the outset.^{22,23} Progress across these directions would move Ayurvedic manufacture decisively from inspection-based quality towards quality by design.

Conclusion

Advanced manufacturing in the Ayurvedic pharmaceutical industry is best understood not as the importation of a single technology but as the integration of three mutually dependent capabilities. The regulatory and pharmacopoeial framework, exemplified by statutory GMP provisions and by the monograph standards of the Ayurvedic Pharmacopoeia of India, supplies the definition of acceptable quality.^{3,5,6} Intensified extraction platforms and particle-level characterisation of incinerated preparations supply the means of producing materials whose composition is understood and controlled.^{9–11,14,16}. Process analytical technology, quality by design and chemometric fingerprinting supply the evidence that the control is real and continuous.^{21–25} Where these capabilities are coupled, Ayurvedic medicines become reproducible industrial products without losing their classical identity; where they are not,

variability — already documented between manufacturers of nominally identical preparations¹⁹ remains the principal threat to the credibility of the sector. The future of the field therefore lies less in novel unit operations than in the disciplined connection of measurement to process, and of process to specification.

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Conflicts of Interest

There are no conflicts of interest.

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