FSSAI & Ayush GMP
Basic Compliance Action Plan

A consolidated checklist for Food Business Operators under FSSAI Schedule 4 and Ayush GMP Rules 2008 (amended). Also covers nutraceutical, health supplement, functional food, and Ayurvedic / Siddha / Unani (ASU) drug manufacturers.

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Key: Standard rows apply to all FSSAI-licensed FBOs. **Amber rows** are Ayurveda/ASU-specific requirements under Ayush GMP Rules 2008.

1. Location & Surroundings

Applies to all FBOs (Parts I–V) and all ASU manufacturers. Physical location must meet hygiene and safety conditions before operations begin.

Area	Requirement	Action Items
Pollution-Free Zone	Unit must be away from smoke, chemical fumes, offensive odours, industrial pollutants, and chemical hazards	Scout sites away from industrial areas, garbage dumps, heavily polluted roads, and chemical storage zones; photograph surroundings within 50 m
Flood / Water Risk	Premises must not be prone to flooding or stagnant water accumulation	Check municipal flood maps; ensure adequate drainage and elevation before signing any lease
Sanitary Surroundings	No proximity to open drains, sewage lines, or pest breeding grounds	Conduct site visit checklist before signing; record and photograph all surroundings
Adequate Space	Enough room for people and equipment movement to avoid cross-contamination	Plan floor layout in advance - physically separate raw, processing, packaging, and finished goods zones
Internal Roads & Access	Good internal roads and access paths for material movement and emergency vehicles	Ensure paved/concrete roads within premises; maintain clear emergency exit routes and signage

2. Building & Facility Design

Covers building construction, floor plan, and physical zones. Critical for GMP and ASU drug manufacturing compliance.

🟡 **Amber rows** indicate Ayurveda/ASU-specific requirements beyond standard FSSAI Schedule 4.

Area	Requirement	Action Items
Walls, Floors, Ceilings	Must be smooth, non-absorbent, washable, damp-free, and free from flaking paint or plaster	Use ceramic tiles or food-grade epoxy coating; inspect and repair cracks annually; maintain a repair log
Unidirectional Flow	Materials and personnel must flow in one direction to prevent cross-contamination (Part II)	Design layout: Receiving → Storage → Prep → Processing → Packaging → Dispatch; mark flow with floor arrows
Zone Segregation	Dedicated areas for raw material, processing, packaging, quarantine, and storage	Use physical partitions or separate rooms; colour-coded floor markings; post zone-entry rules at entrances
Quarantine Area	Separate locked area for raw materials and finished goods awaiting QC release	Designate quarantine bay with 'HOLD' labels; only QC-authorised staff may release items to production
Drainage System	Efficient drains with grease traps to prevent clogging and sewage backflow	Install floor drains with wire mesh covers; clean grease traps weekly; ensure flow away from food areas
Ventilation & Lighting	Exhaust fans and shatter-proof lighting mandatory; HEPA filters recommended for nutraceuticals	Install exhaust fans in processing areas; use shatter-proof tube lights; maintain lux level log (min 220 lux)
Doors & Windows	Fitted with insect-proof screens; self-closing doors at entry to production zones	Install insect-proof mesh (max 1.5 mm); use self-closing or air-curtain doors; seal gaps <10 mm at floor level

Area	Requirement	Action Items
Ayurvedic / ASU - Additional Zone Requirements (Ayush GMP Rules 2008)		
Pulverizing / Grinding Section	Dedicated room for pulverizing and grinding - must have dust extraction system to prevent cross-contamination and fire hazard	Install dust extraction / cyclone separator in grinding room; close-circuit grinders preferred; validate cleaning between products
Extraction / Decoction (Kashayam) Area	Separate area for aqueous and solvent-based extraction; must be ventilated and heat-resistant	Use SS-lined extraction vessels; install ventilation hoods; record temperature, time, and solvent volumes in BMR
Fermentation Area (Asava / Arishta)	Separate, temperature-controlled fermentation room; no cross-contamination with other dosage forms	Maintain fermentation room at 25–30°C; use certified earthen or SS vessels as per AFI; log fermentation progress daily
Bhasma / Kupipakwa Section	Separate, clearly demarcated area for metallic/mineral processing; strict containment required	This section requires dedicated personnel trained in Rasa Shastra; install fume hoods; document every incineration stage
Taila / Ghrita (Medicated Oil/Ghee) Section	Dedicated heating and filtration area for oil and ghee-based preparations; fire safety mandatory	Use stainless steel jacketed boilers; install fire extinguishers nearby; filter finished product before filling; log temperatures
Tablet / Churna / Capsule / Syrup Sections	Separate rooms or clearly demarcated areas for each solid and liquid dosage form	Prevent powder carry-over between Churna and Tablet sections; use air locks where feasible; document line clearance

3. Equipment & Utensils

All equipment must be stainless steel, rust-free, calibrated regularly, and cleaned per SOPs. Ayurvedic manufacturing requires specialised equipment for each dosage form.

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Area	Requirement	Action Items
Food-Grade / Drug-Grade Materials	All product-contact surfaces must be non-toxic, rust-free, non-reactive (SS316 preferred); no crevices that trap residue	Audit all equipment; replace reactive surfaces; obtain supplier certificates; inspect for dead spots weekly
Equipment Placement	Equipment must be placed away from walls for easy cleaning and inspection access	Ensure minimum 30 cm gap from walls/floor; include in facility layout plan; document in plant SOP
Calibration Records	Weighing scales, thermometers, and process instruments must be calibrated periodically	Set up calibration schedule (quarterly minimum); log date, result, and technician sign-off
Maintenance Records (PPM)	Planned Preventive Maintenance schedule to be maintained for all critical equipment	Create Equipment Maintenance Log per machine; track breakdown history; maintain spare parts inventory
Dedicated Equipment for High-Risk	Separate dedicated equipment required for allergens, probiotics, or high-potency ingredients	Label equipment clearly (e.g., 'Allergen Only'); verify cleaning before changeover; document in BPR
A. Herbal Preparation Equipment (Ayurveda-specific)		

Area	Requirement	Action Items
Pulverizers, Grinders & Sifters	Pulverizers, grinders, and sieving machines required for Churna and raw herb processing	Use SS-lined pulverizers; install mesh sievers of appropriate size per AFI spec; clean and validate between different herbs
Extraction Tanks & Boiling Vessels	SS extraction tanks, steam-jacketed boiling vessels, and filter presses for Kwath/Kashayam	Size vessels to batch requirements; maintain temperature logs; inspect gaskets and seals monthly
Filter Presses & Centrifuges	Required for clarification of extracts, decoctions, and liquid formulations	Validate filter pore size per product spec; log filtration parameters in BMR; clean and inspect filter cloths after each use
Fermentation Tanks (Asava / Arishta)	SS or approved earthen vessels for fermentation; temperature-monitored environment required	Record vessel material and capacity in Master Equipment List; log fermentation period, temperature, and specific gravity daily
B. Solid Dosage Form Equipment (Tablets, Churna, Capsules)		
Tablet Compression & Coating Machines	Tablet machines, capsule fillers, powder mixers, and coating apparatus as applicable	Qualify all tablet machines (IQ/OQ/PQ); maintain punch/die records; validate coating parameters per product
Powder Mixers & Blenders	High-shear and ribbon blenders for uniform Churna and granule blending	Validate blend uniformity (RSD ≤5%); document mixing speed, time, and load in BMR
C. Taila / Ghrita (Medicated Oil/Ghee) Equipment		
Heating Pans & Boilers	Heavy-duty SS heating pans with temperature control for Sneha-Siddhi process	Install calibrated temperature probes; log heating curve (Snehapaka stages) in BMR per AFI method
Filtration Units	Multi-stage filtration units to clarify medicated oils and ghee-based preparations	Use appropriate filter grades; collect and retain filtrate samples; clean and sanitise after each batch

4. Raw Material Standards & Control

Covers approved vendor management, incoming QC, and storage protocols. Ayurvedic raw materials have additional classical identification and purification requirements under Ayush GMP Rules.

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Area	Requirement	Action Items
FSSAI / Ayush-Registered Vendors Only	All raw materials must be purchased from FSSAI-registered or Ayush-approved suppliers	Collect FSSAI/Ayush licence copies of all vendors; review annually; maintain an Approved Vendor List (AVL)
Certificate of Analysis (COA)	COA required for each batch of vitamins, minerals, botanicals, amino acids, and actives	Create a COA Review SOP; QC officer to verify COA against product spec before GRN is raised
Incoming Temperature Check	Chilled items at ≤5°C; frozen at ≤-18°C; temperature-sensitive actives per supplier specification	Use infrared thermometer at loading bay; log temperatures in delivery register; reject non-compliant lots
Expiry Date Verification	Incoming materials checked for expiry; minimum 70% shelf life remaining at receipt	Train staff to reject items with <70% shelf life remaining; record in GRN form; QC to approve all incoming lots

Area	Requirement	Action Items
FIFO / FEFO	Always rotate stock: First-In-First-Out or First-Expiry-First-Out	Label all incoming stock with receipt date; train staff to pick from front; conduct weekly stock audits
Pallet & Rack Storage	Ingredients on racks 15 cm off floor and 30 cm from walls (Parts I, II, WH)	Purchase food-grade pallets; label racks with product category and storage conditions
Allergen Segregation	Allergen-containing materials (soy, dairy, tree nuts, gluten) stored separately	Designate labelled allergen bays; use physical barriers; never store allergens above non-allergen items
Temperature-Controlled Storage	Probiotics, omega oils, and heat-sensitive ingredients stored at defined temperature and humidity	Install temperature/humidity data loggers; set alarm thresholds; review logs daily
A. Herbal / Botanical Raw Materials (Ayurveda-specific)		
Botanical Identification	Every herbal raw material must be botanically identified by microscopy, morphology, and/or TLC before use	Maintain a Botanical Reference Library; train QC botanist; reject any lot that cannot be identified to species level
Adulterant-Free Verification	Raw herbs must be free from adulterants, substitutes, and foreign matter	Conduct foreign matter test per API/AFI method; retain reference samples of each lot; file test reports
Pesticide & Contaminant Testing	Herbal materials must pass tests for pesticide residues, heavy metals, aflatoxins, and microbial load	Define limits per API/WHO guidelines; test from each new vendor and periodically; reject lots failing limits
B. Mineral / Metallic Raw Materials - Rasa Shastra		
Shodhana (Classical Purification)	Mineral and metallic raw materials must undergo classical Shodhana (purification) before use in Bhasma, Sindoor, or Kupipakwa preparations	Follow procedures specified in Rasa Tarangini / API; document every Shodhana step with quantities, time, and temperature in a dedicated log
High-Caution Minerals	Extra caution required for Parada (Mercury), Gandhaka (Sulphur), Sisaka (Lead), and compounds used in Bhasma and Kupipakwa Rasayana	Dedicated trained Rasa Vaidya/chemist must supervise; test finished Bhasma for particle size and elemental analysis; maintain batch records indefinitely
Stage-by-Stage Documentation	Every stage of mineral/metallic processing must be documented: Shodhana → Marana → Amritikarana → QC release	Create a Rasa Shastra Batch Processing Record (separate from standard BMR); photos of each stage recommended for audit trail
C. Packaging Materials		
Inert, Non-Reactive Packaging	Packaging must be inert, non-reactive, and suitable for Ayurvedic formulations (glass, HDPE, PET, amber bottles)	Test packaging compatibility with product (especially oils and acidic decoctions); obtain material safety certificates from vendor

5. Water, Steam & Utility Requirements

Safe water is foundational across all parts of Schedule 4 and Ayush GMP Rules. Critical for formulations, decoctions, extractions, and CIP/SIP.

Area	Requirement	Action Items
Potable Water Only	All water used for food prep, formulation, and cleaning must be potable - IS 10500 standard	Get water tested at NABL-accredited lab every 6 months; display certificates on-site; maintain test records
Purified / Process Water	RO/UV-treated water recommended for syrups, extracts, critical formulations (Purified Water standard)	Install RO + UV purification system; test conductivity and microbial counts daily; maintain batch water quality log
Separate Labelled Pipelines	Treated and untreated water pipelines must be separate, colour-coded, and labelled at every junction	Use blue for potable, green for treated/process water; inspect for cross-connections annually
Water Source Records	Document and verify source; borewell water requires annual municipal approval	Maintain water quality logbook; record all test results with lab reports
Steam Quality	Steam used in processing must be food-grade; no toxic boiler additives	Use only food-grade boiler additives; test steam condensate annually; document and file results

6. Personal Hygiene & Health of Workers

Applies across all parts. One of the most audited areas during FSSAI/Ayush inspections. Ayurvedic manufacturing adds specific requirements for workers handling mineral and metallic preparations.

🟡 **Amber rows** indicate Ayurveda/ASU-specific requirements beyond standard FSSAI Schedule 4.

Area	Requirement	Action Items
Medical Fitness Certificate	Mandatory annual medical exam for all food/drug handlers; must cover communicable diseases (Part II)	Coordinate with a local clinic; maintain fitness certificate file per employee; update annually
Protective Gear	Aprons, gloves, hairnets, and clean uniforms mandatory in all production zones	Issue uniforms on Day 1; conduct daily uniform checks before shift start; maintain spare sets
No Jewellery / Accessories	No jewellery, watches, strong perfumes, or mobile phones in production areas	Add jewellery and mobile-check to pre-shift inspection routine; document in shift supervisor checklist
Handwashing Protocol	Hands washed with soap for at least 20 seconds before work, after toilet, and after handling waste	Install touch-free taps near each workstation; post visual reminder posters; conduct handwash audits monthly
Health Status / Illness	No person with infectious disease, open wounds, or skin infections should handle food/drugs	Maintain daily health register; train supervisors to identify illness symptoms; create 'return to work' clearance process
Vaccination	Staff vaccinated against enteric diseases (Typhoid, Hepatitis A) - Part II	Coordinate annual vaccination camps; maintain vaccine records per employee
Prohibited Acts	No smoking, spitting, chewing tobacco, or eating in production areas	Display 'No Smoking/Eating' signage in all production zones; include in onboarding induction
Beard Cover (Ayurveda)	Workers with beards must wear beard covers in all processing and filling areas - especially during herbal powder and Churna manufacturing	Include beard covers in PPE kit; add to daily uniform checklist; enforce in herbal powder, Churna, and Bhasma sections
Special PPE for Rasa Shastra	Workers handling mercury, sulphur, lead compounds, or other toxic minerals must wear N95 masks, chemical-resistant gloves, and eye protection	Provide dedicated PPE for Rasa Shastra section; train workers on safe handling, MSDS review, and decontamination procedures

Area	Requirement	Action Items
No Sick Workers Near Minerals	Workers with cuts, skin diseases, or respiratory illness must not handle metallic/mineral preparations	Strict daily health screening for Rasa Shastra section workers; maintain a separate exclusion register

7. Manufacturing & Process Control

All manufacturing must follow GMP (FSSAI Schedule 4 / Ayush GMP Rules 2008). Ayurvedic manufacturing must additionally follow classical steps as per Ayurvedic Formulary of India (AFI) or Pharmacopoeia of India (API).

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Area	Requirement	Action Items
GMP-Compliant Manufacturing	All manufacturing must follow Good Manufacturing Practices per FSSAI Schedule 4 Part II / Ayush GMP Rules 2008	Develop a GMP manual; conduct internal GMP audits quarterly; correct findings within 30 days; file audit reports
Batch Manufacturing Record (BMR)	BMR prepared and reviewed for each production batch - formula, quantities, process steps, in-process checks	Standardise BMR templates per product; QC manager to review and sign off before batch release
Batch Packing Record (BPR)	BPR compulsory for all packaging operations - material reconciliation and label details	Create BPR templates; include line clearance, coded artwork details, and label reconciliation
Cross-Contamination Controls	Strict controls for herbal extracts, probiotics, high-dose vitamins, allergens, and metallic preparations	Implement equipment change-over cleaning verification; use dedicated lines where feasible; apply line clearance SOPs
In-Process Checks (IPC)	In-process quality checks at critical stages - blend uniformity, granule size, fill weight, pH	Define IPC parameters per product; train QC staff; define action limits and rejection criteria
Process Validation	Critical processes (blending, compression, encapsulation) must be validated	Create Process Validation Master Plan; execute 3-batch validations for new products; re-validate after major changes
Yield & Reconciliation	Material reconciliation and yield calculation must be done at end of each batch	Calculate theoretical vs actual yield; investigate variances >2%; document findings and corrective actions in BMR
Ayurvedic / ASU - Classical Process SOPs (Ayush GMP Rules & AFI / API)		
Churna Preparation SOP	Churna preparation must follow classical procedure: grinding, sieving, mixing in defined proportions per AFI/API	Create product-specific Churna SOP citing AFI/API reference; validate particle size (mesh 80); document each step in BMR
Kwath / Kashayam Preparation SOP	Decoction prepared per classical ratio (e.g., 1:4 herb to water, reduced to 1/8th) as per AFI/API specification	Define water quality, heating time, and concentration parameters in SOP; validate pH and specific gravity; record in BMR
Sneha-Siddhi (Oil / Ghee) SOP	Medicated oil/ghee prepared per classical Snehapaka method - Mrudu, Madhyama, or Khara Paka stages as per formulation	Document Paka stage indicators in SOP (water bead test, smell, colour); validate by specific gravity; record temperature curve in BMR
Bhasma Preparation SOP	Bhasma prepared by classical Marana process - multiple incineration cycles in Musha/Kupipakwa as per API	SOP must cite API method; document number of Puta (incineration cycles), temperature, and weight; test Bhasma by Rekhapurnata, Varitaratwa, and Apunarbhava tests

Area	Requirement	Action Items
Asava / Arista Fermentation SOP	Fermentation process per AFI specification - correct alcohol content (5–10%) must be achieved; fermentation period defined	Log specific gravity and alcohol content at intervals; use a certified hydrometer; seal vessels during fermentation; test final product per AFI
Tablet / Capsule / Syrup SOPs	Additional classical Ayurvedic tablet (Gutika), suspension, and syrup SOPs required alongside standard pharmaceutical SOPs	Create product-specific SOPs citing classical texts + modern GMP requirements; validate disintegration and dissolution where applicable

8. Cleaning & Sanitation

A structured Cleaning & Sanitation (C&S) plan is mandatory for all licensed operations. Ayurvedic facilities must also address herbal residue and mineral/metallic contamination.

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Area	Requirement	Action Items
Cleaning Schedule	Documented schedule covering frequency, chemicals used, and responsible person per area (Part II)	Create area-wise C&S Schedule template; shift supervisor to sign off daily; QC to audit compliance monthly
Approved Food/Drug-Safe Chemicals	Cleaning chemicals must be food/drug-safe, properly diluted, and stored separately from product areas	Maintain list of approved chemicals with SDS; provide measuring cups for dilution; no harsh chemicals near product
Equipment Cleaning SOPs	Specific cleaning SOPs for each equipment type; CIP (Clean-in-Place) where applicable	Develop equipment-specific cleaning SOPs; QC to verify via swab testing after changeovers
Cleaning Verification	Cleaning effectiveness verified - especially before allergen or product changeovers	Conduct ATP swab tests after cleaning; maintain swab test logs; define acceptance criteria
Waste Bins & Production Waste	Foot-operated bins lined with bags; garbage removed frequently to prevent contamination	Schedule waste removal at least 3 times per shift; log all disposal times
Cleaning Chemical Storage	Cleaning chemicals stored in a separate, labelled, locked area away from product ingredients	Designate locked chemical store; label all containers with name, concentration, and hazard symbols
Herbal Residue & Powder Accumulation	Prevent accumulation of spilled herbs, powders, or plant materials in processing areas - fire and contamination hazard	Sweep and vacuum herbal residue after every batch; use explosion-proof vacuum in grinding areas; document cleaning in area log
Mineral / Bhasma Section Decontamination	After processing mercury, lead, or sulphur compounds, all equipment and surfaces must be decontaminated per MSDS protocol	Use certified neutralising agents per MSDS; dispose of contaminated cleaning waste as hazardous material; train cleaning staff on mineral decontamination

9. Pest Control

All units must prevent pest entry and maintain documented pest management records. Ayurvedic raw herb stores are particularly high-risk for pest infestation.

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Area	Requirement	Action Items
Physical Exclusion	Windows and doors fitted with mesh screens; door gaps <10 mm (Parts I, WH)	Install insect-proof mesh (max 1.5 mm); use door sweepers; seal cracks in walls and floors
4Ds Principle	Deny entry, Deny shelter, Deny food, Destroy - integrated pest management (Part II)	Walk through all potential pest entry/shelter points; remove clutter; seal gaps; eliminate food/herb debris after each shift
Rodent Traps, Insect Zappers & Glue Pads	Placed strategically around the facility at all entry points and storage areas	Create a Pest Map showing placement of all traps/zappers; inspect weekly; record findings and replacements
Professional AMC	Annual Maintenance Contract with a licensed pest control agency required	Hire certified pest control vendor; schedule quarterly treatments; file treatment reports and chemicals used
Chemical Storage	Pest control chemicals stored in a separate, locked area away from product areas	Designate locked chemical storage room with MSDS labels; never store pest chemicals in food/drug production zones
Pest Control Records	Documented records of inspection, treatment, monitoring, and sighting reports	Maintain Pest Control Register with dates, chemicals, areas treated, sighting reports, and inspector sign-off
No Spraying During Production	Pesticide spraying is strictly prohibited inside processing rooms during production hours	Schedule all chemical pest treatments outside of production hours (overnight or weekend); ventilate thoroughly before resuming production; document in pest control register
Herb Store Pest Protection	Raw herb stores are especially vulnerable to weevils, rodents, and moths - heightened monitoring required	Inspect herb store weekly; use pheromone traps for moth/weevil; store dried herbs in sealed SS/food-grade containers; fumigate if infestation detected

10. Waste Management

Covers removal, segregation, and legal disposal of food, drug, and industrial waste. Rasa Shastra mineral waste is classified as hazardous and requires licensed disposal.

🟡 **Amber rows** indicate Ayurveda/ASU-specific requirements beyond standard FSSAI Schedule 4.

Area	Requirement	Action Items
Covered, Colour-Coded Bins	Waste bins must be covered, food/drug-grade, and colour-coded for different waste streams	Green = organic/wet; Blue = dry/recyclable; Red = hazardous/condemned; use foot-pedal bins in all areas
Daily Removal	Waste removed daily from production premises (Part II)	Schedule daily waste pickup; display waste removal log in waste storage area; supervisor to sign
Wet / Dry Segregation	Waste segregated into wet (organic) and dry (recyclable/non-recyclable) streams	Install colour-coded bins at every workstation; train all staff on segregation rules; supervisor to verify
No Accumulation Near Production	No accumulation of waste near production area at any time	Waste bins emptied when 2/3 full; supervisor to conduct spot checks; document findings
Pollution Board Compliance	Disposal must comply with local Pollution Control Board rules; hazardous waste requires licensed vendor	Tie up with registered waste disposal contractor; collect and file waste disposal receipts
Condemned / Expired Material	Rejected or expired materials and finished goods disposed of per FSSAI/Ayush condemned goods protocol	Use sealed, labelled containers for condemned items; arrange licensed vendor pickup; maintain condemned goods register

Area	Requirement	Action Items
Herbal Waste Disposal	Used plant material, spent herbs, and extraction residues must be disposed of safely - not mixed with general waste	Arrange bio-waste composting or licensed organic waste contractor; do not dump spent herbs near water sources or drains
Mineral / Rasa Shastra Waste	Waste from mercury, lead, arsenic, sulphur, and other metallic/mineral processing is classified as hazardous under Hazardous Waste Management Rules	Engage a CPCB-authorised hazardous waste disposal agency; maintain disposal manifests; never mix mineral waste with general or biological waste; file annual hazardous waste returns with State PCB
Used Filters & Packaging Waste	Used filter cloths, muslin bags, and packaging waste from Ayurvedic production must be disposed of separately	Collect used filters and packaging waste in designated labelled bags; arrange periodic collection by licensed recycler

11. Storage & Warehouse

Covers FIFO/FEFO, cold chain, and specific storage conditions for Ayurvedic raw materials, oils, and finished goods.

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Area	Requirement	Action Items
FIFO / FEFO Compliance	First-In-First-Out or First-Expiry-First-Out must be followed at all times	Label incoming stock with receipt date; train staff to pick from front; conduct weekly stock rotation audits
Temperature-Controlled Storage	Temperature-sensitive materials (probiotics, omega oils, heat-sensitive actives) stored at defined conditions	Install temperature/humidity data loggers; set alarm thresholds; calibrate sensors quarterly; review logs daily
Finished Goods Protection	Finished goods protected from dust, pests, moisture, and physical damage during storage	Use sealed cartons; store on pallets off the floor; inspect storage area daily; do not stack beyond safe limits
Vehicle Hygiene	Delivery vehicles must be clean, food/drug-grade, and free from contamination; no mixing with non-food goods	Inspect vehicles before loading; maintain vehicle cleaning log; use dedicated vehicles where possible
Pallet & Rack Standards	Food/drug-grade pallets; 15 cm from floor and 30 cm from walls; no direct floor contact	Label racks with product category and storage conditions; check rack integrity monthly
Herb Storage - Odour & Moisture Control	Dried herbs must be stored away from strong odours, moisture, and direct sunlight; segregated by botanical identity	Use sealed SS or food-grade containers with desiccants where needed; label with botanical name and lot number; separate aromatic herbs from moisture-sensitive herbs
Oil / Ghee Temperature Control	Medicated oils and ghee-based products must be stored at cool, controlled temperature to prevent rancidity	Store Taila and Ghrita products below 25°C; away from light; use amber or opaque containers; conduct periodic rancidity tests
Segregated Storage - Raw, Processed, In-Process, Finished	Separate, clearly labelled storage areas for raw material, in-process, processed, and finished goods (Ayush GMP Rule requirement)	Use physical partitions, separate rooms, or clearly marked zones with access controls; maintain a storage area register

12. Quality Control & Lab Testing

Every ASU unit must maintain a QC department. Records must be retained for at least 5 years (Ayush GMP) or shelf life + 1 year (FSSAI), whichever is longer.

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Area	Requirement	Action Items
Raw Material Testing	All raw materials tested for purity, potency, microbiological limits, and contaminants before use	Create raw material testing matrix; QC to sample each incoming lot per sampling plan; release only after COA and test pass
In-Process Samples	In-process quality checks at critical stages - blend uniformity, pH, moisture, fill weight	Define IPC parameters in BMR; train QC staff; define rejection limits and corrective actions
Finished Product Testing	Finished product tested for purity, potency, microbiological limits, heavy metals, and contaminants	Create finished product specification sheet per product; test every batch; retain samples for shelf-life period + 1 year
Microbiological Testing	Total Plate Count (TPC), Yeast/Mould, E. coli, Salmonella testing per FSSAI standards	Establish in-house micro lab or tie up with NABL-accredited lab; define acceptance criteria per product category
Heavy Metals Testing	Lead, Arsenic, Mercury, Cadmium limits to be met - especially for herbal and mineral products	Test from new vendors and every 6 months for recurring vendors; reject if limits exceeded; maintain all records
NABL Accredited Lab	External NABL-accredited lab mandatory where in-house lab is not available; mandatory for label claims	Identify nearby NABL lab; schedule semi-annual testing calendar; file all reports against batch records
Stability / Shelf Life Testing	Products must be supported by stability data justifying claimed shelf life	Conduct accelerated and real-time stability studies per ICH Q1A guidelines; review results to set shelf life and storage conditions
Retain Samples	Retain samples from each batch for shelf life period + 1 year for traceability and dispute resolution	Set up labelled retain sample library; log batch number, date, and quantity; review retention policy annually
Ayurvedic / ASU - Additional QC Tests		
Foreign Matter Test	Herbal raw materials tested for foreign matter (sand, soil, insect parts, non-botanical matter) per API/AFI method	Perform foreign matter test on each lot per API procedure; define acceptance limit (<2% by weight); record in RM QC report
Microscopy Identification	Botanical identity confirmed by microscopy (cell morphology, starch granules, calcium oxalate crystals etc.)	Train QC staff in botanical microscopy; maintain reference slides; document microscopy findings with photographs in RM QC register
pH & Specific Gravity (Liquids)	pH and specific gravity tested for all liquid formulations - Kashayam, Arishta, Asava, Syrup, Tailam	Test pH and SG of each batch; define acceptance range per AFI/API specification; record in finished product QC report
Particle Size (Churna / Powders)	Particle size and mesh compliance tested for all Churna and powder formulations	Use standard mesh sieves as per API/AFI spec; test each batch; record % passing through defined mesh size in QC report
Alcohol Content (Asava / Arishta)	Alcohol content of Asava and Arista must be tested - acceptable range: 5–10% v/v per API	Use a calibrated alcohol meter / distillation method; test each batch; reject if outside 5–10% range; record in QC report

Area	Requirement	Action Items
Disintegration / Hardness / Friability (Tablets)	Weight variation, friability, hardness, and disintegration tests for all tablet formulations (classical or modern)	Test per API/IP method; define acceptance limits in product spec; test every batch; record in finished product QC report
Moisture Content	Moisture content tested for all powders, Churna, and dry herbal extracts to prevent microbial growth	Use Karl Fischer titration or LOD method; define limit per product spec; test each batch; reject if moisture exceeds limit
Bhasma Quality Tests	Bhasma tested for Rekhapurnata (fineness), Varitaratwa (floatability), Apunarbhava (irreversibility), and elemental composition by ICP-MS or XRF	Set up or outsource Bhasma-specific QC tests; retain Bhasma samples indefinitely; obtain elemental analysis for each batch from NABL lab

13. Documentation & Records

Records must be maintained for at least 5 years (Ayush GMP) or product shelf life + 1 year (FSSAI), whichever is longer. All documents must be version-controlled and available for audit.

🟡 **Amber rows** indicate Ayurveda/ASU-specific requirements beyond standard FSSAI Schedule 4.

Area	Requirement	Action Items
SOPs	Written SOPs for all key activities - production, QC, cleaning, hygiene, pest control, distribution	Create SOP library with version control; review and reapprove annually; train staff on SOP changes
Quality Policy & Quality Manual	Documented quality policy signed by senior management; Quality Manual covering all GMP systems	Draft quality policy; get MD/CEO sign-off; keep current version displayed; review annually
Batch Manufacturing & Packing Records (BMR/BPR)	BMR and BPR compulsory for each batch; reviewed and approved by QC before batch release	Standardise templates per product; QC manager to review and sign; archive for product shelf life + 1 year (min 5 years for ASU)
Cleaning Schedules	Documented cleaning schedules with frequency, chemicals, and responsible person per area	Create area-wise C&S schedule; supervisor to sign daily; QC to audit compliance monthly
Calibration Records	Calibration logs for all instruments - weighing scales, thermometers, pH meters, data loggers	Set up calibration schedule (quarterly); log date, result, and technician; label instruments with 'next due' stickers
Pest Control Records	Register of all pest control inspections, treatments, chemicals used, and findings	Maintain Pest Control Register; file vendor AMC reports; schedule and record all monitoring activities
Supplier Approval Documents	Vendor qualification records including FSSAI/Ayush licence, COA, and audit reports	Maintain Approved Vendor Master with all documents; re-qualify annually; document vendor quality issues
Equipment Maintenance Logs	Preventive maintenance records for all critical equipment	Create PPM schedule per machine; log all maintenance; track breakdown history and root cause analysis
Training Records	Attendance registers and competency records for all training sessions	Maintain Training Register per employee; include topic, date, trainer, and sign-off; archive for 3 years minimum

Area	Requirement	Action Items
Master Formula Record (MFR)	Master Formula Record for each product must contain: product name, batch size, all ingredients with quantities, classical reference (AFI/API), and complete manufacturing steps	Create MFR for every product before first commercial batch; MFR is the template for BMR; QC Head must approve and sign MFR
Raw Material Inward Register	All incoming raw materials to be logged in a dedicated RM Inward Register with: supplier, lot number, quantity, COA reference, and QC disposition	Maintain a physical or digital RM Inward Register; cross-reference with GRN and COA; QC to countersign each entry
Deviation & Change Control Records	Any deviation from SOPs or BMR must be documented, investigated, and closed; changes to processes or formulas require Change Control	Create a Deviation Log and Change Control Register; QA Head to review and approve all deviations; close within 30 days with CAPA
Distribution Records	Records of where each batch has been dispatched - essential for effective recall and traceability	Maintain batch-wise dispatch records with distributor/retailer name, quantity, and invoice number; retain for minimum 5 years

14. Recall & Complaint Handling

Mandatory for all licensed FBOs. Traceability must be maintained from raw material to end consumer. Consumer complaints must be investigated and closed.

Area	Requirement	Action Items
Batch Traceability System	Each batch must be traceable from raw material to finished product to end consumer	Implement batch coding; maintain production batch records, GRN, and dispatch logs; link RM lots to FG batches
Recall SOP	Documented Product Recall SOP for rapid recall of unsafe food/drug from the market (Part II)	Draft Product Recall SOP; identify recall team, contact list, and distribution records; test with mock recall annually
Mock Recall Exercise	Recall procedure must be tested through a mock recall at least once per year	Conduct mock recall drill; record time to trace and account for 100% of a batch; document findings and improve process
Consumer Complaint Log	All consumer complaints related to quality or safety must be recorded and investigated with full investigation report	Create complaint log with severity classification; investigate and close all complaints within 30 days; trend monthly; report serious complaints to Ayush/FSSAI if required
Finished Product Testing for Release	Products tested in NABL-accredited lab; results must be available before batch release	Schedule semi-annual product testing; ensure batch is held until test results are satisfactory
eCommerce Recall Integration	For e-commerce operations, recall systems must flag and block affected batches in WMS/OMS instantly	Integrate recall flag in WMS so affected SKUs are auto-blocked at checkout and dispatch; notify platform partners

15. Training & Competency of Personnel

Comprehensive and documented training is the backbone of GMP and ASU drug manufacturing compliance. Ayurvedic manufacturing requires additional training in herb and mineral safety.

🟡 **Amber rows** indicate Ayurveda/ASU-specific requirements beyond standard FSSAI Schedule 4.

Area	Requirement	Action Items
Induction Training	All new staff must receive induction training before starting work (Part II)	Create induction module covering GMP, personal hygiene, food safety, allergens; maintain attendance register
GMP Training	Staff trained in Good Manufacturing Practices relevant to their role	Conduct role-based GMP training on joining and annually; test comprehension; remediate failures with re-training
Personal Hygiene & Contamination Control	Training on hygiene practices, handwashing, protective gear, and contamination prevention	Schedule quarterly refresher sessions; include practical demonstrations; document attendance and assessment scores
Allergen Management Training	All production and QC staff trained on allergen cross-contamination risks and controls	Conduct dedicated allergen training annually; test with scenario-based assessment; update if product range changes
Refresher Training	Periodic refresher training on food safety: cleaning, allergens, temperature, hygiene	Schedule quarterly refreshers; cover one theme per session; track pass rates; re-train failures
Food Safety Supervisor (FSS)	1 certified Food Safety Supervisor required for every 25 food handlers (Part V)	Send eligible staff for FSSAI-approved FSS certification; display certificate prominently; renew as required
Training Records	Attendance registers and competency records for all training sessions must be maintained	Maintain Training Register per employee; include topic, date, trainer, and sign-off; archive for minimum 3 years
Safe Handling of Herbs & Botanicals	Training in correct identification, handling, storage, and cross-contamination prevention for herbal raw materials	Conduct herb identification training with reference samples; include in onboarding for all production/QC staff in herb sections
Safe Handling of Minerals & Metals (Rasa Shastra)	Workers in Bhasma and Kupipakwa section must be trained in safe handling of toxic minerals (mercury, lead, arsenic, sulphur) per MSDS	Conduct dedicated Rasa Shastra safety training; include PPE, emergency decontamination, first aid, and waste disposal; maintain training certificate per worker
Emergency Procedures	All staff must be trained in fire safety, chemical spill response, first aid, and emergency evacuation procedures	Conduct bi-annual emergency drills; post emergency contact numbers and evacuation maps in all zones; maintain first aid kits and fire extinguishers

16. Packaging & Labelling Requirements

Nutraceutical labels comply with FSSAI Health Supplements & Nutraceuticals Regulations 2022. Ayurvedic drug labels comply with Drugs & Cosmetics Act 1940 (Schedule M) and Ayush label guidelines.

🟡 **Amber rows** indicate Ayurveda/ASU-specific requirements beyond standard FSSAI Schedule 4.

Area	Requirement	Action Items
Product Name & Category	Label must state correct product name and category (health supplement / nutraceutical / functional food)	Review FSSAI 2022 Nutraceutical Regulations; ensure product category is correctly classified before label design
Ingredient List	Complete list of all ingredients in descending order of weight; botanicals to include plant part and extract ratio	Create master ingredient list per product; verify against FSSAI permitted ingredient list; legal QC review before print

Area	Requirement	Action Items
RDA % Declaration	% of Recommended Daily Allowance of vitamins and minerals declared where applicable	Refer to FSSAI-notified RDA values; calculate and declare RDA% per serving in nutritional information table
Recommended Usage / Dosage	Recommended dosage and directions for use must be clearly stated on label	Define dosage based on clinical/classical evidence; get reviewed by regulatory consultant before printing
Lot / Batch Number & MFG / EXP Date	Lot/batch number, manufacturing date, and best before / expiry date are mandatory	Set up batch coding system; include in BPR; verify on every printed label before dispatch
Storage Conditions	Storage conditions (temperature, humidity, light) to be stated on label	Define conditions from stability studies; state on label, e.g. 'Store below 25°C in a cool, dry place'
Not for Medicinal Use	'Not intended to diagnose, treat, cure, or prevent any disease' disclaimer mandatory for nutraceuticals	Add disclaimer in legible font size; position prominently on label; verify in every label version
Caution Statements	Required cautions: 'Keep out of reach of children', allergen warnings, drug interaction warnings if applicable	Review formulation for interactions; consult regulatory expert; include all applicable caution statements
Allergen Declaration	8 major allergens declared in bold on ingredient list per FSSAI guidelines	Identify all allergens; bold/highlight on ingredient list; review allergen list if formulation changes
Net Quantity	Net quantity (weight or volume) declared in metric units	State net quantity per pack and per serving; verify against fill weight during BPR checks
Food-Grade Packaging Material	Packaging materials must be food-grade, non-toxic, and protective; material certificates required	Source from FSSAI-approved packaging vendors; request food-grade certificates; retain for audit
Ayush Manufacturing Licence Number	Ayurvedic / ASU drug labels must display the Ayush Manufacturing Licence number (in the format 'Mfg. Lic. No. ...')	Ensure current Ayush licence number is printed on all labels; update immediately after licence renewal; do not ship with expired licence
Name of Drug - Classical / Proprietary	Label must clearly state whether the drug is a classical formulation (as per AFI/API) or a proprietary Ayurvedic medicine	Classical formulations: cite AFI/API reference on label; Proprietary: submit to Ayush authority before marketing; review label with regulatory consultant
Ingredients - Full Disclosure with Sanskrit Names	All ingredients to be listed with both Sanskrit/Latin botanical name and common name; quantity per dosage	Create bilingual ingredient list (Sanskrit/Latin + common name); specify plant part (root, bark, fruit, leaf); list excipients separately
Method of Preparation	For classical formulations, the method of preparation (e.g., 'Prepared as per AFI Part I') must be mentioned on label	Include method reference on label or package insert; update if manufacturing process changes
Dosage & Anupana (Vehicle)	Dosage instructions must include Anupana (vehicle such as honey, milk, warm water) if specified in classical reference	Add Anupana instructions per AFI/API; if no classical Anupana, state 'with water'; get reviewed by Ayurvedic physician
'For External Use Only' Disclaimer	Preparations for external application (Tailam, Lepa, Ointment) must clearly state 'For External Use Only'	Add 'For External Use Only' in a prominent, legible location on label; add a warning 'Not to be taken orally'

17. Licensing & Registration Summary

Ensure your business has the correct FSSAI registration/licence AND Ayush Manufacturing Licence (for ASU drugs) based on the table below.

Category	Threshold / Description	Applicable Licence / Part
FSSAI Registration	Turnover up to ₹12 lakhs OR ≤100 kg/day production; local petty food business operators	Part I
FSSAI State Licence	Turnover ₹12 lakh–₹20 CR or specific capacity thresholds for meat/dairy	Part II
FSSAI Central Licence	Turnover above ₹20 CR; all nutraceutical & health supplement manufacturers; e-Commerce FBOs; import/export	Part II + applicable parts
Dairy FBOs	Any dairy food business irrespective of size	Part III
Meat & Meat Products	Any meat FBO - local shop to large processing plant	Part IV
Catering / Food Service	Restaurants, caterers, cloud kitchens, canteens, institutional catering	Part V
eCommerce / Quick Commerce	Online food platforms, dark stores, delivery aggregators	Parts II + V + IV (if meat)
Nutraceuticals & Health Supplements	Manufacturers of vitamins, minerals, probiotics, botanicals, protein supplements, functional foods - Central Licence mandatory	Part II + FSSAI Nutraceutical Regulations 2022
Ayurvedic / Siddha / Unani (ASU) Drugs	Any manufacturer of classical or proprietary ASU drugs - Churna, Tablets, Kashayam, Asava/Arishta, Bhasma, Tailam, Ghrita etc.	Ayush Manufacturing Licence (State Drug Controller) + Drugs & Cosmetics Act 1940 + Ayush GMP Rules 2008
ASU + Nutraceutical Combined	Units manufacturing both ASU drugs AND nutraceutical/health supplements under the same roof	FSSAI Central Licence + Ayush Manufacturing Licence (separate; cannot be combined into one licence)

This document is a consolidated working reference based on FSSAI Schedule 4 Regulations, FSSAI Health Supplements & Nutraceuticals Regulations 2022, Ayush GMP Rules 2008 (amended), Drugs & Cosmetics Act 1940, Ayurvedic Formulary of India (AFI), and Pharmacopoeia of India (API). Always verify with the latest FSSAI and Ayush notifications. Consult a qualified regulatory expert for your specific business category and product portfolio before implementation.