

INDUSTRIAL CASE STUDY

Residual Solvent Removal from API Intermediate

Batch Rotary Vacuum Drying System — 500 kg per Batch Capacity

Designed, Engineered & Validated by KERONE Engineering Solutions Limited

500 kg / BATCH PLANT CAPACITY — API Wet Cake Input	65 degC (Jacket) PROCESS TEMP. — Vacuum Drying	-650 mmHg VACUUM LEVEL — Controlled Deep Vacuum	6 hrs CYCLE TIME — Optimal Drying
480 ppm RESIDUAL SOLVENT — Post-Processing (IPA)	99.72 % ASSAY PURITY — HPLC Basis	95 % SOLVENT RECOVERY — Condenser Recovery	~1.8 Yrs PAYBACK PERIOD — Regulated Market Premium

PROJECT REFERENCE DETAIL

Field	Detail
Client Organisation	Leading Indian API Manufacturer — name withheld per client confidentiality (NDA)
KERONE Reference	KRDC/ICS/APISolvent/2026-03 Based on KRDC Lab Report 62/KRDC/LAB/09
Technology	Batch Rotary Vacuum Dryer (RVD) with Jacketed Heating & Solvent Recovery Condenser
Feedstock	API Intermediate Wet Cake — 8.4% w/w Residual Isopropyl Alcohol (IPA), as-centrifuged
Product Output	Dried API Intermediate — Residual Solvent 480 ppm (ICH Q3C Class-3 Compliant)
Plant Location	Client facility (bulk drug / API manufacturing unit) — Inline with existing DSIR process
Document Date	July 2026 Validated on KRDC Lab Data — May 2026

Active Pharmaceutical Ingredient | Residual Solvent Reduction | ICH Q3C Compliance | Vacuum Drying | Regulatory Batch Release | Pharmaceutical / Bulk Drug

Executive Summary

The client, a leading Indian manufacturer of Active Pharmaceutical Ingredients (APIs) serving both domestic and regulated export markets, faced a recurring quality and compliance challenge: a key API intermediate, isolated by centrifugation from its isopropyl alcohol (IPA) crystallisation step, retained 8.4% w/w residual solvent after conventional tray drying — nearly 17 times above the ICH Q3C Class-3 permissible limit of 5,000 ppm (0.5% w/w) for regulated market release.

KERONE Engineering Solutions Limited was engaged to design, validate, and specify a batch thermal vacuum drying system capable of consistently reducing residual solvent to well within pharmacopoeial and ICH limits, while preserving API assay, polymorphic form, and particle characteristics, at a working batch size of 500 kg.

Following structured laboratory validation at KRDC (Kerone Research & Development Centre) using a bench-scale vacuum tray dryer across multiple temperature, vacuum, and hold-time combinations, the optimal industrial process envelope was established. The KERONE batch Rotary Vacuum Dryer (RVD) system — operating at 65 degrees C jacket temperature with -650 mmHg vacuum over a 6-hour cycle — reduces residual IPA from 8.4% w/w to below 480 ppm, while holding assay purity above 99.7% and recovering approximately 95% of the evaporated solvent for reuse.

CHALLENGE	KERONE SOLUTION	OUTCOME ACHIEVED
API wet cake retaining 8.4% w/w residual IPA — non-compliant with ICH Q3C, restricting sale to domestic, non-regulated buyers at INR 900-1,200/kg.	Batch 500 kg Rotary Vacuum Dryer at 65 degrees C jacket temp, -650 mmHg vacuum, 6-hr cycle — validated from KRDC lab trials on client's own intermediate.	Residual IPA at 480 ppm, assay >99.7% — regulated-market-ready API commanding INR 3,200-4,200/kg.

Key Performance Summary

KPI	Raw Wet Cake (Baseline)	After KERONE Processing (500 kg Batch)	Improvement
Residual Solvent (IPA)	8.4% w/w (84,000 ppm)	< 480 ppm	~99.4% reduction
Loss on Drying (LOD)	9.1%	< 0.3%	97% reduction
Assay Purity (HPLC)	97.8%	> 99.7%	+1.9 pts
Solvent Recovery	Nil (vented)	~95% recovered & reused	New value stream
Market Classification	Domestic bulk drug only	Regulated-market (US/EU) grade	Grade uplift
Realisable Price	INR 900-1,200/kg	INR 3,200-4,200/kg	~3x price premium

Industry Context & The Business Challenge

India is among the world's largest suppliers of APIs and bulk drugs, exporting to more than 200 countries and accounting for a significant share of global generic drug production. A large proportion of these APIs are manufactured through solvent-based crystallisation and isolation steps, leaving residual process solvents — such as isopropyl alcohol, methanol, acetone, and dichloromethane — entrained within the isolated wet cake.

Regulatory frameworks including ICH Q3C (Impurities: Guideline for Residual Solvents), USP <467>, and the corresponding CDSCO/WHO-GMP requirements impose strict permissible daily exposure (PDE) limits on residual solvents in finished APIs. Class-3 solvents such as IPA carry a permitted limit of 5,000 ppm (0.5% w/w); Class-2 solvents carry substantially tighter limits. Batches that fail these limits cannot be released to regulated markets (US FDA, EMA, PMDA, TGA) and are typically diverted to lower-value domestic or non-regulated buyers, or reprocessed at additional cost and yield loss.

For many mid-sized Indian API manufacturers, conventional tray or fluid-bed drying is often insufficiently controlled to reliably achieve sub-5,000 ppm residual solvent on a consistent batch-to-batch basis, particularly for solvent-retentive crystal habits — creating a persistent gap between what is manufactured and what can be sold into premium, regulated markets.

The Commercial Problem — Why Non-Compliant Batches Have Low Value

Quality Parameter	Raw Wet Cake (As Isolated)	Regulated Market Requirement (ICH Q3C)	Gap
Residual Solvent (IPA)	8.4% w/w	< 0.5% w/w (5,000 ppm)	FAIL — ~17x over limit
Assay Purity	97.8%	> 99.0%	FAIL — below spec
Loss on Drying	9.1%	< 1.0%	FAIL — excess volatile content
Market Access	Domestic / non-regulated only	US FDA / EMA / PMDA eligible	FAIL — market restricted
Price Realised	INR 900-1,200/kg	INR 3,200-4,200/kg	~3x revenue gap

Table 1: Raw wet cake quality parameters vs regulated market specification | Source: KRDC Analysis & ICH Q3C Residual Solvent Guideline

Revenue Opportunity — Upgrading an Existing Process Stream

The Opportunity: At 500 kg per batch with two batches processed per day across 300 operating days/year, annual throughput is approximately 300 tonnes of dried API intermediate. At current non-compliant pricing of INR 1,000/kg, this generates approximately INR 30 Cr/year. Post-processing through KERONE's system, the same volume qualifies for regulated-market sale at an illustrative INR 3,700/kg, generating approximately INR 111 Cr/year — a revenue increase of over INR 81 Cr annually, from an existing manufacturing stream, without any change to the upstream synthesis or crystallisation process.

About the Client

The client is a well-established, GMP-certified Indian API manufacturer with an existing multi-product bulk drug facility and export approvals under review with multiple regulated-market authorities. Its operations span synthesis, crystallisation, isolation, and drying of small-molecule APIs and intermediates — positioning it as a natural anchor client for KERONE's vacuum drying and solvent-recovery technology. The KRDC trial was conducted on the client's actual production wet cake (5 kg sample, dispatched under chain-of-custody in April 2026) to ensure industrial relevance of all process parameters. Client identity is withheld throughout this document per mutual non-disclosure agreement.

Process Validation — From KRDC Lab to Industrial Scale

KERONE's engineering approach mandates laboratory-scale validation before any industrial system specification. The KRDC (Kerone Research & Development Centre) conducted a structured experimental programme on the client's actual API wet cake over 5 days, using a precision bench-scale vacuum tray dryer to establish the process envelope that informs the 500 kg/batch industrial plant design.

KRDC Experimental Programme — Key Findings

Test Condition	Jacket Temp / Vacuum	Hold Time	Residual Solvent (IPA)	Assessment
Control (as-received)	Ambient / atmospheric	0 hr	8.4% w/w (84,000 ppm)	Baseline — non-compliant wet cake
Trial A	60 degC / -500 mmHg	2 hr	~1.9% w/w (19,000 ppm)	Insufficient — exceeds ICH Q3C limit
Trial B	65 degC / -650 mmHg	4 hr	~0.31% w/w (3,100 ppm)	Compliant — general regulated grade
OPTIMAL	65 degC / -650 mmHg	6 hr	0.048% w/w (480 ppm)	Optimal — premium regulated grade
Trial D (over-dry check)	70 degC / -700 mmHg	8 hr	0.021% w/w (210 ppm)	Marginal gain — risk of API degradation

Table 2: KRDC Laboratory Results — bench-scale vacuum tray dryer trials on client's API wet cake | KRDC Test Report 62/KRDC/LAB/09 | Residual solvent by GC headspace per ICH Q3C / USP <467>

Scale-Up Methodology — Lab to 500 kg/Batch

KERONE's scale-up process follows a structured engineering framework where laboratory parameters are translated to industrial equipment specifications using validated heat- and mass-transfer models under vacuum. The key translation factors for this project are:

Parameter	KRDC Lab (Vacuum Tray Dryer)	Industrial Plant (500 kg RVD)	Scale-Up Factor
Jacket Temperature	65 degrees C	65 degrees C	1:1 (direct)
Vacuum Level	-650 mmHg	-650 mmHg	1:1 (direct)
Optimal Hold Time	6 hr	6 hr (batch cycle)	1:1 (direct)
Batch Size	~2 kg/run	500 kg/batch	250:1
Atmosphere	Vacuum / N2 blanket (selectable)	Continuous N2 blanket + vacuum	Direct
Agitation	Static tray	Slow rotary tumble (2-4 rpm)	Configuration change
Heating Mode	Batch (static shelf)	Jacketed rotary vessel, hot-water heated	Configuration change
Solvent Handling	Open bench extraction	Closed-loop condenser + recovery receiver	Enhanced / closed system

Industrial Plant Design — 500 kg/Batch Vacuum Drying System

The KERONE-designed system processes wet cake through a closed, GMP-compliant sequence: Wet Cake Charging -> Vacuum Drying (Rotary Vacuum Dryer) -> Solvent Vapour Condensation & Recovery -> Product Discharge & Milling -> Quality Analysis -> Product Packing, with nitrogen inertisation maintained throughout to manage the flammability hazard of IPA vapour.

System Architecture — Major Process Units

Unit / Section	Equipment	Design Parameters	Function
U-01: Charging	Vacuum Charging Port + SS Hopper	500 kg/batch rated Dust-tight, GMP charging	Transfer wet cake into dryer without solvent vapour escape or contamination
U-02: Rotary Vacuum Dryer (Primary Process Unit)	KERONE Batch Rotary Vacuum Dryer (RVD)	500 kg capacity 65 degrees C jacket - 650 mmHg vacuum 6-hr cycle 2-4 rpm agitation	Core thermal-vacuum processing — residual solvent removal while preserving crystal form and assay
U-03: Inertisation System	N2 Generator + Purge Control Manifold	99.5% purity N2 O2 < 1% inside vessel Continuous blanket	Prevent flammable-atmosphere formation from IPA vapour; maintain inert headspace
U-04: Vapour Condensation	Shell & Tube Condenser + Chilled Water Unit	Duty sized for peak evaporation rate Outlet 10-15 degrees C	Condense evolved IPA vapour for recovery; minimise vacuum pump loading
U-05: Solvent Recovery	Receiver Vessel + Vacuum Pump (liquid-ring)	Recovery efficiency ~95% SS316L wetted parts	Collect and store recovered IPA for reuse or off-site recycling
U-06: Discharge & Milling	Bottom Discharge Valve + Contained Mill	Contained transfer Particle size reduction as required	Discharge dried API under containment; achieve target particle size distribution
U-07: Product Handling	IBC / Drum Filling Station	GMP stainless steel contact parts, load-cell filling	Transfer dried API to validated containers; prevent contamination and cross-contact
U-08: Emission Control	Scrubber (for pump exhaust) + HEPA Vent Filter	VOC capture efficiency > 99% Compliant with SPCB norms	Control fugitive solvent vapour and particulate emissions
U-09: Process Control	PLC/SCADA Control Panel with 21 CFR Part 11 Data Logging	Siemens S7 / Allen Bradley Batch record generation Remote monitoring capable	Automated temperature, vacuum, agitation and cycle-time control; audit-trail data logging

Table 3: Process Unit Descriptions — KERONE 500 kg/Batch API Vacuum Drying Plant | U-02 (Rotary Vacuum Dryer) is the primary process unit; all others are ancillary

Core Equipment Specification — KERONE Rotary Vacuum Dryer

The KERONE Batch Rotary Vacuum Dryer (RVD) is the heart of the API residual-solvent-removal system. Designed and manufactured in-house at KERONE's Ambernath facility to cGMP fabrication standards, it directly scales the validated laboratory parameters from KRDC trial 62/KRDC/LAB/09 to industrial batch size while maintaining the identical thermal profile, vacuum level, and hold time that produced the 480 ppm residual solvent result.

Rotary Vacuum Dryer — Core Specifications

Parameter	Specification
Design Batch Size	500 kg (wet cake input)
Operating Temperature	65 degrees C jacket (max design: 90 degrees C)
Vacuum Level	-650 mmHg (adjustable -400 to -700 mmHg)
Cycle Time	6 hr (adjustable 2-8 hr via process recipe)
Vessel Dimensions	ID 1,800 mm x L 2,600 mm (double-cone / bi-conical, SS316L)
Agitation	Slow rotary tumble, 2-4 rpm, VFD-controlled
Atmosphere	N2 blanket (continuous) O2 < 1%
Drive System	VFD-controlled 5.5 kW gear motor
Installed Power	~28 kW (total connected load, dryer + ancillaries)
Product Contact Material	SS316L, mirror-polished (Ra < 0.4 micron)
Insulation	Mineral wool with SS cladding — 75 mm
Sealing	PTFE rotary union with double mechanical seal (vacuum & GMP tight)
Classification	ATEX Zone 1 rated (flammable solvent vapour duty)

Utilities & Ancillary Requirements

Utility	Specification	Consumption (per 500 kg Batch)	Source
Electrical Power	415V, 3-phase, 50Hz	~28 kW connected ~20 kW avg demand	Site utility
Nitrogen (N2)	99.5% purity 3-5 bar supply	15 Nm3/batch (blanket + purge)	Onsite N2 generator or bulk
Hot Water (Jacket)	70-75 degrees C supply closed loop	~4 m3/batch circulated	Boiler / hot water generator
Chilled Water (Condenser)	8-12 degrees C supply closed loop	~6 m3/batch	Chiller unit
Vacuum Utility	Liquid-ring vacuum pump, seal fluid cooled	Continuous during 6-hr cycle	Dedicated vacuum pump skid
Space Requirement	Building / covered GMP area	L 8m x W 6m x H 6m	Existing production block or new bay

Emission Compliance

Emission Point	Pollutant	Expected Level	SPCB / CPCB Limit	Status
Vacuum pump exhaust (post-scrubber)	VOC (IPA)	< 15 mg/Nm3	20 mg/Nm3	COMPLIANT
Vent filter outlet	Particulate (API dust)	< 5 mg/Nm3	20 mg/Nm3	COMPLIANT
Condenser non-condensables	VOC / TOC	< 10 mg/Nm3	20 mg/Nm3	COMPLIANT

Mass Balance & Energy Analysis — 500 kg/Batch Operation

Detailed Mass Balance — Per Batch at Full Load

Stream	Material	Mass (kg/batch)	Notes
Feed (IN)	API wet cake (as-centrifuged)	500	8.4% w/w IPA, ~1.2% surface moisture
Solvent Removed (Vapour)	IPA + trace moisture	~44	8.8% of feed; condensed and recovered
Solvent Recovered (Liquid)	Recovered IPA (for reuse/off-site recycle)	~42	~95% recovery of evolved solvent
Solvent Lost (Non-condensable/vent)	IPA vapour to scrubber	~2	Captured by scrubber; meets SPCB norms
Product (OUT)	Dried API intermediate	~456	480 ppm residual IPA; > 99.7% assay; bagged
Fines (recovered)	Milling/handling fines	~3	Recovered to product lot after QC check

Table 4: Mass balance — 500 kg/batch API vacuum drying plant | Based on validated KRDC lab data scaled to industrial batch size

Energy Consumption Estimates

Energy Category	Equipment / Unit	Power (kW)	Load Factor	Consumption (kWh/batch)
Jacket Heating	Hot water generator + circulation pump	18	80%	~86
Drive Systems	Rotary drive + agitation	5.5	70%	~23
Vacuum System	Liquid-ring vacuum pump	7.5	100%	~45
Chilled Water / Condenser	Chiller + circulation pump	9	90%	~49
Emission Control	Scrubber pump + vent filter fan	3	85%	~15
Utilities & Controls	N2 generator + PLC/SCADA + lighting	4	60%	~14
TOTAL		~47 kW		~232 kWh/batch

Table 5: Energy consumption estimate — 500 kg/batch API drying plant | Based on KERONE engineering estimates; actual values to be confirmed during detailed engineering

Product Quality Specification & Market Applications

Expected Product Specification — KERONE Processed API

Parameter	Test Method	Raw Wet Cake (Input)	Processed API (4-hr cycle)	Processed API (6-hr cycle)	ICH Q3C / Regulated Limit
Residual Solvent (IPA)	GC Headspace (ICH Q3C)	8.4% w/w	3,100 ppm	480 ppm	< 5,000 ppm
Loss on Drying	USP <731> / IP	9.1%	~0.6%	< 0.3%	< 1.0%
Assay (HPLC)	In-house / USP monograph	97.8%	~99.3%	> 99.7%	> 99.0%
Related Substances (Total)	HPLC	0.85%	~0.55%	< 0.40%	< 0.50%
Residue on Ignition	USP <281>	0.12%	~0.10%	< 0.10%	< 0.10%
Product Grade	Classification	Domestic / non-regulated only	General regulated grade	Premium regulated grade (US/EU)	Regulated market entry

Table 6: Product quality specification — raw wet cake vs processed API at 4-hr and 6-hr cycles vs ICH Q3C/regulated limits | 6-hr processed column highlighted as recommended for premium regulated-market applications

Market Applications for Processed API

- Regulated Market Export (US FDA / EMA / PMDA / TGA): Residual solvent below 5,000 ppm and assay above 99% meets the filing requirements for Drug Master File (DMF) / CEP submissions, opening access to premium export markets.
- Domestic Formulation Manufacturers (Schedule M / Revised GMP): High-purity, low-solvent API meets tightening domestic GMP norms for finished dosage form manufacturers, commanding a domestic quality premium.
- Contract Development & Manufacturing (CDMO) Supply: CDMOs servicing regulated-market innovator and generic customers require consistent sub-5,000 ppm solvent compliance as a standard qualification criterion.
- Parenteral & Sterile-Grade Precursors: Very low residual solvent and related-substance levels support use as starting material for higher-value sterile and parenteral formulations, which carry stricter impurity thresholds.
- Solvent Recycling & Reuse: Recovered IPA (~95% of evolved solvent) can be reused directly in the crystallisation step after a distillation polish, reducing fresh solvent purchase and hazardous waste disposal costs.

Financial Analysis & Return on Investment

CAPEX Estimate — 500 kg/Batch Plant

Cost Head	Scope	Estimated Cost (INR Lakhs)	Notes
Rotary Vacuum Dryer (Primary Equipment)	KERONE supply, factory tested, ATEX rated	38-45	FOT Ambernath; includes drive, seals, controls
Condenser & Solvent Recovery Skid	Shell & tube condenser + receiver + pump	9-11	SS316L construction, GMP finish
Vacuum System	Liquid-ring vacuum pump + seal fluid chiller	7-9	Explosion-protected motor
N2 Generator System	PSA N2 generator + receiver	4-5	99.5% purity, 30 Nm3/hr capacity
Emission Control	Scrubber + HEPA vent filter	5-6	SPCB-compliant stack system
Product Handling	Discharge valve, mill, IBC filling station	4-5	GMP contact parts, load-cell filling
Electrical & Instrumentation	MCC panel, PLC/SCADA, 21 CFR Pt.11 logging	8-10	PLC/SCADA by KERONE; site electrical by client
Civil & Structural (GMP)	Foundation, room finishes, utility tie-ins	5-6	Client scope; KERONE to provide layout drawing
Commissioning, Qualification & Training	IQ/OQ/PQ documentation, 15-day site support	3-4	Includes operator training and performance test
TOTAL CAPEX		INR 83-101 Lakhs,[object Object]	Approx. range; formal quotation on enquiry

Table 7: CAPEX estimate — 500 kg/batch API vacuum drying plant | All figures indicative; formal quotation on receipt of detailed enquiry

Revenue & OPEX Model — Annual Basis (600 batches/yr operation)

Item	Basis	INR/Year (Lakhs)	Remarks
API Product Sales	456 kg/batch x 600 batches x INR 3,700/kg	INR 10,123 Lakhs	Conservative regulated-market price; range INR 3,200-4,200/kg
Electricity & Utilities	232 kWh/batch x 600 batches x INR 8/kWh	INR 11 Lakhs	Industrial tariff basis
Hot Water / Steam	Boiler fuel for jacket heating	INR 9 Lakhs	Can substitute with waste-heat recovery
N2 Consumption	Onsite PSA; power included above	INR 3 Lakhs	Maintenance + N2 top-up cost
Labour (Operations & QA)	6 operators/shift x 2 shifts x 12 months	INR 36 Lakhs	At INR 30,000/operator/month CTC, incl. QA support
Maintenance & Spares	3% of CAPEX per annum	INR 3 Lakhs	Annual maintenance provision
Solvent Recovery Credit	42 kg/batch x 600 batches x INR 60/kg (avoided purchase)	INR (15) Lakhs credit	Reduces net fresh-solvent purchase cost
Miscellaneous & Overheads	QC testing, consumables, admin	INR 8 Lakhs	Includes GC/HPLC analysis consumables
NET PROFIT BEFORE TAX (illustrative)		INR ~10,068 Lakhs/yr,[object Object]	Reflects the value of full regulated-market access; see note below

Note: the revenue and profit figures above illustrate the value of the price uplift attributable to regulated-market compliance across the client's full annual production volume; they should not be read as incremental profit from the drying step in isolation, since raw material, synthesis, and other conversion costs are unchanged and are excluded from this comparison, which focuses only on the drying/solvent-removal cost-benefit. On a standalone incremental-investment basis (CAPEX of the RVD system vs. the price uplift it enables), payback is estimated at approximately 1.8 years.

Project Execution & KERONE Scope of Supply

Implementation Timeline

Phase	Activity	Duration	KERONE Deliverable
Phase 0 — Pre-Order	Technical consultation, site visit, process design freeze, commercial negotiation	3-4 Weeks	Process Design Basis (PDB), GA drawing, utility list, commercial offer
Phase 1 — Engineering	Detailed engineering: mechanical, electrical, GMP layout, P&ID finalisation	6-8 Weeks	Complete engineering package, vendor drawings, URS/DQ documentation
Phase 2 — Procurement	Long-lead items: vessel shell, jacket, vacuum pump, N2 generator, ATEX components	10-12 Weeks	Material test certificates, QC inspection reports, FAT invitation
Phase 3 — Fabrication	RVD fabrication, condenser assembly, scrubber, SCADA panel	10-12 Weeks	Factory Acceptance Test (FAT) at KERONE Ambarnath; client witness invited
Phase 4 — Installation	Equipment erection at client site; piping, electrical, instrument hook-up	3-4 Weeks	KERONE site supervision; civil and electrical by client as per KERONE drawings
Phase 5 — Commissioning & Qualification	Cold trials, hot trials with actual wet cake, IQ/OQ/PQ, operator training	3-4 Weeks	Commissioning report, IQ/OQ/PQ documentation, O&M manual, training records
TOTAL PROJECT TIMELINE	Order to commercial (validated) production	~35-44 Weeks,[object Object]	From purchase order to first qualified commercial batch

KERONE Scope of Supply & Services

Category	KERONE Scope (INCLUDED)	Client Scope (EXCLUDED from KERONE supply)
Process Design	Process design basis, mass balance, heat & material balance, P&ID	Feedstock quality guarantee; plant operating schedule
Primary Equipment	Rotary vacuum dryer (complete), condenser, N2 system, discharge & milling unit	Upstream centrifugation/isolation equipment (if not in enquiry scope)
Emission Control	Scrubber, HEPA vent filter (SPCB compliant)	Stack height design and consent-to-operate from SPCB/CPCB
Controls	PLC/SCADA, MCC panel, all instruments and field wiring, 21 CFR Pt.11 logging	DG set, main power supply connection, transformer
Civil & Structural	Foundation load drawings, GA layout, anchor bolt drawings	All civil work, GMP room finishes, HVAC, drains
Commissioning	FAT, site commissioning, IQ/OQ/PQ support, operator training (15 days)	Consumables (N2, IPA) for commissioning trials; feedstock for trials
Documentation	P&ID, GA drawings, O&M manual, spares list, test certificates	Client-side regulatory approvals (DMF/CEP filings), insurance

Conclusions & Why KERONE

The KERONE-designed 500 kg/Batch Rotary Vacuum Drying System represents a proven, commercially validated solution to one of the most significant value-unlock opportunities in India's API manufacturing industry. The process is built on rigorous KRDC laboratory data — not theoretical projections — and the industrial design directly replicates the exact process conditions that produced measurable, certified results on the client's actual production wet cake.

Proven Technology

Every process parameter in the 500 kg/batch plant — 65 degrees C jacket temperature, -650 mmHg vacuum, 6-hour cycle — is directly derived from KRDC lab trial 62/KRDC/LAB/09 on the client's actual feedstock. No extrapolation; no assumptions.

Quantified Outcome

Residual solvent reduction from 8.4% w/w to below 480 ppm, and assay improvement from 97.8% to above 99.7%, are measurable, certified results — not marketing claims.

Commercial Clarity

The financial model demonstrates a standalone payback period of approximately 1.8 years on the incremental drying investment, unlocking regulated-market pricing across the client's existing production volume.

Full Ownership

KERONE designs, manufactures, supplies, installs, and commissions the complete plant from a single point of accountability — eliminating multi-vendor coordination risk in a GMP-regulated environment.

Scalable Platform

The rotary vacuum drying platform is scalable. A 500 kg/batch system validated for this client creates the reference installation for 250 kg, 1,000 kg, and multi-vessel systems for other API manufacturers across India and internationally.

Compliance-Ready

Emission control, N2 inertisation, and 21 CFR Part 11-compliant data logging are integral to the KERONE supply scope — the system is designed to GMP and regulatory expectations from the outset, not retrofitted for compliance after the fact.

ENQUIRE ABOUT YOUR API DRYING & SOLVENT RECOVERY PROJECT

KERONE Engineering Solutions Limited | KRDC — Kerone Research & Development Centre

B/47 Addl. MIDC, Anand Nagar, Ambarnath (East), Thane - 421 506, Maharashtra, India

Tel: +91-251-2620542 / 13 / 44 / 45 / 46

Email: info@kerone.com | Web: www.kerone.com

To initiate a project discussion, please share: feedstock/wet cake quality report + daily/annual batch volume + site location + target regulated market(s) and compliance requirement

ISO 9001:2015 | ISO 14001:2015 | ISO 45001:2018 | CRISIL Rated Company | AIMCAL Member | IHEA Member | EMItech Certified | 50+ Years of Engineering Excellence

DISCLAIMER: All financial projections are indicative and based on illustrative market pricing as of July 2026. Process performance figures are derived from KRDC laboratory data (Report 62/KRDC/LAB/09) conducted on the client's actual API wet cake under a mutual non-disclosure agreement; client identity and product identity are withheld throughout this document. Actual industrial performance may vary. This document is intended for discussion purposes; a formal quotation will be issued following detailed enquiry.