ESTABLISHED 2015

KALINTIS HEALTHCARE PVT LTD

Corporate Presentation - 2025

Ethos: Driving Transformation Through Science, Collaboration, Ingenuity

Corporate Profile Privately Owned

ABOUT THE COMPANY

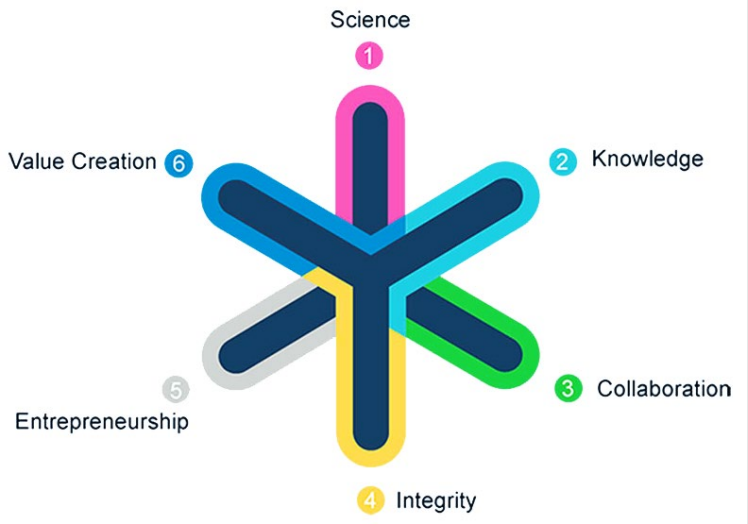
Established in 2015, Kalintis Healthcare Private Limited has quickly emerged as a prominent force in the global pharmaceutical sector. With a comprehensive portfolio of Active Pharmaceutical Ingredients (APIs), intermediates, and specialty chemicals, we are strategically located in Vadodara, Gujarat, India—the heart of the pharmaceutical industry—just 22 km from the city center. Our cutting-edge manufacturing facility covers 55,000 square meters, with more than 8,000 square meters dedicated exclusively to production.

Commercial Manuftcuring Facility

Business Area:

- Chemistry Synthesis, Small Molecule
- API-Generics, Commercial FDF- FR&D, Q1Q2
- Analytical Service; Regulatory Support,
- QSAR Genotoxic assessment Support

Science-powered solutions for scalable success



Chemistry

Expertise in Tackling Complex Chemistry Challenges:

Proficient in solving intricate problems involving small and complex APIs, ensuring innovation and precision in every solution.

Specialized Handling Capabilities: Experienced in managing sterile, controlled, and dye API molecules with utmost care and adherence to industry standards.

Cost-Effective and Reliable Sourcing: Skilled in sourcing high-quality raw materials (RMs) from cost-effective and dependable suppliers to optimize production processes.

Capacity

- **High Production Capacity:** The 1000 KL+ reactor capacity and the presence of over 50 reactors ensure that we can scale up production quickly, catering to large orders and increasing market demands.
- **Operational Efficiency:** The integration of reactors with the dedicated raw material facility streamlines operations, minimizes delays, and optimizes production time lines.
- **Quality Control:** The backward integration ensures tight control over the quality of the raw materials, products. By manufacturing raw materials in-house, we reduce procurement costs and mitigate the risk of supply chain disruptions.

Compliance

Unwavering Commitment to Quality:
Dedicated to maintaining exceptional standards across all operations, ensuring consistency, reliability, and excellence.
Exemplary Regulatory Compliance: Demonstrating an impeccable track record of regulatory adherence, sustained flawlessly over the past decade through rigorous oversight and best practices.
Global Recognition and Trust:
Successfully audited by renowned global regulatory authorities, including the FDA, and trusted by leading clients. A proven regulatory track record that reflects excellence over the last decade.

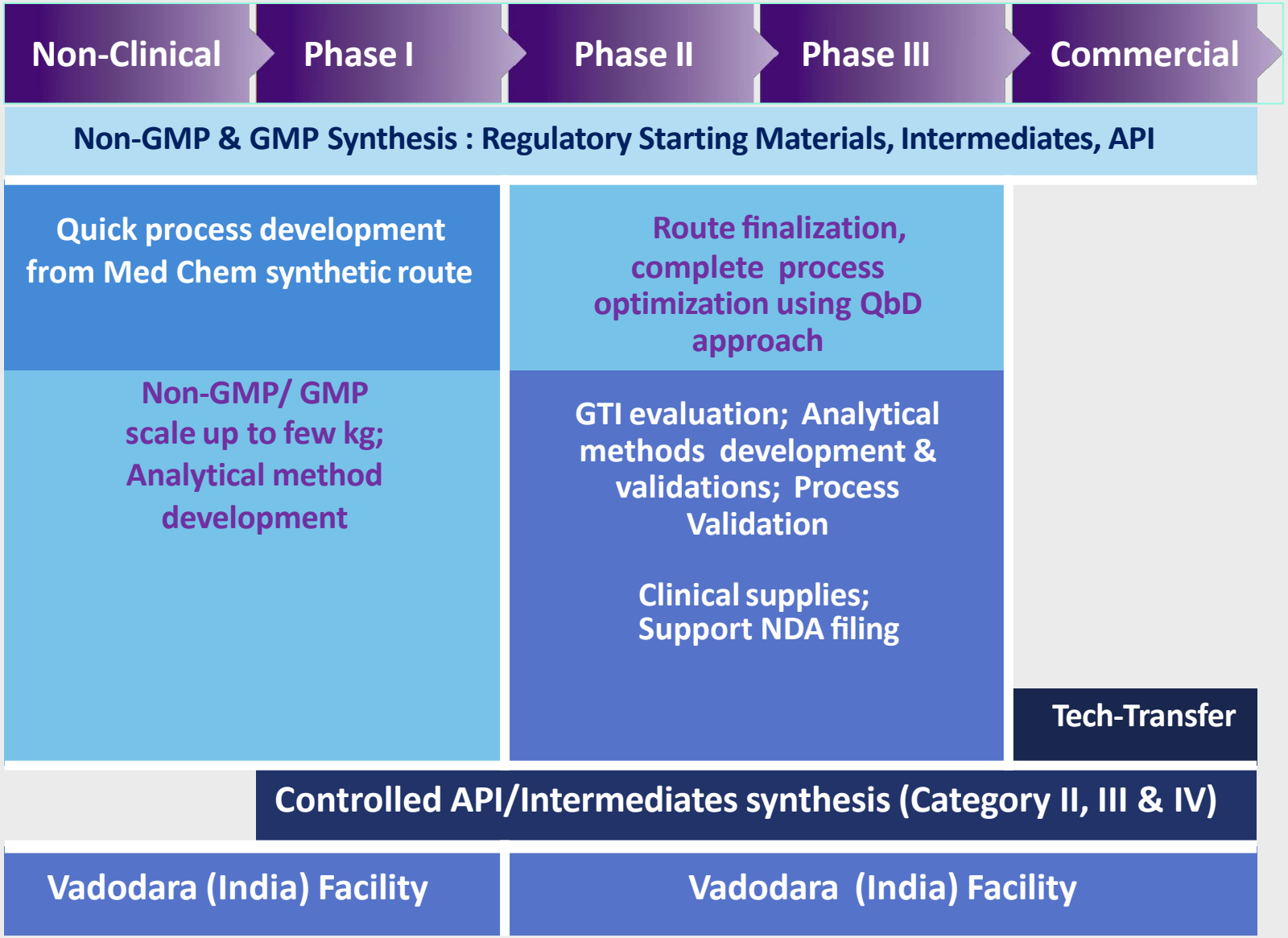
Competence

- **Proven Track Record of Success**: Spearheaded and supported 5 successful commercial launches in 2019-20, demonstrating expertise in delivering results.
- **End-to-End Expertise:** Over a decade of experience in seamlessly navigating the product lifecycle, from Pre-Clinical development to Commercialization, while ensuring adaptability to meet diverse customer needs.
- **Balanced Focus**: Strong emphasis on driving success across both early-stage innovation and late-stage execution, ensuring holistic project management and impactful outcomes.

Kalintis Health Care

CDMO/CMC Services

Drug Substance Development and Manufacturing Chemistry Services



Core Values

- **Innovation**:
  - Pioneering unique and non-infringing synthetic routes.
- **Quality**:
  - Embedding excellence at every stage of production.
- **Compliance**:
  - Meeting and exceeding national and international regulatory requirements.
- **Sustainability**:
  - Ensuring eco-friendly practices and zero-discharge operations.
- **Customer Centricity**:
  - Offering customized manufacturing and comprehensive support.

Kalintis Today

24/7
Manufacturing

USFDA approved Manufacturing site located at Vadodara

7+

Commercial DMFs for US Market

10+

Countries of business for API and Intermediates

30+

Forecasted Regulatory Filings within next 3 year Period

100+

Experienced professionals including scientists

Chemistry Capabilities & Strengths

Strong Expertise
Two decades
In development of robust & Cost-effective processes for rapid scale up & Commercial

Experience
Two decades of experience in pharmaceuticals manufacturing to several global clients

Drug discovery medicinal Chemistry Library molecule synthesis

High Potent
HPAPI (Oncology/ Cytotoxic)and Corticosteroids development & manufacturing

Catalyst Chemistry
Metal catalyzed reactions (Pd; Ru; Pt, Ni) reactions

Temperature Operations
Cryogenic reactors operating within temperature range up to -100 C to + 200 C

Controlled (C-II; C-III; C-IV)
Development & Commercial Manufacturing of Different Class Controlled API'S

Natural product & Intermediates Chemistry

NCE Development Custom Synthesis

Peptide Chemistry Generic API

DEPARTMENT SPECIFIC EMPLOYEES

Operations	Count
Quality Assurance, Quality Control & Regulatory Affairs	40
Research & Development (Ph.D. and Master)	20
Human Resources	3
Finance & Accounts	4
Administration and BD	2
Production	40
Company Secretary & Legal Affairs	1
Sales	3
Projects / Engineering & Maintenance	25
Purchase	2
Environment Health Safety & Quality	8
Information Technology	1
Warehouse	4

Kalintis
Health Care

CDMO/CMC Services for Drug Substances

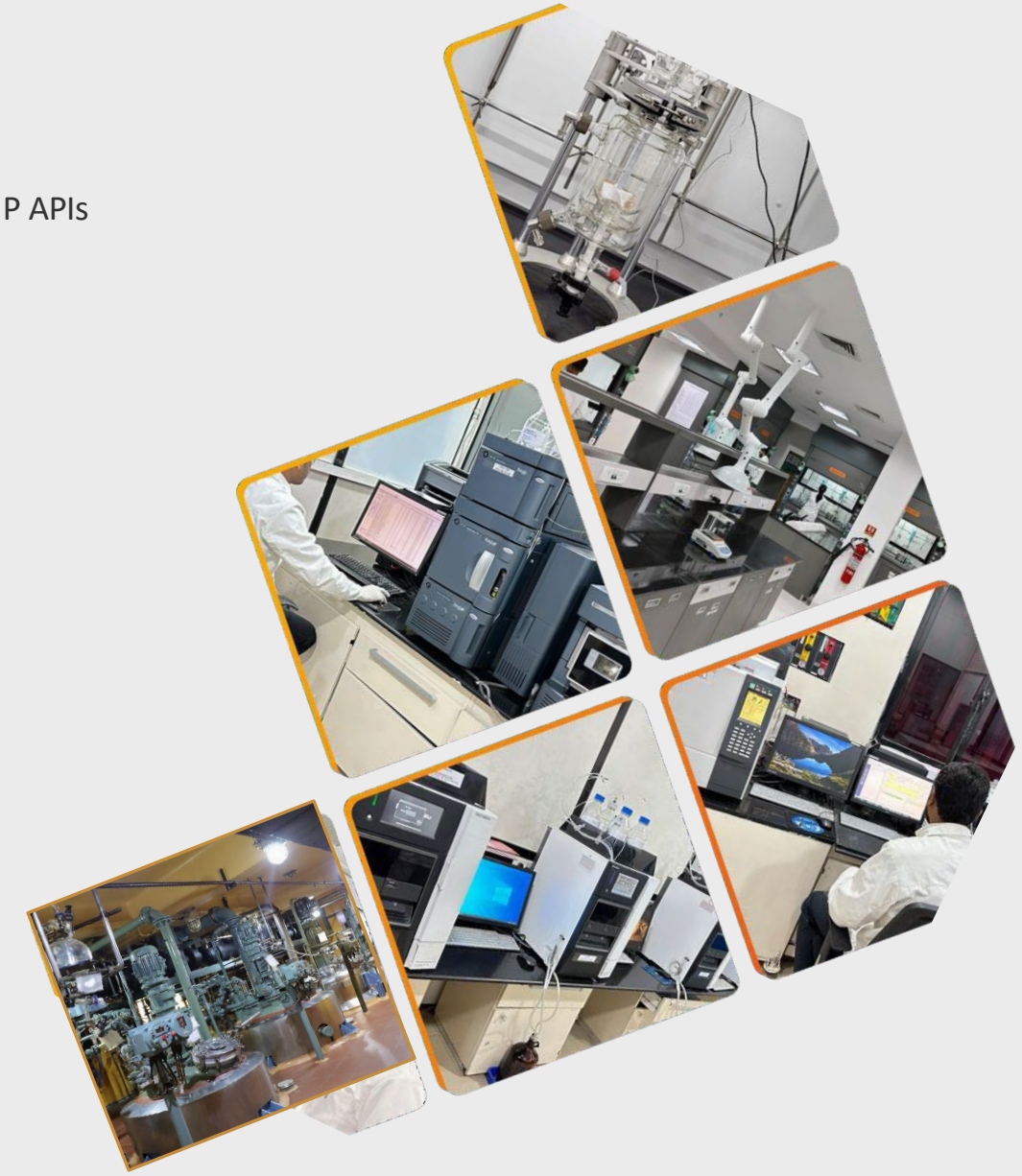
- Process Development and Manufacturing of KSMs, RSMs, Intermediates & GMP APIs for small molecule NCEs
- Early clinical phase trial to commercial supplies
- HPAPIs development and manufacturing
- Complete CMC documentation support & DMF filing

Generic APIs and Intermediates

- Therapeutic categories: Anti-Cancer, Anti-Asthmatic, Cardiovascular, Anti-Coagulant, Anti-Diabetic, CNS, Dermatology, Ophthalmic
- Dedicated blocks for Anti-Cancer products
- Regulated markets: USA, EU, Korea & Japan
- Backward integrated intermediates for APIs

Analytical & Regulatory Service

- Analytical Method development for API and intermediates.
- Analytical Method Validation
- Analytical Impurities and standard support.
- ICH Stability studies.
- **QSAR Genotoxic Assessment using CASE ULTRA (ICH M7)**
- **DMF filing support US&EU.**



We Offer Products and Services

Products

- **Active Pharmaceutical Ingredients**
  US; EU; ROW markets
- **Intermediates**
  Analytical
  standards/Impurities

Services

- **CRAMS Services**
  Analytical Services
- **Customer Exclusive development**
- **Co-Development**

Kalintis Health Care

Accreditations: Compliance with India Schedule M, USFDA, WHO-GMP, EU-GMP, ICH Q7, and other international norms
DUNS: 876817087
USFDA FEI: 3013455974
US NDC Labeler Code: 72166
EDQM Organization ID: ORG-100050535
INDIA FDCA License: G-25-2249
Control Substance and Narcotics Manufacturing License.

Plot Area: 55,000 square meters. (originally: 11164 SQM +acquired and Adjoined 44,000 SQM)

Building: 8,000 square meters,

Green Belt: 2,720 square meters

Internal Roads: 1,580 square meters

GPCB Permission: 39.40 KL Per Month.

Future Expansion: Over 80 % Land is available within the same land block that is been registered with USFDA under single FEI Number and having EU ORG ID and available with Purpose changed to chemical and pharmaceutical product manufacturing.

Advantage: No additional registration or permission is required from GPCB, the state government, or the USFDA. The facility operates under a Single Facility Fee, with future scope for expansion to include API, intermediates, containment products (including ONCO), and formulation manufacturing

Regulatory Excellence:

Accreditations: Compliance with India Schedule M, USFDA, WHO-GMP, EU-GMP, ICH Q7, and other international norms

- DUNS: 876817087
- USFDA FEI: 3013455974
- US NDC Labeler Code: 72166
- EDQM Organization ID: ORG-100050535
- INDIA FDCA License: G-25-2249
- Control Substance and Narcotics Manufacturing License.

Regulatory Filings:

- Eight dossiers were filed, including seven USDMFs and one CEP.
- Upcoming filings for niche and CDMO APIs and novel molecules.
- Every year 5 to 6 Molecule Developments and 4 Dossirer fillings

Inspection and Compliance Success:

- Passed USFDA inspections without observations (zero 483).
- Regular audits by customers from the USA and Europe.
- Continuous lifecycle management of DMFs, with five approved DMFs and several under review.
- Consistent updates to regulatory authorities on process changes, ensuring transparency and compliance.

List of API Products

#	API's in Commercial
1	Lorazepam
2	Benztropine Mesylate
3	Furosemide
4	Ketotifen Fumarate
5	Methenamine Hippurate
6	Mexiletine Hydrochloride
7	Oxazepam
8	Torsemide
9	Cevimeline Hydrochloride
10	Pemetrexed disodium heptahydrate
11	Methylene Blue
12	Chlorpromazine Hydrochloride
13	Methimazole
14	Diphenoxylate HCl & Atropine Sulphate
15	Omeprazole Magnesium Dihydrate
16	Esomeprazole Magnesium Trihydrate
17	Methenamine
18	Voriconazole

#	API's Ready for Exhibit
1	Apixaban
2	Linezolid
3	Atorvastatin
4	Metaxalone
5	Mesalamine
6	Upadacitinib
7	Ticagrelor
8	Rivaroxaban
9	Sitagliptin
10	Ferric carboxy maltose
11	Isosulfan Blue
12	Roxudastat
13	Miragobilin
14	Linagliptin
15	Bempedoic Acid
16	Empaglifozin
17	Vonaprazan
18	Brexipiprazole

#	API's R&D Completed
1	Levo Carnitine
2	Risperidrone
3	Iohexol
4	Indocyanine green
5	Latanoprost
6	Iron sucrose
7	Netrasudil
8	Dorzolamide
9	Metaxalone
10	Clomiphene
11	Pilocarpine
12	Dexmeditomidine
13	Propofol
14	Fomepazole
15	N-Acetylcystine
16	Foscarnet Sodium
17	Colestipol, Pentosan, Sucralfate, Glatiramer Acetate

CEP – Certificate of Sustainability (European Pharmacopeia)
USDMF – United States Drug Master File
CN DMF – China Drug Master File
KDMF – Korea Drug Master File

Manufacturing facility

1. Common facility:

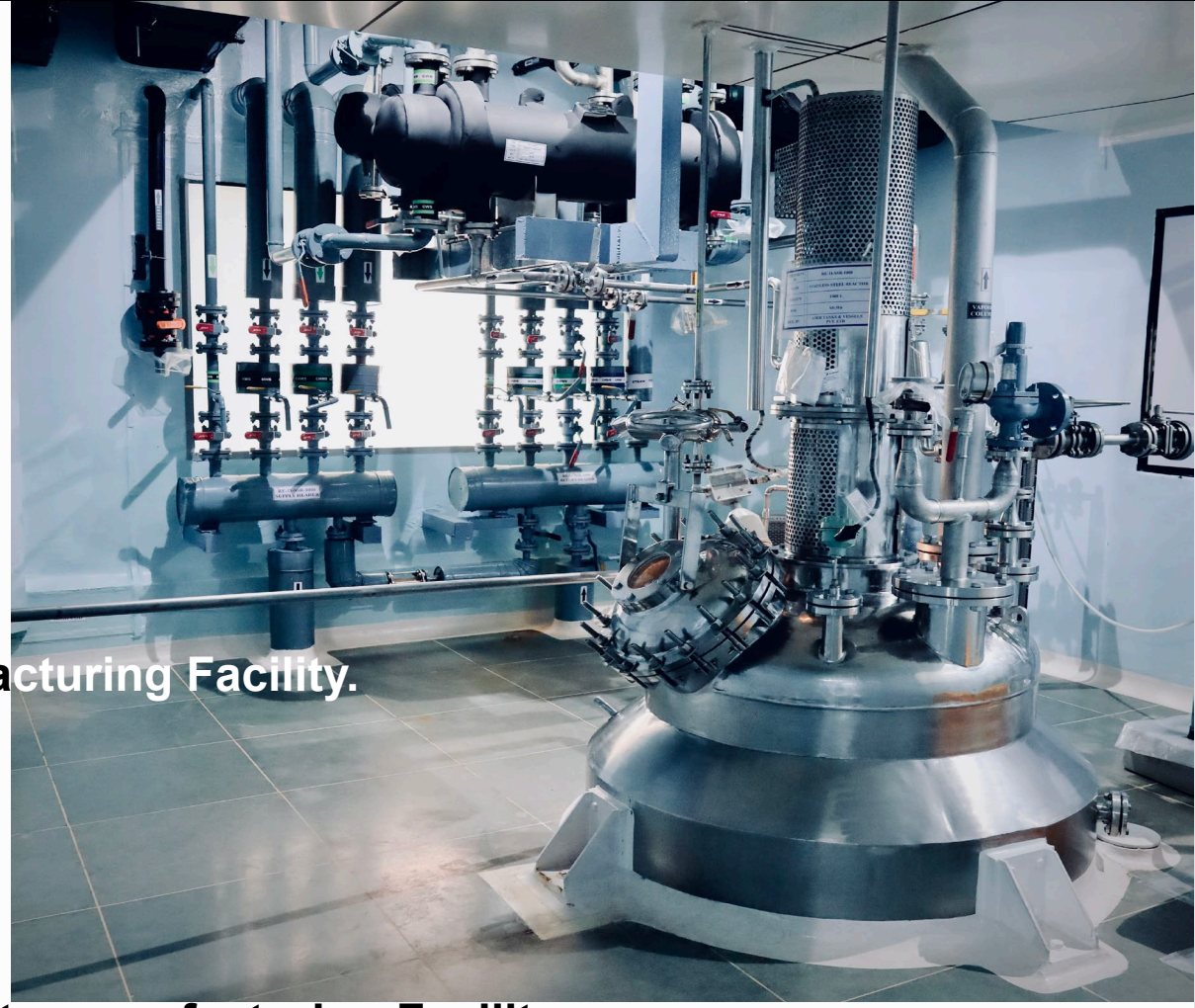
- Warehouse for solid, and packaging material.
- Solvent storage and carbon dispensing rooms.
- Dispensing room with day store.
- Control material storage room
- Finished API and intermediate Storage room.

2. Multiproduct large volume API and intermediate manufacturing Facility.

- Intermediate manufacturing zones
- API crystallization zone
- API powder processing zone
- Dedicated Blender Room

3. Dedicated Small Volume-High value API and intermediate manufacturing Facility.

- Intermediate and API manufacturing zone
- API powder processing zone



Facility picture

Utilities

USP Purified water with 24 X 7 Loop circulation

- Purified water pre-treatment system
- Purified water Generation system
- Purified water circulation and filtration system.

Heating, ventilation, and air conditioning (HVAC) systems for all the areas.

- 5-micron filtered once through air supply, in the intermediate chemical processing area and warehouse.
- HEPA filtered once through air in API crystallization area (ISO class-8) with temperature and humidity control.
- HEPA filtered re-circulation air in powder processing area (ISO class-8) with temperature and humidity control.
- HEPA filtered once through air in small volume API crystallization area (ISO class-8) with temperature and humidity control.
- HEPA filtered re-circulation air in blender and small volume powder processing area (ISO class-8) with temperature and humidity control.

Other Critical utilities

- Oil free compressed air system
- Cooling tower
- Steam generation and circulation system
- Brine generation and circulation system
- LDO fired boiler
- UPS and DG for power Backup.
- Effluent Treatment Plant

Quality Unit

Quality Control area occupies the first floor of the plant and features a vast area with dedicated sub-zones for analytical method validations and routine release testing of the products.

- HPLC instrument room: 8 Waters HPLCs and an Empower 3 secure acquisition and data storage server system.
- GC room: two Perkin Elmer HSGCs with auto samplers.
- Dedicated instrument room: it houses a UV spectrophotometer, FTIR, Metrohm Auto titrator, and Karl Fischer, as well as microbalances.
- Wet analysis Room: it has vacuum Oven, Dryer, Fumehood, Milli-Q Water system, and all the essentials for the wet analysis and sample preparation.
- Stability room: it houses four stability chambers and standard storage cooling cabinets.
- Control sample room: secure area for preservation of commercial API and key raw material samples.
- Document storage room: for placement of all routine QC document storage.

Quality Unit

Quality Assurance and Regulatory affairs:

- The Quality Assurance and Regulatory Affairs department manages the quality management system and ensures regulatory compliance. they oversees DMF lifecycle management and collaborates with other departments to maintain Good Manufacturing Practices (GMP) and quality standards.
- The department conducts internal audits, trains employees on GMP, and ensures all documentation is accurate and up-to-date to meet customer and regulatory needs.

Future Goals

- Expand the Plant with New Onco block & API portfolio to include high-value products.
- File 10-20 DMFs annually for the US and European markets.
- Expand Horizons into the entire world market with quality molecules.
- Continue investing in infrastructure and R&D to meet evolving global healthcare needs.

ESG and Sustainability

Eco-Sustainability: Zero-discharge effluent systems and eco-friendly practices.

Zero-Discharge Effluent Systems

A zero-discharge effluent system (ZLD) is an advanced wastewater treatment process designed to eliminate liquid waste. By treating, recovering, and reusing all water and by-products within an industrial facility, ZLD ensures that no wastewater is discharged into the environment.

Key Components of ZLD Systems:

Pre-Treatment: Removes large particles and contaminants from effluent.

Evaporation and Crystallization: Concentrates and crystallizes salts and other solids from the water.

Water Recovery: Recycled water is reintroduced into the production process, reducing freshwater dependency.

Community Support

- Cluster & Rural Development
- Education & Skill Development
- Childcare & Healthcare Facilities
- Women Empowerment & Livelihood Opportunities
- Disaster Relief & Rehabilitation
- Water Conservation & Environment
- Research & Development for Upliftment of Society

Why to Choose Kalintis

End-to-End Support: From research and development (R&D) to regulatory filings, Kalintis provides comprehensive solutions.

First-Time-Right Quality Culture: Ensuring consistent product quality through robust systems and employee accountability.

Regulatory Compliance Expertise: A dedicated team ensures smooth lifecycle management of DMFs, CEPs, and other regulatory requirements.

Robust Infrastructure: State-of-the-art facilities designed to ensure operational efficiency and regulatory compliance.

Innovation Pipeline: Over 30 molecules ready for scale-up, with a strong focus on niche APIs.

THANK YOU

Address

Vadodara, Gujarat
India

Contact Numbers

+1 7325980645
+91

Email Address

kishore@kalintis.com