REVIEW PAPER

Classics to Clinics: Mapping Ayurveda Dosage Forms to Modern Drug Delivery Systems

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Abstract

Ayurvedic pharmaceutics (*Bhaishajya Kalpana*) codifies dosage forms with explicit preparation rules for solvent choice, process intensity, and matrix design principles that closely parallel modern drug delivery science. The objectives of study that maps classical Ayurvedic dosage forms to modern drug delivery analogues, specifies quality control (QC) and Chemistry, Manufacturing and Controls (CMC) expectations (including stability and release testing) and summarizes controlled clinical evidence and a translational roadmap for development. Methodology of narrative review of authoritative primers (AFI/API), pharmaceutics/QC resources (HPTLC/HPLC/ICP MS/XRD/TEM), WHO herbal QC guidance, and controlled trials in osteoarthritis and rheumatoid arthritis. Sneha kalpana (medicated lipids) aligns with Lipid based drug delivery systems (LBDDS) and demands oxidation microstructure metrics; Bhasma parallels engineered micro/nano particulates requiring XRD/TEM/ICP MS; Asavaariṣhta operate as hydro alcoholic extraction/permeation systems; *Avaleha/Vati* behave as matrix and sustained release platforms. Robust QC uses orthogonal analytics (HPTLC/HPLC/GC MS, ICP MS, XRD/TEM, microbes/aflatoxins/pesticides), with GMP under Schedule T and pharmacopeial anchors (AFI/API). Controlled trials show excellent safety and modest, clinically meaningful efficacy; one multicentre Osteoarthritis (OA) study demonstrated equivalence to celecoxib or glucosamine, supporting equivalence non inferiority designs. Ayurvedic dosage forms are intentional formulation technologies that can be evaluated with contemporary drug delivery rigor through Quality Target Product Profiles (QTPPs) and Chemistry, Manufacturing and Controls (CMCs) stability and release testing, and clinically aligned specifications.

Keywords: Ayurveda dosage forms, drug delivery, HPTLC/HPLC, ICP MS, XRD/TEM, Schedule T GMP

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Introduction

Bhaishajya Kalpana known as Ayurvedic pharmaceutics organizes medicines into dosage forms with explicit rules for solvent choice, heat or cold process intensity and matrix design. Classical primers consistently describe the primary preparations like *Panchavidha kashaya Kalpana* included *Swarasa* (expressed juice), *Kalka* (paste), *Kwath* (decoction) prepared by water, quantity of water depends on hardness of the drug. Soft drug used 4 parts of water, hard drugs used 8 parts of water and very hard drug used 16 parts of water, reduced 1/8th of total quantity. *Hima* (cold maceration 1:6 overnight), and *Phanta* (brief hot infusion). These foundational extracts seed a wide array of secondary forms.[1,6] Secondary liquid platforms include *Tail* (oil), *Arka* (distillates), *Asava-Aarishta* (self-generated hydro alcoholic ferments using jaggery or sugar), and *Sneha* (medicated ghee/oil processed at ~1:4:16 *kalka: drava: Sneha* to empirically defined end points). *Ksheerapak* (Milk decoction in 1 part of drug 8 part of milk 32 part of water boiling till milk remains) *Kanjika* (Sour liquid made by fermentation grains and paddy), *Peya* (make thick decoction by boiling 1 part of cereals and 14 parts of water), *Manda* (make decoction of one part of rice or cereals and 14 parts of water), Modern pharmaceutics reviews and teaching materials align on these processes and on the classical rationale stability, palatability, dose accuracy and clinical adaptability.[2,3] Beyond liquids, authoritative sources enumerate semi solid (*Avaleha, Lehya, Rasakriya, Ghana, Malahara, Siktha taila,*

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Ghruta, lepa) and solid (*Churna, Vati, Gutika, Varti, Anjana, Kshara, Mashi, Lavaṇa, Pishti, Kupipakwa Parpati*) forms, plus gaseous (*Dhupana, Dhumapana*), all with reproducible stepwise logic e.g., *paka lakshan* for linctus sealed flask sand bath for *Kupipakwa* hot melt flaking for Parpati.[1,6,12] Contemporary analyses show these forms are amenable to orthogonal analytics by HPTLC/HPLC/GC–MS; ICP–MS; XRD/TEM; microbial, aflatoxin pesticide limits; rheology and dissolution creating a practical bridge to modern drug delivery science.[1,3,9]

Taxonomy and preparation logic [1-6]

Swarasa is freshly expressed juice (method adapted by drug texture) used directly and as a bhavana medium. *Kwath* (decoction) boils coarse powder with water (1:4/1:8/1:16) to one eighth, serving as a backbone for many secondary preparations. *Hima* (1:6 cold maceration overnight) preserves thermolabile and volatile constituents; *Phanta* (brief hot infusion) is suitable for mild extraction. *Arka* yields aromatic waters by distillation of soaked drugs. *Asava Aarishta* employ controlled fermentation of juices and decoctions with jaggery or sugar to generate ethanol that aids extraction, acts as a preservative and supports long shelf life; immediate QC hooks include detection of percentage of alcohol by distillation method or Gas chromatography (GC), pH by digital pH meter for acidity or alkalinity of formulations, specific gravity by pycnometer for concentration of dilution, sugar profile, and HPTLC/HPLC fingerprints with microbial/aflatoxin limits.[3]

Sneha means medicated oil or ghee prepared by cooking 3 things together *kalka: drava*: lipid (~1:4:16) to characteristic end points using traditional heating and classical signs. modern characterization adds peroxide value to check whether the oil has started spoiled or not. Fresh and stable oil indicates low value or anisidine indices measures secondary oxidation products show how much oil has degraded. Droplet size or vesicle size measures how much small particles of medicine are in the oil if better absorption in the body particles size is small and (PDI) Polydispersity index checked by instruments Dynamic light scattering (DLS) or Transmission Electron Microscopy (TEM) where relevant zeta potential for measure stability of particles, rheology understand spreading and absorption of oil and chemical markers.

Among semi solids, *Kalka* is a wet paste prepared by grinding fresh and dry drugs for internal and external use. Its fine particles are better absorption property, maximum therapeutic effect and breaks cell wall to release active constituents and maintain potency. *Avaleha* or *Lehya* are linctus dosage form cooked with sugar or jaggery act as preservative base, sugar concentration prevents microbial growth and paka lakshan *Rasakriya* or *Ghana* are concentrated extracts enabling dose sparing and tableting.[1,12,15] *Malahara* or *lepa* and Siktha taila are topical semi solids whose rheology, microbial quality, absorption, drug solubility and consistency can be specified as for ointments, creams and gels.

The solid dosage class includes *Churna* means mesh-controlled powders or granules, *Vati* and *Guti* includes tablet, pills, capsules form prepared with or without binders such as *guggul* or honey. Dissolution and disintegration readily defined accurate dosage and long shelf life, and *Varti* is solid wick shaped medicated preparation used for local application elongated units for rectal and vaginal mucosa. Additional engineered forms *Kshara* (alkalies from plant ash), *Mashi* (controlled carbonization), *Lavana* (salt-based composites via *Leha* and *Putapaka*), *Pishti* (fine triturates conditioned with liquids/light), and *Kupipakwa Parpati* (sealed flask sublimation/sintering; hot melt flaking) illustrate the breadth of classical unit operations. Gaseous forms *Dhupana* and *Dhumapana* mainly refers to medicated fumigation or smoke for purification and prevention purpose.[12,16]

Quality control and standardization

Cross form QC mirrors modern herbal pharmaceutics increasing demand for evidenced based standardization and quality control measures technique such as organoleptic macroscopic, microscopic, High performance liquid chromatography (HPLC) High performance thin layer chromatography (HPTLC), Gas Chromatography mass Spectroscopy (GC–MS), Fourier Transform Infrared Spectroscopy (FTIR) for identity, fingerprint assay; physicochemical indices (pH, ash, extractives); microbial and aflatoxin limits; pesticide residues; and, for mineral or metallic preparations, heavy metals by Inductively Coupled Plasm Mass Spectrometry (ICP–MS).[9] Form specific panels are well documented *Bhasma* means nanomedicine studied by X-ray diffraction (XRD) for phase composition and crystalline size

and structure, Transmission Electron Microscopy (TEM) determine exact particle size and internal structure by high resolution imaging, Scanning Electron Microscopy(SEM),Dynamic Light Scattering(DLS) studies surface morphology and size of nano particles, suspensions, ICP–MS (elements) with classical finesse tests recorded as heritage adjuncts;

Where applicable, the Ayurvedic Pharmacopoeia of India (API) and Ayurvedic Formulary of India (AFI) serve as statutory references under the Drugs and Cosmetics Act and Rules, while Schedule T codifies GMP for ASU medicines (premises, documentation, QC, storage).[10] The PCIM&H/PLIM act as national standard setting and testing bodies supporting pharmacopeial implementation. WHO guidance further harmonizes methods for herbal QC worldwide.[9,18]

Drug delivery parallels

Understanding drug delivery from both modern pharmacology and ayurvedic principles together simultaneously not replacing one with the other. *Sneha Kalpana* is lipid-based systems. Co processing drugs with ghee or oils anticipates LBDDS logic (lipophilic solubilization/stabilization, microstructural control, oxidative stability, and altered oral exposure resolvable by DLS/TEM, peroxide/anisidine, rheology, and biorelevant release).[2,3,6] For example medicated ghee works according to modern review stated enhance bioavailability, improves fat soluble drug absorption and lipid-based delivery system. Ayurvedic fundamental shows *yogavahi, rasayana, deepan* and *Srotoshodhana* property

Bhasma has micro or nano particulates. The *Shodhana-marana* sequence targets biocompatible, fine, lustreless particulates; modern appraisal fixes phase/size/elemental profiles by XRD/TEM/ICP–MS, then probes GI dissolution, uptake and toxicology. [11,14]

Asava and *Aarishta* is hydro alcoholic platforms. Self-generated ethanol, pH/SG, sugar matrix, and fingerprints together describe a codified hydro alcoholic system with preservation and permeation roles.[16] For *Avaleha* and *Vati* has matrix or sustained release strategies. Viscous linctus and compressed solids invite rheology guided exposure and disintegration or dissolution mapping using chemical markers paralleling sustained release and matrix tablets.[1,2,3]

A complementary personalization lens (Co.M.S.) framework maps physicochemical features of drug according to modern scientific properties such as heavy, light, oily, dry, hot, cold, stable, mobile etc. with five basic elements of *Mahabhutas prithvi, aap, tej, vayu, aakash* stated in Ayurveda. With the help of *Mahabhutas* and their qualities we understand guna and their effect on *tridoshas (Vata, Pitta, Kapha*). Specific effects of tridoshas on body predict therapeutic action of the drug. This framework generating hypothesizing constitution linked variability that means persons may respond differently to the same drug based on dosha dominant. This hypothesis scientifically connects drug chemistry with ayurvedic principles to understand personalized response but it complements not replaces, modern pharmacology Pharmacokinetics (PK) & Pharmacodynamics (PD).[5]

Evidence from controlled clinical studies[4]

Randomized, blinded and Good clinical trial (GCP) compliant trials have evaluated standardized polyherbal formulations in rheumatoid arthritis (RA) and osteoarthritis (OA). These studies used validated outcomes measures such as Western Ontario and Mc Master Universities Osteoarthritis index (WOMAC) which used questionnaire in patients. ACR core sets is standard method to check improvements in rheumatoid arthritis, pain Visual Analogue Scale (VAS) used to measurement of pain intensity. Active ingredients were standardized using HPLC and analyses were conducted using the intent to treat approach. Across studies, safety has been found to be excellent, with modest but clinically meaningful benefit. Notably, in a 24-week multicentre osteoarthritis trial, Ayurvedic formulations showed equivalence to celecoxib or glucosamine. Reductions in Rheumatoid factor (RF) titters and improvements in functional outcomes provide mechanistic plausibility to immunomodulatory and chondroprotective effects, which are consistent with the classical Rasayana concept.

These findings justify the use of equivalence or non-inferiority trial designs and support formal linkage between Chemistry, Manufacturing and Control (CMC) and clinic outcome linkage for examples, correlating Sneha microstructure (lipids vesicle size in sneha) with therapeutic outcomes or marker

guided dissolution rate studies with clinical performance correlate in future development.[15]

Translational roadmap and limitations[13]

Translational roadmap is the scientific pathway from classical knowledge and laboratory research to clinical validation and patient use. A rigorous QTPP/CMC per form should define acceptance ranges: *Sneha* (oxidation indices, microstructure, markers), Bhasma (phase/size/elements), *Asava* and *Aarishta* (alcohol %, pH/SG, fingerprints), and *Avaleha/Vati* (rheology, disintegration/dissolution with marker release), supported by stability data under ICH like conditions.[7,8,10] Study designs familiar to the broader pharmaceutics community randomized controlled or equivalence trials, powered and endpoint justified are already feasible.[4] Limitations remain several sources are narrative or educational useful for methods and taxonomy but not for analytic or efficacy claims, industry profiles are contextual; Co.M.S. personalization is interpretive pending empirical correlation of prakriti with outcomes/side effects, mechanistic complexity and regulatory gaps.[15]

Stability, packaging, and release testing practical guidance

Stability, release testing, and packaging of Ayurvedic dosage forms should be scientifically aligned with their physicochemical nature and therapeutic intent.

Semi solid dosage form such as Avaleha and Lehya monitor rheology regulatory checking and measuring the flow and Viscosity. (LOD) loss on drying or water content, HPTLC/HPLC markers, microbes and aflatoxins (accelerated/real time), following WHO herbal QC sampling.[2,3,9]

For *Vati* and *Gutika* requires disintegration time and dissolution profile, assay of active markers and stability, with hardness and friability scientifically correlate to marker guided dissolution to marker guided dissolution to maintain clinical consistency despite process variations.[2,3]

In *Sneha kalpana* oxidative stability must be controlled through peroxide and anisidine values, along with marker fingerprinting under light and temperature stress, if emulsified, droplet size analysis may be required, with documentation aligned to Schedule T GMP.[10]

For *Asava and Aarishta*, traditional fermentation parameters should be translated into measurable ranges such as alcohol percentage, pH, specific gravity, and chromatographic fingerprints, with batch records capturing mass balance, temperature logs, and daily Brix/pH monitoring, followed by microbial and aflatoxin limits[7,8,16].

Packaging systems should be selected based on the physicochemical nature of the dosage form *Avaleha* and *Vati* Require moisture-barrier containers to prevent hygroscopic degradation. *Sneha Kalpana* Require light-protective and oxygen-restrictive packaging to prevent oxidation. Asava and Aarishta Require chemically inert, airtight, and pressure-resistant containers. Container-closure integrity testing and stability compatibility studies should be conducted as per WHO recommendations. Proper labelling, storage instructions, and batch traceability are essential components of quality assurance. moisture barrier containers (*Avaleha and Vati*), light opaque and oxygen limiting vessels (*Sneha*), inert, pressure tolerant containers (*Asava* & *Aarishta*); WHO provides sampling and container closure guidance.[9]

Safety and compliance

Prioritize ICP–MS for elementals, validated HPTLC/HPLC for identity/impurities, and WHO style sampling plans; for *Bhasma*, include XRD (phase) and TEM/SEM/DLS (size/morphology) before dissolution/uptake/tox.[9,11] Align dossiers with API/AFI and Schedule T; note PCIM&H's role as central standards testing body to streamline regulatory dialogue.[19]

Conclusion

Viewed through a modern drug delivery lens, Ayurvedic dosage forms are intentional formulation technologies: lipidic solubilization and stabilization (*Sneha*), particulate engineering (*Bhasma*), hydro alcoholic extraction/permeation (*Asava– Aarishta*), and matrix mediated exposure (Avaleha and Vati). With orthogonal analytics, explicit QTPPs anchored to API/AFI, and equivalence grade trials aligned to Schedule T/PCIM&H practice, these systems can be evaluated with the same rigor as contemporary platforms; a disciplined personalization layer may be explored without displacing conventional pharmacology. [17,18] Future research should integrate classical ayurvedic pharmaceuticals with modern analytical pharmaceuticals with modern analytical and regulatory frameworks to strengthen dosage form validation, personalization and global acceptance.

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