

Synthimed Labs Private Limited



Our Commitment : At Synthimed Labs, our core ethos is centered on meeting the global demand for a healthier world through the provision of top-quality products and services to our esteemed clientele. Backed by a team with diverse industrial experience, we endeavor to deliver tailored pharmaceutical products, ingredients, and solutions that precisely align with each client's unique business requirements.

Our People and Values : At Synthimed, we firmly believe in the transformative power of people empowerment, recognizing the pivotal role of competent, talented, and empowered individuals in shaping our journey to success. Our unwavering commitment to investing in talent and embracing a shared success ethos has been fundamental to our organizational philosophy. We are firm believers in the potential of diverse skill sets converging towards a common purpose, catalyzing remarkable achievements.

Pioneers in Pharmaceutical Excellence

Headquartered in Chandigarh, India, Synthimed Labs Pvt. Ltd. has emerged as a global leader in the manufacturing of APIs, Intermediates, and formulations through collaborative efforts. Boasting three cutting-edge manufacturing sites in Punjab and Jammu, we diligently cater to the API requirements of regulated markets such as USFDA, EDQM, PMDA, ANVISA, EU-GMP, KFDA, NMO, ANSM, Cofepris, TGA, WHO, and ROW.

Our company has established a significant presence in manufacturing APIs related to Cardiovascular health, Antihistamine, Antidiabetic, Antipsychotic, Antimigraine, Parkinson's Disease, Antineoplastic, ADHD Symptoms, Analgesics, Alcohol Abstinence, and Bone Resorption Inhibitor, with global leadership positions in the Macrolide Antibiotic segment.



Our Manufacturing Facilities

Situated within 1
hour drive from
Chandigarh
International Airport



Existing infrastructure
spread over 150,000
square meters
Additional 30,000
square Feet is available
for future expansion
Personnel : 2000 +



R&D Centre located at
Chandigarh, Punjab

Situated within 1 hr drive
from Chandigarh
International Airport

Existing infrastructure spread
over 40,000 square ft
Additional 40,000 square ft
is available for future
expansion



Manufacturing Capabilities - expansion

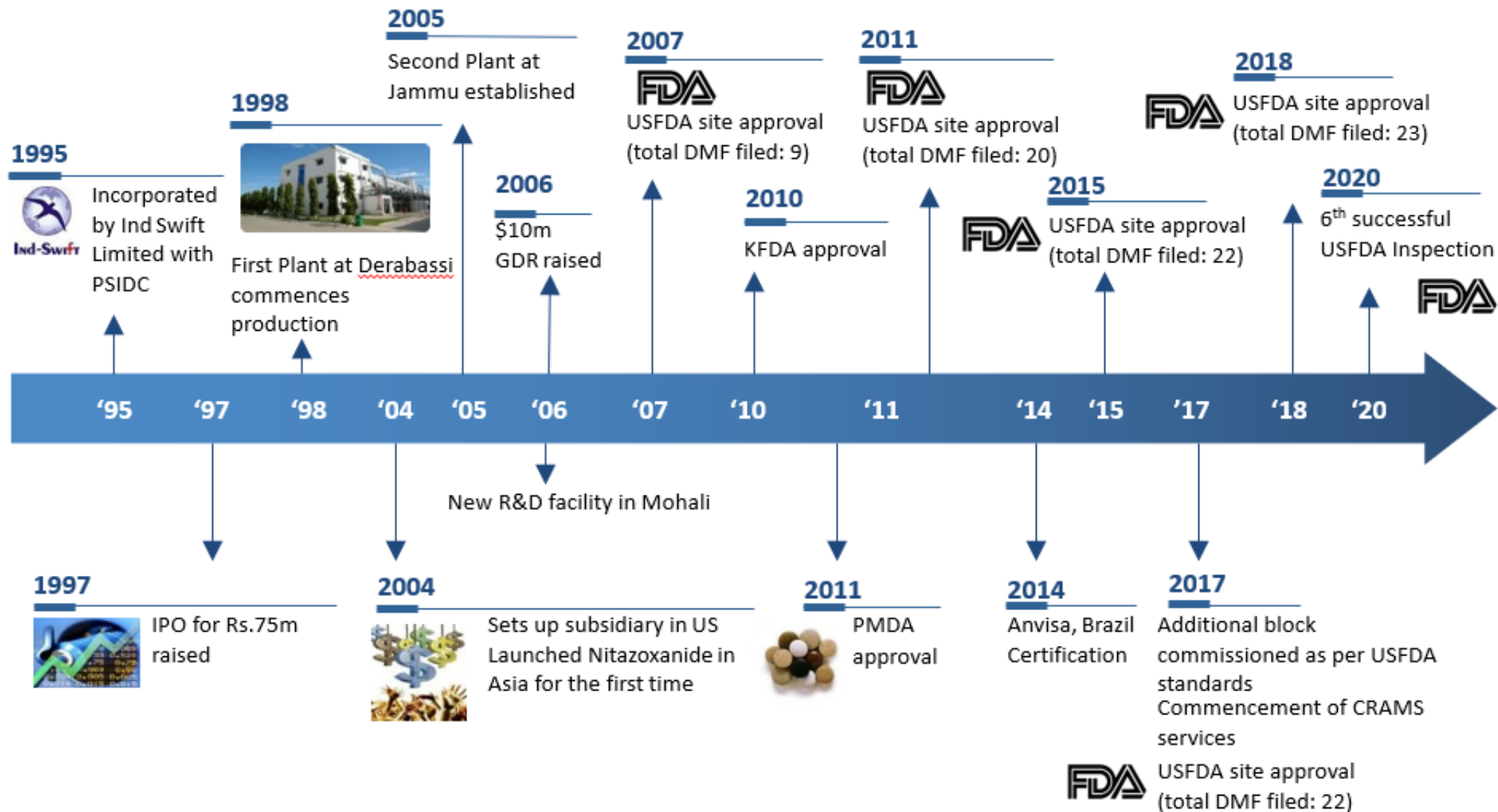
Adding 2 new production blocks
to increase total production
blocks to 24

Adding 25 new SS and GL
reactors to increase total
reactors to 250

Adding 100,000 Liter reaction
capacity to increase total
capacity to 800000 Liter

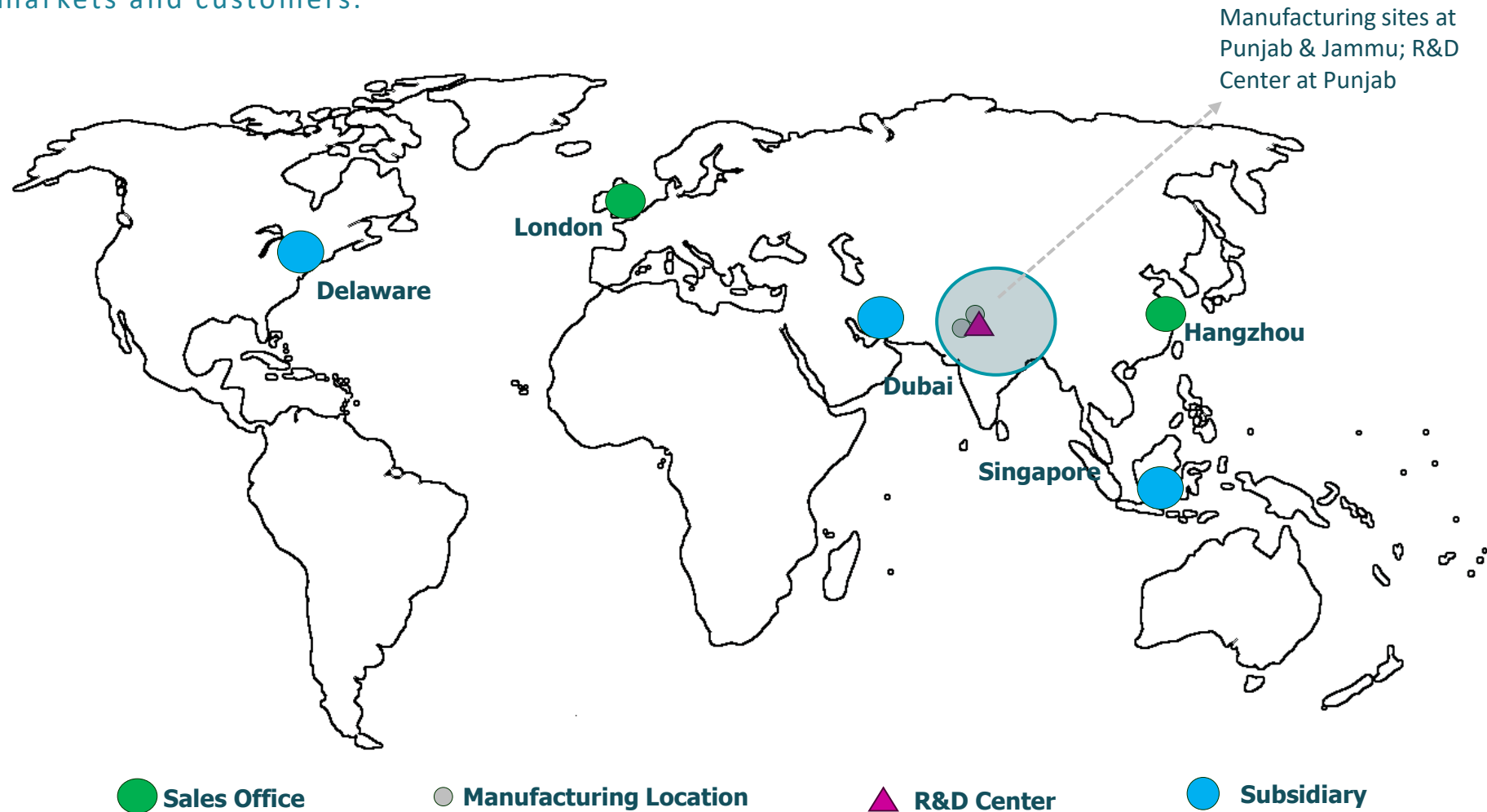


Corporate History



Global Presence

- ✓ Plants in Asia , establishments across the global (offices / subsidiaries) ensure proximity to key markets and customers.



Principle Thrust Areas

CRAMS / API Development

- Route Scouting
- Process Research and Development
- Process Optimization & QbD
- Process Validation
- Scale-up and Tech Transfer
- Complete Cycle of Development and life cycle management of products

Analytical Development

- Method Development and Optimization
- Traces level analysis of organic impurities (Mutagenic, Nitrosamine and Elemental).
- Impurity Profiling, Isolation and Identification
- Characterization of polymorphs/pseudo polymorphs.
- Stability Testing Services as per ICH guidelines

CRAMS /Kilo Lab / Tech Transfer / Manufacturing

- Development of molecules for Material science
- Contract research of intermediates and APIs
- Specialty Molecules including HPAPIs
- Custom Chemical Synthesis

CRAMS Business Model

We have capabilities in handling following type of exclusive projects for the novel compounds – API, Intermediates (pharma) and Non-pharma molecules on FTE / FFS model

- CRO (Custom Research/Exclusive Synthesis): To make target compound based on "chemical structure" without any technical information from client.
- CDMO (Custom Development & Manufacturing): To make target compound with “process modification” by reference to client’s technical information.
- CMO (Custom Manufacturing): To make target compound by completely following “client’s technical information”.

Product Range Capabilities:

Pharma - Other New Products: NCE APIs & Intermediates, APIs & Intermediates which are currently not in our product list. Exclusive projects of other compounds required by pharma companies.

Non-Pharma - Material Science Chemicals: Material science chemicals required by customers for monomers, organic ligands, low volume high grade polymers, deuterated compounds, with metal traces in PPB / PPT levels.

Services

Custom Chemical Synthesis

- Advance Intermediates
- Building blocks
- Specialty chemicals

Process Research

- Offer cost competitive, operationally feasible, Regulatory and Intellectual Property compliant processes as per QBD forms

Analytical Services

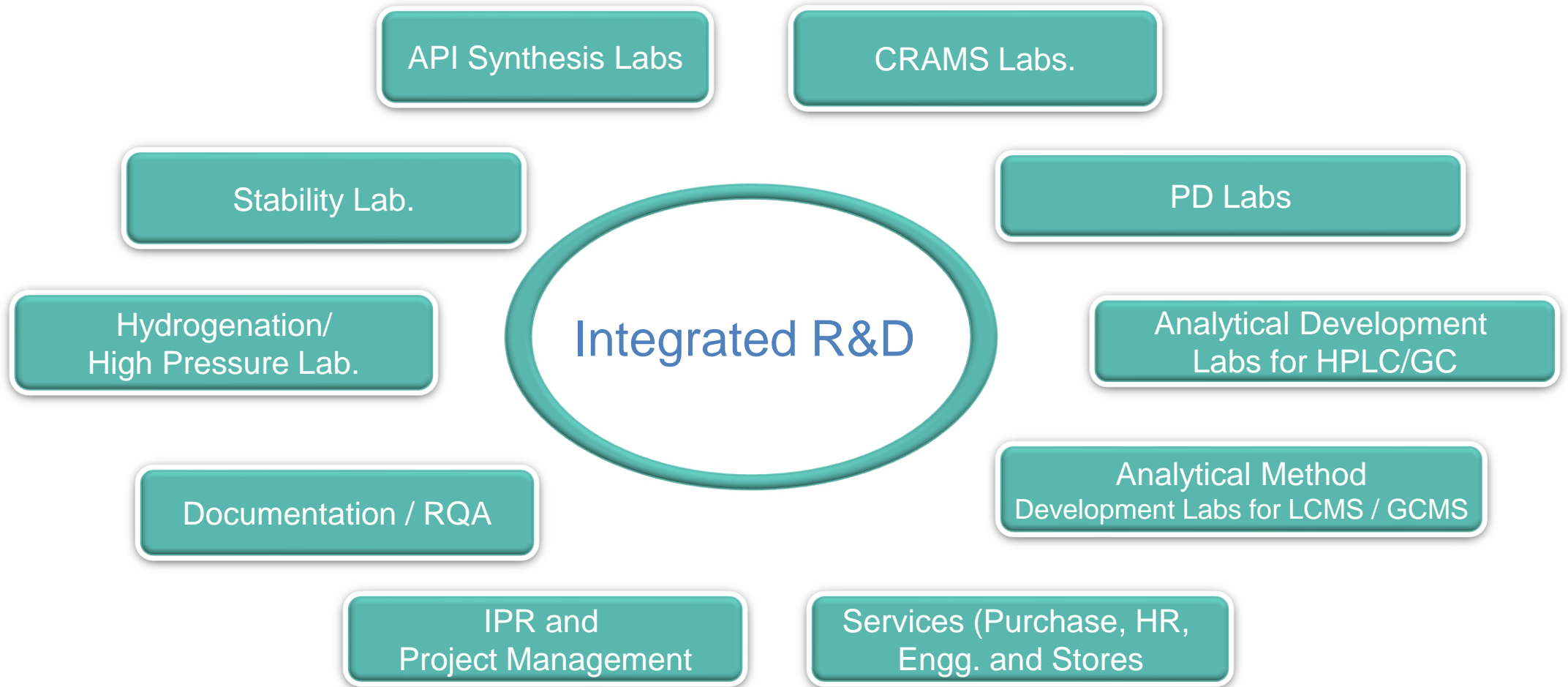
- Analytical method development, validations and transfer
- Impurity profiling, isolation, identification & characterization
- Stability studies as per ICH guidelines (also at low temperature)
- Characterization of polymorphs/pseudo polymorphs

R&D Highlights ...

- State of the art R&D facility spread across 40,000 sq. ft. (2 acres campus).
- Expertise of CRAMS projects requiring complex chemistry and higher purity molecules.
- Strong capabilities to develop non - infringing APIs involving multi step synthesis.
- Access controlled 8 synthetic laboratories (32 fume hoods) for process chemistry.
- Expansion is ongoing for 04 additional labs (50 % increase)
- 04 labs for Analytical method development and optimization.
- Recognized by Department of Science & Industrial Research (DSIR).
- ISO 14001 and ISO 45001 certified.



Research and Development



Intellectual Property and Information Resources

- In house team for assessment and guidance on Intellectual Property (IP) related matters.
- Total patent application filed = 242
- Services available for the literature search and market intelligence includes

Name of Software / Service	Supplier
ROW-2 Technologies	ROW-2 Technologies
Scifinder	American Chemical Society (ACS)
Research literature support along with articles, reference volumes and books available.	GPN Scientific Services
Cortellis	Clarivate Analytics (India) Private
CaseUltra Software Toxicity End point - ICH M7 Package - Bacterial & Mutagenicity	Neotel Systems and Services
Exim data (All Port) Annual	INFODRIVE INDIA PRIVATE LIMITED
Questel Orbit Intelligence	Questel

Online Resources :

Sci Finder, ROW-2 Technologies, Cortellis, CaseUltra Software

Studies

- Process development; process optimization and scale-up
- Scale up at Kilo lab & tech transfer
- What if studies
- Analytical method development & validation
- Deuterium Chemistry
- Nitrosamine Impurities / Elemental Impurities
- Genotoxic impurity studies
- Impurity identification and synthesis
- Enzymatic Transformation
- IP and Innovation
- Polymorph / Salt
- Tech Transfer
- Route Scouting

Chemistry Capabilities

C-C & C-X Bond Forming Reactions

- ✓ Organometallic reactions (RLi, RMgX, Organo Zinc etc.,)
- ✓ Condensation, Cyclization, Friedel-Crafts (acyl/alkyl), Cyanation etc.,
- ✓ Transition Metal Catalyzed reactions (Heck, Suzuki, Negishi etc.)
- ✓ C-X bond (X= N, O, halogens) formation reactions
- ✓ Amidation reactions

Asymmetric Synthesis

- ✓ Stereoselective synthesis using Chiral Ligands, Chiral Pools & Chiral Auxiliaries
- ✓ Resolutions (Chemical, Enzymatic)
- ✓ Asymmetric reductions (Substrate controlled, Reagent controlled)
- ✓ Asymmetric Transfer Hydrogenation.

Enzymatic Transformation / Bio-catalysis

- ✓ Stereoselective synthesis using enzymes
- ✓ Ketoreductase, Lipase and Transaminase are some of enzymatic reactions

Differentiated Salt / Polymorph

- ✓ Differential products like New Salts for salt switch and alternate Polymorphs.
- ✓ Expertise for complete characterization of new salt / polymorph and contamination studies

Deuterium Chemistry

- ✓ Substitution of a hydrogen atom with its heavy isotope deuterium
- ✓ Capability to achieve % D more than 99% for material science and pharmaceutical projects

Flow Chemistry and Continuous Process

Chemistry Capabilities

Reaction Capabilities

- Grignard Reaction
- Organometallic Reaction
- Deuterium chemistry
- Bromination, Chlorination, fluorination
- Organoboron chemistry
- Palladium Chemistry
- Cyanation
- Chiral Reduction
- Chemical Resolution
- Nitration
- Reductive Amination
- Catalytic Hydrogenation
- LAH Reduction
- Gewald reaction
- Cyclization
- Friedel crafts
- Diazotization
- Wittig
- Mesylation
- N-Alkylation
- Demethylation
- Dehydrogenation
- Condensation
- Cyclization

Key Reagents handled in bulk

- RMgX
- Pd reagents, Phospho Ligands
- Enzyme mediated resolution using Hydrolases
- S-CBS reagent
- Alkyl Lithium
- Boran.DMS
- D (+) CSA, L (+) Tartaric acid
- NaCN
- POCl₃, HCl
- Bromine/ HBr in Acetic acid
- HNO₃/ H₂SO₄
- L-Selectride
- Dimethyl Titanocene
- NaOCl, ACN, water
- Potassium amide
- Acyating reagent/AlCl₃
- NaNO₂/ HBr
- Methyltriphenylphosphonium bromide
- Methanesulfonyl chloride
- MeI/KOH, Dimethyl sulphate/KOH
- TEOF (Triethyl orthoformate)
- N-Demethylation using Sodium acetate/I₂
- DDQ, N,O-Bis(trimethylsilyl)trifluoroacetamide (BSTFA) in Toluene
- EDCI / HOBT
- KHMDS (Potassium hexamethyl disilazane)
- Hydrazine hydrate, Pd/C
- H₂, Raney Nickel, Pd/C
- NaBH₄, LiAlH₄

Dedicated R&D Infrastructure

R&D Value Proposition

- State of the art R&D facility spread across 40,000 sq. ft. with 8 synthetic labs; a kilo lab supported by well equipped analytical development labs
- Each laboratory has 4 working hoods
- Supported by over 150 experienced scientific staff
- PMP certified Project Managers
- Training, development and service-oriented work culture

Synthetic Laboratory Capabilities

- Equipped with 3 standard and 1 low bench fume hood (Kewaune) each
- Each lab equipped with dedicated utilities
- 6 station parallel synthesizer (Metler Toledo)
- Jacketed glass reactors (capacity: 0.5L, 1.0L, 5.0L), temperature range: - 40°C to 140°C
- Homogenizer (IKA, Germany) for particle size reduction (nanoparticles), rpm 40,000, capacity 150 ml
- Flash chromatography units (Teledyne ISCO) with UV detector and autosampler
- Lyophilizer (Virtis, Benchtop SLC)
- Equipment for routine lab operations, including rotary evaporators, ovens, TLC / UV chambers, weighing balance, deep freezer and 2-8°C storage, etc.



Dedicated R&D Infrastructure (cont'd)

Analytical Capabilities

- Analytical method development, validations and method transfer
- Impurity profiling, isolation, identification & characterisation
- Suitable and sensitive analytical method development for genotoxic impurities
- Stability studies as per ICH guidelines
- Characterization of polymorphs / pseudo polymorphs
- Development and validation of suitable analytical methods for cleaning procedures



Kilo Lab Capabilities

- Dedicated Kilo lab at R&D facility, Mohali
- All glass Assembly Reactors
 - 4 x 100 Ltr, 2 x 50 Ltr, 2 x 20 Ltr
 - Temperature range : – 80°C to +180 °C
 - Drying equipment; Steam tray dryer – (02 Nos)
- SS – Hydrogenator
 - 1 x 0.4 Ltr, 1 x 2 Ltr, 2 x 25 Ltr
 - Parr Hydrogenator Assemblies (6 Nos)
 - Operating pressure up to 25 kg/cm²
 - Temperature range : -5°C to +115°C
 - Pressure range: up to 60 kg/cm²
- Filtration equipment
 - Centrifuge and Nutsche filter
- Post production equipment in class 100,000 area
 - Vacuum tray Dryer, Multimill, Sifter and Micronizer



R&D – Kilo lab Capabilities

Dedicated Kilo lab at R&D facility , Mohali

All Glass Assembly

1 x 100 L

2 x 50 L

2 x 20 L

Temperature range : – 60 °C to +180 °C

SS - Hydrogenator

1 x 2 L

1 x 25 L

Operating pressure upto 25 kg/cm²

Temperature range : -5°C to +115 °C

Filtration equipments

Centrifuge, Nutsche filter

Supporting post production equipments

Steam tray Dryer, Vacuum tray Dryer

Multimill, Sifter and Micronizer

Managed by team of Chemical engineers and chemists



R&D- Analytical Capabilities

- ✓ Analytical method development, validations and transfer
- ✓ Impurity profiling, isolation, identification & characterization
- ✓ Suitable and sensitive analytical method development for genotoxic impurities
- ✓ Stability studies as per ICH guidelines
- ✓ Characterization of polymorphs/pseudo polymorphs
- ✓ Development and validation of suitable analytical methods for cleaning procedures



Best-in-class API Manufacturing Infrastructure

Manufacturing Facility in Jammu&Kashmir

- Facility spread across 8 acre land
- 4 cGMP manufacturing blocks, catering to domestic / unregulated markets
- Products include fexofenadine, ivabradine atorvastatin, clopidogrel bi-sulphate and nitazoxanide



26 cGMP compliant manufacturing blocks

Spread across two locations

643kL reactor capacity

695MT capacity for bulk drugs

5.5MW captive power plant

Spread over 650,000 sq ft area

Jammu & Kashmir

Dera Bassi

Manufacturing Facility in Dera Bassi, Punjab

- Facility spread over 33 acres land
- 22 cGMP manufacturing blocks for regulated markets
- USFDA / TGA / MHRA / PMDA approved facility
- Containment facility catering to high potency drugs
- Dedicated facility for oncology products with world class isolators
- Dedicated oral solid dosage facility for Clarithromycin Granules
- Four solvent recovery plant



Manufacturing Capabilities

- Installed reaction capacity of 700,000 Litres with 180 stainless steel reactors systems and 45 glass lined reactors systems; facility is equipped with cryogenic reactor
- 200 MT production capacity every month for intermediate and APIs
- 2.5M Litre solvent distillation capacity every month
- High pressure hydrogenation facility up to 20 kg/cm²
- GMP pilot plant suitable for advance intermediate, key starting material and for API
- Purified water system to meet USP39 Quality
- Zero discharge facility



Support Capabilities

- The facility is equipped with: Chilled Brine (388 TR), Chilled Water (2,292 TR), Cooling Tower (10,760 TR), Compress Air (2,958 CFM), Nitrogen Plant (360 m³/hr), Power Plant (5.5 MW), DG Set for power backup (6,250 KVA).

Positioning

Amongst Larger API Manufacturers








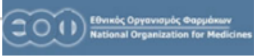




Manufactures APIs for 10 of the top 25 blockbuster drugs with a global market ~ US\$ 35 billion.

Strong portfolio of 40+ products across 20 therapeutic categories.

Worldwide presence in over 50 markets including mature markets (US, European Union and Japan) and “pharmerging” markets.

Amongst largest global manufacturers of Atorvastatin, Clarithromycin powder, Clarithromycin granules, Fexofenadine and Lisdexamphetamine.

Regulatory Accreditations

Regulatory body	Country/ Region	Products	# Successful Inspections	Last Approval Date
	US	• Approval for all 15 products for which DMF was filed	✓✓✓✓✓✓✓	2020
	Japan	• Risedronate sodium, Pioglitazone HCL, Trityl Olmesartan Medoxomil (intermediate)	✓✓	2018
	Europe	• Clarithromycin, Clopidogrel	✓	2016
	Germany	• Atorvastatin, Clopidogrel, Aripiprazole	✓✓	2011
	Korea	• Risedronate sodium, Ezetimibe	✓	2010
	Australia	• Clarithromycin, Donepezil, Letrozole, Ropinirole, Acamprosate, Aripiprazole, Pioglitazone, Atorvastatin	✓✓	2013
	Hungary	• Anastrozole	✓	2007
	Greece	• Clarithromycin, Clarithromycin coated granules (CCG)	✓✓	2015
	Brazil	• Clarithromycin	✓	2015
	Jordan	• Clarithromycin coated granules	✓	2019
	Mexico	• Dutasteride, Quetiapine Fumerate, Atorvastatin, Aripiprazole, Clopidogrel, Fexofenadine, Risedronate sodium	✓	2015
	Slovenia	• Clopidogrel, Imatanib, Clarithromycin, Clarithromycin (CCG)	✓	2019/2024

Thank You