DOCUMENT APPROVAL PAGE

User Requirement Specification (URS)

Production-Scale Hot Melt Extrusion System

Document Title	HME Production System URS	**Site**	Hikma-APM
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User Requirement Specification (URS)

Production-Scale Hot Melt Extrusion System

(Multiproduct HME for Solid-Dispersion Development, Technology Transfer and Commercial Production)

Document Title	HME Production System URS	**Site**	Hikma-APM
Reference Basis	N/A	**Document Type**	User Requirements Specification

Purpose	This URS defines the user, process, functional, GMP, safety, automation, data-integrity, hygienic-design, qualification and lifecycle requirements for a production-grade pharmaceutical hot-melt extrusion line.
Reason of the Request	To procure a multiproduct HME line for formulation development, technology transfer, process optimization, exhibit/scale-up batches and commercial production of solid dispersions for solubility enhancement.
Main Functions	Premix charging; gravimetric loss-in-weight feeding; co-rotating twin-screw extrusion; controlled heating/cooling; modular process ports; melt pressure and temperature monitoring; optional vacuum devolatilization; modular cooling/pelletizing or flaking; milling, sieving and closed collection; recipe, trend, alarm, audit-trail and report functions.
Benefits	Provide a scalable and repeatable HME process, minimize product loss, enable multiproduct cleaning and changeover, improve feeding accuracy and process visibility, support product-quality evaluation, and provide a maintainable GMP system with documented lifecycle support.
Requirements	21 CFR Parts 210/211; risk-based application of 21 CFR Part 11; EU GMP Part I including Chapters 3-5; EU GMP Annex 11 and Annex 15; ; applicable CE machinery/electrical safety requirements; hygienic design and pharmaceutical data-integrity expectations.
Scope	• Production-grade twin-screw HME base system sized for a guaranteed 0.5-5 kg/h operating range. • One pharmaceutical gravimetric loss-in-weight twin-screw feeder for premixed powder, with small-batch and production feeding capability. • Minimum eight independently controlled process temperature zones plus die control. • Main feed, future side-feed/liquid-injection readiness, vent/vacuum and future PAT provisions. • Modular downstream system, pharmaceutical mill and sieve, closed collection and sampling provisions. • PLC/HMI, electronic process records supporting a paper batch-record strategy, qualification documents, training, spares and support.

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General Review and Resulting Design Basis

Topic	R&D response / status	URS treatment
Intended use	R&D development, technology transfer, process development and commercial production; multiproduct line.	Production-grade, multipurpose system with frequent-changeover design and development flexibility.
HME purpose	Solid dispersions for solubility enhancement.	HME configuration and vendor trials shall be linked to amorphous/solid-state quality and dissolution performance.
Temperature / barrels	40-240 °C; minimum eight barrels requested.	URS specifies at least eight independently controlled process zones plus a separate die zone; barrel count may differ and shall be justified.
Downstream route	Strand/pelletizing and chilled-roll/flaking are both generally applicable; no product-specific selection yet; second route may be future.	Vendor shall quote modular routes separately. One primary route will be selected after trial; interfaces for the future route are mandatory.
Cleaning	Multiproduct; dry/wet/washroom cleaning; complete cleaning with optimum time reduction; visual plus swab/rinse verification.	Direct access, removable product-contact parts, washroom carts/lifting aids and cleaning-validation support are mandatory.

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Requirements	Description	Classification
1 Design Qualification, Intended Use and Project Governance		
System Configuration	The supply shall be a complete production-grade pharmaceutical hot-melt extrusion line comprising material charging, gravimetric feeding, co-rotating twin-screw extruder, temperature-control system, process ports, melt sensors, selected downstream cooling/size-reduction equipment, PLC/HMI controls, utility interfaces and all accessories required for safe GMP operation.	Mandatory
Intended Use	The system shall support R&D development batches, technology transfer, process optimization, exhibit/scale-up batches and commercial production of multiproduct solid dispersions intended primarily for solubility enhancement.	Mandatory
Multiproduct Design	The equipment shall be suitable for multiple standard pharmaceutical products and polymers and shall support complete product-to-product cleaning, line clearance and configuration control.	Mandatory
Production-Grade Duty	All mechanical, electrical and control components shall be suitable for continuous duty for up to two shifts per day, including full process-temperature operation, without derating below the guaranteed range.	Mandatory
Upstream Boundary	The commercial feed material will normally be a premix prepared in a separate blender. The supplier shall define the required premix discharge, transfer and charging interface.	Mandatory
Downstream Boundary	The HME intermediate will normally proceed to cooling, pelletizing or flaking, milling, sieving, closed collection and subsequent blending with additional excipients. Scope boundaries shall be explicit.	Optional
Supplier Turnkey Responsibility	The supplier shall be responsible for mechanical, electrical, software, feeder, downstream, utility, safety, hygienic and qualification integration, including third-party equipment supplied within the line.	Mandatory
Compliance Matrix	The supplier shall return a line-by-line response identifying Comply, Partial Compliance, Deviation, Option or Not Applicable, with evidence and assumptions. Silence shall not be interpreted as compliance.	Mandatory
Vendor Trial Before Design Freeze	Because no proven development process window or screw map is available, a representative product/placebo trial at the vendor facility shall be completed before final machine sizing and design freeze.	Mandatory
Design Qualification	A formal DQ/design review shall approve the process architecture, screw diameter, L/D, Do/Di, torque, feeder range, ports, downstream route, utilities, software concept, cleaning concept and all deviations before fabrication.	Mandatory
Change Control	No critical design, software, material, component or process-interface change shall be implemented after design freeze without documented Hikma approval and supplier change control.	Mandatory
Future Flexibility	The design shall reserve practical space, PLC capacity and interfaces for a future second solid feeder, liquid pump, PAT instrument and second downstream route without requiring replacement of the base extruder.	Mandatory

Requirements	Description	Classification
2 Capacity, Operating Model and Performance		
Guaranteed Feed/Output Range	The supplier shall guarantee stable continuous HME operation from 0.5 to 5.0 kg/h using agreed representative formulations, with defined product-quality and process-stability acceptance criteria.	Mandatory
Normal Production Runs	The system shall support continuous lots and scale-up/exhibit/commercial run sizes from 5 to 50 kg, including controlled startup, steady state, sampling, shutdown and reconciliation.	Mandatory
Development Batch Target	The supplier shall state and demonstrate the minimum practical batch size, startup quantity, steady-state quantity, purge quantity and unrecoverable hold-up. A useful batch of 0.5-1.0 kg is a target and shall not be assumed without trial evidence.	Critical target
Minimum-Rate Stability	At 0.5 kg/h the line shall demonstrate stable feeding, acceptable torque/pressure variation, controlled melt temperature and acceptable output. Any restriction on formulation or screw configuration shall be stated.	Mandatory
Maximum-Rate Stability	At 5 kg/h the complete line, including feeder, extruder, cooling, mill, sieve and collection, shall operate without bottleneck or continuous operator intervention.	Mandatory
Continuous Run Duration	The line shall be capable of a continuous run of at least 16 hours or two shifts, subject to product-specific cleaning and campaign controls.	Mandatory
Campaign Operation	The system shall support up to five consecutive batches or lots in one campaign, with defined batch identification, material reconciliation and campaign-cleaning procedures.	Mandatory
Throughput Guarantee Basis	Guaranteed output shall be based on an agreed product or placebo trial, not theoretical screw capacity. Vendor guarantees shall identify feed material properties, temperature range, screw configuration and downstream route.	Mandatory
Process Temperature Range	Each process zone shall provide a usable setpoint range of at least 40-240 °C. Product-contact components and seals shall be rated with suitable engineering margin for this range.	Mandatory
Product Protection	Controls shall prevent excessive product temperature or residence time after low feed, screw slowdown, downstream fault or heater/cooling failure.	Mandatory

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Requirements	Description	Classification
Annual Capacity Confirmation	Final machine selection remains subject to Hikma confirmation of annual demand and design margin. Supplier shall provide capacity calculations using available operating hours and expected yield.	Site confirmation

Requirements	Description	Classification
3 Extruder Processing Section, Screw System and Process Ports		
Extruder Type	Provide a co-rotating, fully intermeshing twin-screw extruder in pharmaceutical/hygienic design, suitable for solid-dispersion HME.	Mandatory
Production Size Selection	The screw diameter shall be proposed and justified by the supplier to meet 0.5-5 kg/h, 5-50 kg runs, low-rate stability and acceptable hold-up. Selection shall not be based only on maximum output.	Mandatory
Processing Length	To be determined by the supplier based on the product.	TBD
Screw Speed Range	Provide continuously variable screw speed over the complete validated operating range. The supplier shall state minimum stable and maximum rated speed and justify the range for low-rate and scale-up operation.	Mandatory
Barrel/Liner Design	Barrels or removable liners shall be modular, wear resistant, replaceable and uniquely identified. Repeated disassembly/reassembly shall not cause leakage, misalignment or screw binding.	Mandatory
Screw Elements	Provide modular conveying, kneading, mixing, reverse/restrictive, sealing and pressure-building elements sufficient for at least three development configurations.	Mandatory
Screw Configuration Records	The HMI/documentation shall allow each validated screw configuration to be uniquely identified and linked to product/recipe records. Supplier shall provide assembly maps and orientation controls.	Mandatory
Spare Screw Elements	Provide an agreed development set of spare elements, spacers, tips, seals and wear parts to optimize residence time, mixing and pressure without waiting for new manufacture.	Mandatory
Screw Removal and Handling	Provide screw-pulling/opening devices, carts, lifting aids and dedicated tools. Removal and reinstallation shall be demonstrated safely by no more than two trained persons after defined cooldown.	Mandatory
Temperature Zones	Provide at least eight independently controlled barrel/process zones plus a separately controlled die zone. Barrel count may differ, but the supplier shall show zone-to-process mapping.	Mandatory
Feed-Zone Cooling	The main feed zone shall have dedicated cooling to prevent softening, bridging or feed-throat blockage.	Mandatory
Main Feed Port	Provide a cooled main feed port designed for the specified premix feeder and closed/dust-minimizing connection.	Mandatory
Future Side-Feed Provision	Provide a flush-blanked barrel position, mechanical interface, structure, power, controls and I/O provision for a future side feeder.	Mandatory
Liquid-Injection Readiness	Provide a flush, capped and pressure-rated liquid-injection port with future pump/nozzle interface. The liquid dosing pump is optional because initial products are expected to be solvent-free and may not require liquid addition.	Optional / future
Atmospheric Vent	Provide or reserve an atmospheric vent position with product-retention and dust-extraction interface where required by process trials.	Optional / future
PAT Provision	Provide at least one flush-blanked, temperature/pressure-rated provision for future NIR/Raman or other PAT probe installation.	Optional / future
Unused Ports	All unused openings shall be closed by flush, secure, cleanable, pressure- and temperature-rated inserts that do not create product traps.	Mandatory
Melt Pressure	Provide a mercury-free melt-pressure sensor at the discharge/die adapter, with range selected from trial data, high alarm, high-high trip and recorded actual value.	Mandatory
Melt Temperature	Provide a product/melt temperature sensor at the discharge, independent from barrel-zone sensors, with alarm limits and continuous recording.	Mandatory
Die System	Provide a quick-change heated die head with interchangeable plates. Initial supply shall include representative strand and sheet/ribbon options selected after vendor trials.	Mandatory
Pressure Rating	Barrels, liners, clamps, plugs, ports, sensors and die shall be rated above the maximum credible pressure and temperature. Supplier shall state design and test pressure and protection philosophy.	Mandatory

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Requirements	Description	Classification
4 Loss-in-Weight Feeder, Premix Charging and Refill System		
Feeder Principle	Provide one pharmaceutical gravimetric loss-in-weight (LIW) twin-screw feeder for premixed powder. A volumetric-only feeder is not acceptable for normal GMP production.	Mandatory
LIW Control Method	The controller shall continuously measure total feeder/hopper weight, calculate actual weight loss per unit time and automatically adjust feeder-screw speed to maintain the mass-flow setpoint.	Mandatory
Feeder Range	The guaranteed continuous feed range shall be 0.5-5.0 kg/h for representative premixes with bulk density 0.2-0.8 kg/L.	Mandatory
Range Change Parts	The supplier shall provide interchangeable feeder screws, hopper/agitator inserts or two product-contact kits as needed to cover both 0.5-1 kg development batches and 5-50 kg production runs with acceptable accuracy and low heel.	Mandatory
Single-Feeder Feasibility	If one feeder platform cannot guarantee the entire range and minimum useful batch, the supplier shall clearly propose and price separate small-batch and production LIW feeders.	Mandatory
Feed Accuracy	Long-term average feed-rate accuracy shall be not worse than ±2% of setpoint over the guaranteed range using agreed materials; a target of ±1% at normal rates of 1-5 kg/h is preferred. Statistical test method shall be defined.	Mandatory
Repeatability	Repeatability shall be demonstrated at minimum, normal and maximum feed rates over an agreed test duration and refill cycle. Vendor shall state standard deviation or coefficient of variation.	Mandatory
Weighing System	The feeder shall use high-resolution load cells or equivalent weight-sensing technology with temperature compensation, overload protection, stable zero, diagnostic status and suitable scale capacity.	Mandatory
Vibration Isolation	The weighing frame shall be isolated from extruder vibration, refill piping, operator contact, cable forces and utility hoses. Flexible connections shall not impose significant force on the scale.	Mandatory
Hopper and Flow Aid	Provide a covered stainless-steel hopper with geometry, agitation/conditioning and twin-screw options suitable for cohesive, poor-flowing and low-bulk-density premixes.	Mandatory
Small-Batch Hopper	Provide a low-volume hopper or insert that minimizes heel and allows practical processing of 0.5-1.0 kg development quantities.	Mandatory
Refill Trigger	Refill initiation shall be configurable within approximately 30-50% hopper occupancy, consistent with feeder accuracy requirements.	Mandatory
Refill During Operation	The feeder shall support refill without stopping the extruder. The refill method may be manual or automatic, but the final design shall minimize mass-flow disturbance and operator dust exposure.	Mandatory
Level and Weight Indication	Display hopper gross/net weight, percentage fill, high level, low level, refill request, refill active and empty status on the HMI.	Mandatory
Feeder Totalization	The system shall continuously totalize actual dispensed mass for batch reconciliation and compare planned versus actual quantity.	Mandatory
Calibration	Provide zero/tare, span and linearity calibration functions; certified test weights or an approved calibration device; protected calibration parameters; and calibration records suitable for IQ/OQ.	Mandatory
Feeder Recipe Parameters	Recipe-controlled data shall include mass-flow setpoint, acceptable deviation, screw type, calibration factor, refill trigger, refill amount/time, agitation settings, limits and total target mass.	Mandatory
Feeder Data Recording	Setpoint, actual feed rate, hopper weight, screw speed, totalized mass, deviation, refill events and alarms shall be continuously recorded and included in the batch/trend report.	Mandatory
Feeder Alarms	Provide clear alarms for feed-rate deviation, empty/low level, high level, refill timeout, load-cell fault, zero drift, bridging/blockage, screw overload, loss of communication and calibration due/failed.	Mandatory
Feeder Interlocks	Feeding shall be prevented unless the extruder screw is running above the configured minimum and required downstream permissives are healthy. Screw trip, high-high torque or pressure shall stop feeding immediately.	Mandatory
Charging Interface	Provide a covered manual charging station and connection for a future vacuum-transfer/refill system, including local extraction interface and ergonomic access.	Mandatory
Future Second Feeder	Reserve mounting space, feed port, structural support, electrical supply, network, PLC I/O and software architecture for a future second solid LIW feeder.	Mandatory
Product-Contact Construction	Feeder hopper, agitator, screws, discharge tube, bellows and metallic product-contact parts shall be 316L or justified pharma-grade material, with Ra ≤0.8 µm unless a better finish is proposed.	Mandatory
Cleaning and Change Parts	All feeder product-contact parts shall be removable without disturbing load-cell calibration where practical, cleanable in the washroom, uniquely identified and supplied with dedicated handling/storage containers.	Mandatory
Check Weighing Strategy	No separate inline ingredient-ratio analyzer is required initially. Dispensed-material check weighing and reconciliation shall be supported through batch records and feeder totalization.	Mandatory

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Requirements	Description	Classification
5 Downstream Cooling, Pelletizing, Milling, Sieving and Collection		
Modular Downstream Concept	The base extruder shall accept interchangeable pharmaceutical downstream modules. The final primary route shall be selected after product/vendor trials.	Mandatory
Route A - Strand/Pelletizing	Supplier shall separately quote a heated strand die, controlled cooling conveyor or equivalent, strand guide and guarded variable-speed pelletizer sized for at least 5 kg/h.	Option for selection
Route B - Chill Roll/Flaking	Supplier shall separately quote a pharmaceutical chilled-roll or cooling-belt/flaker package sized for at least 5 kg/h and suitable for rapid stabilization of amorphous product.	Option for selection
Closed Collection	Final intermediate shall be collected into tightly closed, grounded and labeled drums, bins or IBCs using a clamped chute, liner or equivalent dust-minimizing connection.	Mandatory
Collection Capacity	Collection containers and changeover arrangements shall accommodate 5-50 kg lots without uncontrolled interruption, product mix-up or overflow.	Mandatory
Sampling Points	Provide safe sampling points at extruder discharge, after cooling, after pelletizing/flaking, after milling/sieving and at final collection, with burn and dust protection.	Mandatory
Rods and Films	Special dies and take-off equipment for rods or films are not included in the base scope and shall be offered only as separately priced future options.	Optional
Metal Detection	Metal detection is not required in the initial HME scope because it will be available at subsequent compression/encapsulation steps. Supplier shall identify any internal magnet or screen used for equipment protection.	Not required / disclose
Final Product Temperature	Supplier shall provide a means to measure or verify final collected-product temperature. Product-specific acceptance limits shall be established during process development.	Mandatory

Requirements	Description	Classification
6 Critical Process Parameters, Quality Support, Sampling and Material Status		
Critical Process Parameters	At minimum, feeder rate, feeder totalized mass, screw speed, torque, motor load, each zone set/actual temperature, melt temperature, melt pressure, vacuum and downstream speeds/temperatures shall be continuously monitored.	Mandatory
Recipe Control	Critical process setpoints, limits, timing and downstream configuration shall be controlled through versioned recipes.	Mandatory
Trend Recording	Real-time and historical trends shall be available for all critical process parameters, with batch-based retrieval, zoom, cursor values and export.	Mandatory
Quality Attributes	The system shall support process evaluation against appearance, assay, polymorphic/amorphous state, related substances, dissolution, water content/LOD, particle-size distribution, bulk density and tapped density.	Mandatory
In-Process Sampling	The design shall support initial, middle and end sampling, plus event-driven sampling after process interruption, without unsafe access or uncontrolled exposure.	Mandatory
Feed Blend Sampling	Provide a practical sampling arrangement for the premix before or at feeder charging, according to site procedure.	Mandatory
Discharge Sampling	Provide a guarded/insulated sampling point at or immediately after extruder discharge, recognizing hot-product and pressure hazards.	Mandatory
Post-Process Sampling	Provide sampling after cooling, after pelletizing/milling and at final collection.	Mandatory
Material Status Identification	Good, startup, transient, sample, purge and rejected material shall be physically separated and clearly identified.	Mandatory
Manual Rejection	Initial design may use manual diversion/rejection. The system shall record operator, time and reason and shall be pre-engineered for future automatic diversion.	Mandatory
PAT Readiness	PAT is not required initially. Mechanical/electrical/software provisions shall permit future NIR/Raman or moisture/solid-state monitoring without major machine redesign.	Mandatory future provision
Mass Balance	The system shall provide planned input, feeder totalized mass, collected good mass, samples, rejects, purge and waste values to support batch reconciliation in the paper record.	Mandatory
Hold-Time Information	Supplier shall minimize warm hold-up and permit rapid transfer to closed containers.	TBD

Requirements	Description	Classification
7 Materials of Construction, Hygienic Design, Cleaning and Changeover		
Product-Contact Materials	Product-contact parts shall be 316L stainless steel where mechanically suitable. Hardened corrosion/wear-resistant pharmaceutical grades may be used for screws, liners, cutters and wear parts with full justification and certificates.	Mandatory
Non-Product-Contact Construction	External frames, covers, cabinets and supports in the GMP area shall be stainless steel AISI 304 or better, with smooth cleanable finishes.	Mandatory

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Requirements	Description	Classification
Non-Metallic Materials	Product-contact seals, hoses, belts, plastics, bellows and gaskets shall be suitable for pharmaceutical use and 40-240 °C operation, with FDA/EC compliance declarations where applicable.	Mandatory
Welds and Passivation	Product-area welds shall be continuous, smooth and free from crevices. Fabricated stainless parts shall be cleaned and passivated as appropriate, with records.	Mandatory
Hygienic Geometry	The design shall minimize product traps, exposed threads, hollow unsealed members, horizontal ledges and inaccessible cavities.	Mandatory
Split/Open Access	The process section shall open or disassemble to permit full visual inspection of screws and bores, swabbing and removal of hardened product.	Mandatory
Cleaning Methods	The system shall support dry cleaning, vacuum cleaning, manual wet cleaning and washroom cleaning of removable parts. CIP/WIP is not required unless separately proposed.	Mandatory
Changeover Target	A complete product-to-product cleaning and reassembly Optimal target used for design and timed demonstration, subject to site final procedure.	Mandatory target
Removable Parts	Feeder product-contact parts, screws, dies, removable liners/barrels, guides, pelletizer/flaker parts, mill parts, screens and containers shall be removable for washroom cleaning where practicable.	Mandatory
Hot-Opening Prevention	No routine cleaning or dismantling shall require handling of hot, pressurized or moving parts. Supplier shall define safe cooldown, depressurization and release criteria.	Mandatory
Cleaning Procedures	Provide detailed dry/wet cleaning, safe cooling, disassembly, washing, rinsing, drying, inspection, reassembly and line-clearance procedures.	Mandatory
Cleaning-Agent Compatibility	Materials shall be compatible with site-approved water, detergents and commonly used alcohol cleaning agents. Final approved agents remain product/site specific.	Mandatory
Cleaning Validation Support	Provide product-contact surface-area calculations, hard-to-clean locations, swab/rinse sampling points, provide material coupons, where requested, and ensure access is available for visual verification of each material in contact with the product. Coupons shall be **10 × 10 cm** in size.	Mandatory
Verification Methods	Design shall support visual inspection and swab/rinse verification as stated by R&D.	Mandatory
Change-Part Identification	Screws, elements, dies, screens, feeder screws, liners, ports and all removable product-contact parts shall have durable unique identification without creating traps.	Mandatory
Storage and Transport	Provide cleanable carts, racks, trays and closed containers for transport and storage of cleaned screws, liners, dies, screens and feeder parts.	Mandatory
Duplicate Product-Contact Set	A duplicate critical product-contact/change-part set shall be separately quoted to reduce downtime and support campaign continuity.	Optional
Cable and Hose Routing	Cables, cooling hoses and sensor lines shall be routed in protected stainless channels or organized supports; loose loops on the process section and contact with hot surfaces are not acceptable.	Mandatory
Quick Connections	Frequently disconnected utilities and instruments shall use labeled, keyed, hygienic and drip-minimizing quick connections to prevent wrong reconnection.	Mandatory

Requirements	Description	Classification
8 Utilities and Installation Environment		
Electrical Supply	Design basis shall be 400 VAC, 3-phase, 50 Hz, TN-S with protective earth, subject to site confirmation. Control circuits shall use 24 VDC where practical.	Site confirmation
Electrical Load Schedule	Supplier shall provide connected load, normal/peak demand, breaker/cable size, short-circuit requirements and heat dissipation for every module.	Mandatory
Cooling System	Provide a closed-loop or site-connected heating/cooling system sized for all barrel, feed-zone, drive and downstream loads. Supplier shall state flow, pressure, temperature and heat rejection.	Mandatory
Compressed Air	Any required air shall be dry, oil-free and suitably filtered. Supplier shall state pressure, flow and quality requirements.	Mandatory
Vacuum Utility	Supplier shall define vacuum capacity, operating range, exhaust, condensate and cleaning requirements.	Mandatory
General Arrangement	Provide dimensioned GA drawings showing operation, maintenance, cleaning, barrel/screw removal, feeder refill, downstream changeover, lifting and extraction clearances.	Mandatory
Floor and Access Loads	Supplier shall state point loads, total weight, center of gravity, transport dimensions and floor-loading requirements.	Mandatory
Ingress Protection	HMI front shall be minimum IP65. Field devices and enclosures shall have suitable ratings for pharmaceutical dust and routine cleaning.	Mandatory
UPS	Provide UPS or equivalent support for PLC/HMI/IPC, data storage and network components sufficient for data retention and controlled shutdown. Minimum 15 minutes is preferred.	Mandatory
Network and Time Source	Provide secure Ethernet and site time-synchronization capability, even if initial operation is standalone.	Mandatory

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Requirements	Description	Classification
10 Automation, HMI, Recipes and Hybrid Batch Records		
Control Architecture	Use a current, supported industrial PLC and HMI/IPC architecture suitable for validated pharmaceutical operation.	Mandatory
Part 11 / Annex 11 Readiness	Electronic data, recipes, audit trails and reports shall support risk-based 21 CFR Part 11 and EU GMP Annex 11 controls.	Mandatory
HMI Overview	Provide clear graphical process overview, equipment status, permissives, actual values, setpoints, limits, trends, alarms, batch status and diagnostics.	Mandatory
Recipe Management	Provide controlled recipe creation, review, approval/use status, versioning, comparison, duplication and retirement. Only authorized versions shall be used for production.	Mandatory
Recipe Content	Recipes shall include feeder parameters, screw speed/limits, zone and die temperatures, torque/pressure limits, vacuum settings, downstream settings, timing, diversion and shutdown parameters.	Mandatory
Batch Identification	Operator shall enter/select product, batch/lot number, recipe/version, planned quantity, feeder/change-part configuration and container IDs as defined by site SOP.	Mandatory
Continuous Data Capture	All critical process parameters identified in Section 6 shall be continuously recorded at a configurable and justified sampling interval.	Mandatory
Batch/Process Report	Generate a report containing machine ID, product/batch, recipe/version, users, start/end time, planned/actual mass, critical parameters, trends, alarms/events, refill events, interventions and Page X of Y.	Mandatory
Trend Export	Reports and trends shall be exportable in human-readable PDF and secure electronic formats without loss of context or metadata.	Mandatory
Alarm Management	Alarms shall include clear text, source/tag, priority, timestamp, status, acknowledgement user/time and guidance where practical.	Mandatory
Interlock Display	HMI shall show start permissives, active interlocks, bypass status and the specific condition preventing start or causing stop.	Mandatory
User Roles	Support unique named accounts and configurable roles including Operator, Supervisor, Maintenance/Engineer, Administrator and QA/Reviewer.	Mandatory
Electronic Signatures	Electronic signature approval of the official batch record is not initially required. The system shall be capable of future e-signature implementation or provide a separately priced option.	Optional / future
Audit Trail	Provide secure time-stamped audit trail for login/logout, user administration, recipe/parameter changes, overrides, calibration/configuration changes and data deletion attempts.	Mandatory
Change Reason	Reason/comment entry shall be required for GMP-critical parameter or recipe changes where configured.	Optional
System Time	Time/date shall be protected, synchronized to a site-approved source when connected and audit-trailed if changed.	Mandatory
Future Integration	Provide documented capability or interface for future historian, MES, LIMS, PAT, network storage and Active Directory integration.	Mandatory future provision
Spare Capacity	Provide at least 20% spare PLC I/O, cabinet, network and software capacity for the future feeder, PAT and automatic diverter.	Mandatory
Licenses and Source Files	Provide perpetual runtime licenses where possible, engineering access, editable commented PLC/HMI projects, tag lists, report/database definitions and verified master backups.	Mandatory

Requirements	Description	Classification
10A Licensing		
Software Licensing	All software licenses required for compliant operation, engineering access, backup/restore, reporting, maintenance and support of the delivered HME system shall be provided by the supplier and documented at handover, including: - Operating system license, where applicable - HMI/SCADA runtime license - PLC engineering software license, if included in supply - Database/reporting software license, if applicable - Third-party driver or license requirements, if applicable	Mandatory
10B Security & System Access		
Access Control	Operating HMIs shall start automatically in production/runtime mode, and only authorized access levels shall be permitted to exit the HMI or browse the underlying operating system. Users shall be able to change their own passwords. The system shall support configurable automatic logoff after inactivity, forced password change at first login, account lock after three consecutive failed login attempts, controlled handling of expired passwords, and deactivation/reactivation of users without loss of their activity history.	Mandatory
HMI Access Restriction	Access to the underlying operating system, engineering environment and non-authorized configuration functions shall be restricted to authorized user levels only. HMI/PLC program backup to approved USB media shall be available under controlled access.	Mandatory

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Requirements	Description	Classification
Named User Authentication	The system shall require login using a unique username and password for GMP-relevant actions.	Mandatory
Anonymous Use Restriction	No GMP-relevant operation, parameter change or record approval shall be permitted without a logged-in named user, except emergency-stop or hardwired safety actions.	Mandatory
User Accounts	The system shall support unique named user accounts with configurable roles and permissions, including at minimum Operator, Supervisor, Maintenance/Technician, Administrator and QA/Reviewer, and shall provide an administrable list of users with associated access rights.	Mandatory
Password Management	The system shall support controlled password management, including user password change, forced password change at first login, masked password entry and password handling aligned with good security practice.	Mandatory
Password Rules	Password controls shall include: - Administrator-configurable minimum length - Configurable expiration period aligned with site policy - Password shall not match the username - Prevention of reuse of a defined number of previous passwords - Configurable complexity rules, including alphanumeric and special characters where supported - Masked password entry - Failed-login error indication and capture where applicable - Administrator-defined roles and permissions - Secure password re-establishment after account reset/reactivation - Deactivated usernames shall not be reassigned in a manner that compromises audit-trail integrity	Mandatory
Auto Logoff / Lockout	The system shall log off or lock automatically after a predefined period of inactivity and shall lock/disable a user account after multiple wrong password attempts.	Mandatory
Administration Rights	Only an authorized administrator level shall create, modify, reactivate, reset or deactivate user accounts and define access rights and roles.	Mandatory
10C E-Records, Audit Trail & Reporting		
Audit Trail Content	The secure computer-generated audit trail shall not be disableable by normal users and shall record, as applicable: login/logout events; creation, modification, disabling, reactivation and deletion of users; parameter changes; recipe changes; GMP-relevant process actions; original and new values where applicable; user identity; and date/time stamp.	Mandatory
Audit Trail Integrity	Audit trails and GMP records shall be retrievable and readable in human-readable form, reproducible, printable/exportable to PDF, and retained for the same retention period as the associated record.	Mandatory
Alarm History	The system shall provide readable historical alarm and fault records including alarm description, event timestamp, status and acknowledgement information where applicable.	Mandatory
HMI Screenshots	Screenshots shall be capturable from the HMI for qualification and 21 CFR Part 11 testing.	Optional

Requirements	Description	Classification
11 Data Protection, Backup, Restore and Cybersecurity		
Backup Scope	Backup shall include PLC/HMI applications, recipes, user/role configuration, reports, databases, trends, alarms, audit trails, licenses, drivers and operating-system image.	Mandatory
Backup Destination	Data shall be stored on controlled local and/or network storage and shall not rely solely on an uncontrolled standalone hard drive.	Mandatory
Restore Demonstration	Supplier shall demonstrate restoration of applications, configuration, recipes, users and representative data to supplied or equivalent replacement hardware during FAT/OQ.	Mandatory
Backup Integrity	Backups shall be uniquely identified, protected and verifiable by checksum or equivalent where supported.	Mandatory
Data Retention	The system shall prevent uncontrolled overwriting and warn before storage capacity is exhausted. Final retention period will be defined by QA/Production.	Mandatory / site confirmation
Raw Data Protection	Direct operating-system/database access and unauthorized modification/deletion of GMP-relevant data shall be restricted.	Mandatory
Power-Loss Recovery	Power loss shall place the system in a safe state, preserve data/time and prevent automatic restart. Recovery events shall be recorded.	Mandatory
Supported Software	Operating system, PLC/HMI firmware and databases shall be vendor-supported at shipment. Supplier shall provide lifecycle and obsolescence statements.	Mandatory
System Hardening	Disable unused ports, services, default accounts and unnecessary software; change default passwords; provide a hardening guide.	Mandatory
Removable Media	USB/removable-media access shall be role/physically controlled and restricted to approved export, backup and maintenance functions.	Mandatory
Disaster Recovery	Provide documented recovery sequence, required backups, compatible replacement hardware/software and post-restore verification.	Mandatory

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Requirements	Description	Classification
12 Safety, Interlocks and Recovery		
Machine Safety and HSE Risk Assessment	Design and document the complete system in accordance with applicable CE machinery requirements and current recognized standards such as ISO 12100, IEC 60204-1, ISO 13849, ISO 13850, ISO 14119 and ISO 14120 or equivalents. The supplier shall provide a risk assessment covering mechanical, thermal, pressure, electrical, ergonomic, dust, fumes, fire, explosion, cleaning, maintenance and unexpected start hazards.	Mandatory
Residual Heat Indication	The system shall provide indication when process components remain above a defined safe-access temperature following shutdown.	Mandatory
Functional Safety Performance Level (PLr)	The supplier shall determine and document the required Performance Level (PLr) for all safety-related control functions in accordance with ISO 13849-1 and demonstrate compliance during the design review and FAT.	Mandatory
Safe Torque Off (STO)	Drives associated with the extruder, feeder and downstream equipment shall utilize certified Safe Torque Off (STO) functionality where available.	Mandatory
Guards and Safety Interlocks	Provide fixed or interlocked guards for screws, couplings, belts, cutters, pinch points, rotating parts and other hazardous components. Opening an interlocked hazardous guard shall cause a defined safe stop and prevent restarting while the guard remains open.	Mandatory
Emergency Stops and Safe Shutdown	Provide accessible safety-rated emergency stops at the operator station, feeder, extruder and downstream equipment. Activation must place the system in a safe condition without creating additional pressure, heat, fire or uncontrolled material-release hazards.	Mandatory
Prevention of Automatic Restart	Restoration of power, utilities, guards, cooling, vacuum, extraction or safety devices must not automatically restart feeding, heating or hazardous movement. A deliberate operator action shall be required before restart.	Mandatory
Start Permissive and Safety Interlocks	Startup shall require a healthy safety chain, closed guards, correctly installed ports and die, available cooling and extraction, healthy safety-critical sensors and readiness of connected equipment. Feeder operation myst be interlocked with screw rotation, and failure of required downstream equipment shall stop feeding and initiate the defined safe response.	Mandatory
Torque, Pressure and Temperature Protection	Screw torque, motor load, melt pressure and process temperature must be monitored. High conditions shall generate alarms, while high-high conditions, sensor failure, cooling loss or heater-control failure shall stop feeding and initiate a safe shutdown before equipment limits are exceeded. Independent overpressure or overtemperature protection must be provided where required by the risk assessment.	Mandatory
Jam, Solidification and Jog/Reverse Recovery	The supplier must provide a safe procedure for power loss, screw seizure, die blockage and material solidification. Jog or reverse operation shall be restricted to authorized personnel, use hold-to-run control and operate within risk-assessed speed and torque limits.	Mandatory
Hot Surface and Hot Material Protection	Insulate or guard hot barrels, dies, piping, adapters, rolls and other heated components. Sampling, venting, die opening and discharge points must prevent personnel exposure to hot surfaces, molten material, splashing, pressure release and hot fumes.	Mandatory
Electrical Safety and Main Isolation	The electrical system must include protective earthing, overcurrent and short-circuit protection, suitable enclosure protection, safe cable routing and segregation of power, control and safety circuits. A clearly identified, accessible and lockable main electrical isolator shall be provided.	Mandatory
Energy Isolation / LOTO	Provide clearly labelled and lockable isolation points for electrical, pneumatic, heating, cooling, vacuum and other hazardous energy sources. Safe means must be provided to isolate, release and verify residual pressure, vacuum, heat and stored mechanical energy before cleaning or maintenance.	Mandatory
Dust and Occupational Exposure Control	Material charging, feeder refill, venting, sampling, milling, sieving, cleaning and maintenance shall use closed or contained methods to minimize personnel exposure to pharmaceutical dust .	Mandatory
Local Exhaust Ventilation and Extraction Interlock	Provide effective local exhaust ventilation at locations where dust, fumes or vapors may be generated. The extraction system shall include operating-status indication and low-airflow or low-pressure alarms. Loss of critical extraction shall prevent startup or stop the hazardous activity where continued operation could expose personnel.	Mandatory

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Requirements	Description	Classification
Process Fume, Vacuum Exhaust and Condensate Control	Process vents and vacuum exhaust shall be assessed for fumes, vapors, thermal-decomposition products and condensates. Exhaust shall be contained, filtered or treated where required and discharged to a safe site-approved location. Direct discharge into the production room shall not be permitted.	Mandatory
Combustible Dust and ATEX	The supplier shall assess combustible dust and explosion risks using available material and process data. Where a hazardous area is identified, electrical and non-electrical equipment shall be suitably ATEX-certified for the identified zone, material group and maximum surface temperature. Required ignition-prevention and explosion-protection measures shall be incorporated into the design.	Mandatory
Static Electricity, Bonding and Earthing	Conductive machine parts, transfer components, extraction ducts and collection containers shall be equipotential bonded and earthed. Flexible hoses, liners and non-metallic components shall have suitable antistatic properties where required. Test points shall be provided for earthing-continuity verification.	Mandatory
Noise and Ergonomics	The A-weighted sound-pressure level at normal operator positions shall not exceed 75 dB(A) during representative operation. Charging, sampling, cleaning and maintenance activities shall be ergonomically designed, and suitable lifting or handling aids shall be provided for heavy or awkward removable parts.	Mandatory
Visual, Audible and Warning Indication	Provide stack-light, audible alarms and clear HMI indication for running, warning, safety trip, high pressure, high temperature, extraction failure and other critical HSE conditions. Durable warning labels shall identify hot surfaces, moving parts, electrical hazards, pressure hazards, required PPE and isolation points.	Mandatory
HSE Verification During FAT and SAT	FAT and SAT shall include testing of emergency stops, guards, safety interlocks, restart prevention, torque, pressure and temperature protection, extraction alarms and interlocks, earthing continuity, noise levels and safe fault-recovery functions.	Mandatory
HSE Deviation Closure	All critical HSE deviations identified during FAT or SAT shall be corrected, retested and approved by Hikma before shipment or routine operation of the system.	Mandatory

Requirements	Description	Classification
13 Calibration, Maintenance, Reliability and Spare Parts		
Critical Instruments	Critical instruments include LIW load cells/mass flow, temperatures, melt pressure, vacuum, cooling flow/pressure, speeds, torque/motor load and downstream parameters.	Mandatory
Instrument Data	Provide range, accuracy, resolution, repeatability, drift, calibration method and recommended interval for every critical instrument.	Mandatory
Calibration Certificates	Calibrate critical instruments using traceable standards before FAT/SAT; certificates shall include as-found/as-left results, tolerance and uncertainty.	Mandatory
Calibration Access	Provide accessible calibration points, simulation methods and test connections without unnecessary product-contact disturbance.	Mandatory
Maintenance Access	Motors, gearbox, heaters, sensors, valves, filters, belts, knives, load cells and electrical parts shall be safely accessible.	Mandatory
Feeder Maintenance Protection	Feeder maintenance shall avoid accidental load-cell overload, cable strain or change in weighing geometry. Reassembly checks shall be documented.	Mandatory
Preventive Maintenance	Provide PM schedules, lubrication plan, inspections, tolerances, replacement intervals and task instructions suitable for site CMMS.	Mandatory
Diagnostics	HMI shall show operating hours, starts, drive/feeder status, communication faults, temperature-loop health, filter differential pressure and maintenance reminders where supported.	Mandatory
Wear Monitoring	Provide methods and acceptance criteria for screw, liner/barrel, die, pelletizer knife, mill screen and seal wear measurement.	Mandatory
Special Tools	Provide dedicated identified tools for screws/barrels/liners, dies, feeder screws, pelletizer, mill, sensors and calibration.	Mandatory
Critical Spares	Provide a priced two-year critical-spares list including load cell/controller, feeder screws, sensors, pressure transducer, heaters, relays, seals, filters, belts, knives, screens and key electronic components.	Mandatory
Commissioning Spares	Include commissioning/startup consumables and spares required to complete FAT/SAT without avoidable delay.	Mandatory
Support Life	Supplier shall state expected component/software support and spare availability; ten years is preferred, with advance obsolescence notice and migration options.	Mandatory
Service Response	State local/regional support capability, remote response, site response, escalation and spare lead times.	Mandatory

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Requirements	Description	Classification
14 Documentation, Vendor Trials, Qualification and Acceptance Testing		
Document Set	Provide controlled English searchable PDFs and editable native files where applicable; final documents shall be as-built, revision controlled, indexed and approved.	Mandatory
Design Documents	Provide FDS/FS, DQ, mechanical/electrical design specifications, hardware/software specifications, Pneumatic Diagram, P&ID/process flow, GA, utility drawings, I/O list, network architecture and cable schedule.	Mandatory
Risk Documents	Provide process/machine FMEA, dust/explosion assessment, cleaning/cross-contamination assessment, alarm matrix, cause-and-effect matrix and safety-function list.	Mandatory
Material and Equipment Documents	Provide BOM, tag list, product-contact material/surface certificates, weld/passivation records, non-metallic declarations, lubricants and instrument datasheets.	Mandatory
Software Documents	Provide architecture, source backups, version list, licenses, tag/parameter list, recipe structure, database/report definitions, audit-trail description, backup/restore and cybersecurity guide.	Mandatory
Manuals	Provide operation, process setup, feeding/refill, cleaning, calibration, maintenance, troubleshooting, administration, backup/restore, safety, transport, storage and decommissioning manuals.	Mandatory
Traceability Matrix	Provide an RTM linking each URS requirement to design documents and FAT/SAT/IQ/OQ evidence.	Mandatory
Pre-Selection Process Trial	Conduct a trial using representative materials to determine screw size/configuration, temperature profile, torque, pressure, residence time, feeder performance, vacuum need, cooling route, yield and product quality.	Mandatory
Trial Report	Provide complete raw data, settings, screw map, material balance, observations, product samples and scale-up recommendation. R&D shall approve the result before design freeze.	Mandatory
FAT Protocol	Supplier shall submit FAT protocol, prerequisites, material requirements and schedule at least six weeks in advance unless otherwise agreed.	Mandatory
FAT Complete Batch	FAT shall include execution of a complete representative batch/lot, not only a short dry run, including charging, refill, steady state, sampling, shutdown, cleaning access and reconciliation.	Mandatory
LIW Feeder FAT	Test feeder calibration, accuracy/repeatability at minimum/normal/maximum rates, refill at 30-50% level, return to gravimetric control, totalization, alarms and extruder interlocks.	Mandatory
Process FAT	Verify zone control, screw speed/torque, pressure, melt temperature, vacuum, downstream performance, yield and full batch data recording.	Mandatory
Quality Testing	R&D/Quality will evaluate FAT/SAT/PQ samples for appearance, assay, polymorph/solid state, PSD, bulk density and tapped density, with product-specific acceptance criteria.	Mandatory
Cleaning/Changeover FAT	Demonstrate safe cooldown, screw/barrel access, product-contact disassembly, timed removal/reassembly, visual access and cleaning procedure. Alignment or binding after reassembly is not acceptable.	Mandatory
Software FAT	Test recipes, users, audit trail, trends, reports, alarms, power recovery, backup/restore and hybrid paper-report workflow.	Mandatory
SAT	SAT shall verify installation, utilities, HVAC/extraction interfaces, safety, calibration, operation, data functions, feeder performance and closure of FAT deviations.	Mandatory
IQ/OQ	Supplier shall provide/support IQ/OQ covering equipment, utilities, calibration, software, security, recipes, reports, alarms, interlocks, process ranges, LIW feeder, backup/restore and power recovery.	Mandatory
PQ Support	Supplier shall support process optimization, scale-up, screw configuration, downstream selection and initial product PQ/commercial batches.	Mandatory
Test Instruments	All supplier test instruments shall have valid traceable calibration certificates and suitable range/accuracy.	Mandatory
Deviation Management	FAT/SAT/IQ/OQ deviations shall be logged, risk assessed, resolved, retested and approved. Shipment with open critical deviations requires written Hikma approval.	Mandatory
Certificates	Provide CE Declaration, electrical safety tests, manufacturer certificates and a Part 11/Annex 11 functionality assessment.	Mandatory

Requirements	Description	Classification
15 Training, Warranty, Service and Final Site Confirmations		
Operator Training	Provide hands-on training for charging, LIW feeding/refill, recipe/batch operation, sampling, downstream processing, alarms, shutdown, cleaning and line clearance.	Mandatory
Process/R&D Training	Provide detailed training on screw configuration, scale-up, specific energy, residence time, temperature profile, die/cooling selection and troubleshooting.	Mandatory
Maintenance Training	Provide training on mechanical/electrical maintenance, calibration, load cells, screw/barrel handling, downstream change parts, PLC/HMI administration and backup/restore.	Mandatory
Warranty	Minimum warranty shall be 12 months after successful SAT/acceptance and not less than 18 months from delivery unless delay is attributable to Hikma. Warranty documents shall be provided.	Mandatory

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Requirements	Description	Classification
Software Support	Provide update/patch policy, engineering access, compatibility support and recovery assistance throughout the supported lifecycle.	Mandatory

Requirements	Description	Classification
15A Documentation, Qualification & Support - Additional Requirements		
Training Records and Competence	Supplier training shall be documented through agendas, attendance records and completion certificates. Training records or evidence of competence for supplier technicians supporting the machine systems shall be available.	Mandatory
Remote Assistance	Remote assistance capability for standard PLC/HMI support shall be available as an option and shall operate only through the site-approved, controlled cybersecurity method.	Optional
Pre-Delivery Inspection / FAT Attendance	Factory acceptance testing and pre-delivery inspection at the manufacturer premises shall be supported in the presence of Hikma representatives.	Mandatory
FAT Testing Materials	The supplier shall confirm testing-material requirements, sample quantities and final material needs sufficiently in advance of FAT to permit approved material preparation and shipment.	Mandatory

Addional charges compared to Leistritz standard

- Provisions for future second feeder, liquid injection, vacuum
- Trial 3 days
- Extensive training
-
- PQ support to be discussed, currently 5 days included remote
- Extended FAT test run
- Electronic signature
- UPS
- Quick connection labelling
- Duplicate process part: barrels, screws, feeder screw, die
- Product sampling container for chill roll
- Commissioning spare parts
- Traceability matrix

Not included:

- Screw configuration record (not clear, how to manage this)
- Automatic refill system (to be discussed and height situation to be considered)
- Collection containers
- Sampling points to be discussed, offered as option for chill roll
- Cleaning validation support to be discussed
- 316L cannot be done for all parts, see quotation
- Raw material for FAT and SAT are not included
- Licensing to be checked
- Containers for transport
- Connection to other system, such as OPC UA
- Noise level cannot be checked during FAT
- Noise level 75 dB(A) cannot be guranteed

Other remarks:

Documentation will be according to Leistritz standard, non editable

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Remarks concerning automation system, resp. passwords:

The following rules apply according to our system

Minimum password length	8 characters
New password	Must differ from previous password
Minimum password age	0 Days (the password can be changed at any time)
Maximum password age	90 Days
Failed login lockout	After entering the password incorrectly three times, the user automatically will be blocked
Lockout reset	Administrator only
Automatic Logout	After 12 hours inactivity
Session visibility	Active user always shown in header bar

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