



TEYRO LABS PRIVATE LTD



**SPECIALITY PHARMACEUTICAL
DEVELOPMENT &
MANUFACTURING COMPANY**

ONCOLOGY | HIGH POTENT PRODUCTS | COMPLEX GENERICS

Our Vision & Mission



One Quality Product World Wide

To be recognized as a leading specialty pharmaceutical company at the forefront of innovation for patients in current challenging and competitive pharmaceutical environment, our business is driven by a strong commitment to quality & compliance and to operating with the highest standards of ethics and integrity.

Sterile & Non-sterile Formulations Facility, Chennai, India



Teyro Labs provides global manufacturing facility for Injectable/ Sterile products & Oral solid dosages based at SIPCOT Industrial complex, Oragadam, Chennai, India. This formulations manufacturing facility operates in accordance to international regulatory requirements like USFDA, MHRA, TGA, WHO. This facility is built in 11 Acres with two independent Manufacturing blocks viz. Oncology Finished Dosage Block for Liquid & Lyophilized Injectable, Tablets & Capsules and Hormone Manufacturing block for Liquid & Lyophilized Injectable, Tablets & Capsules. This facility utilizes Isolator technology and cRABS (Closed Restricted Access Barrier System) for manufacturing of oncology products and other potent molecules which helps to maintain a high degree of containment and sterility assurance. This facility offers CRO/CDMO/CMO/ business activities and own In-house product portfolio for global markets.

R&D Facilities at Chennai (Formulations) & Pondicherry (API)

Teyro Labs has In-house R&D Facilities for Formulation Dosage Forms and Active Pharmaceutical Ingredients (APIs) / Drug Intermediates.

Formulation R&D facility is located at Oragadam, Chennai (India) and API/ Biotech facility is located at Pondicherry in India.

Team has sound knowledge and rich experience in complex product development of multiple dosage forms comprising Tablets, Capsules, Liquid & Lyophilized injectable products, PFS, Complex Injectable & etc..

R&D adopts 'Quality by Design' principles and has successfully handled Para-IV and complex new products development for Clients.

Our R&D offers CDMO business activities for international clients for all category of products.



API Manufacturing Facility at Cuddalore, India



Teyro Lab's API and Biotech manufacturing facility is in 22 acres, and located at SIPCOT Industrial Complex, Kadikadu, Cuddalore, India

This API & Biotech drug manufacturing facility is having 4 dedicated manufacturing blocks for Oncology APIs, Large volume General APIs, Small volume General APIs and Fermentation based Immunosuppressant APIs & Enzymes.

This facility is under commissioning, and shall operate as per international regulatory requirements to cater in-house API requirements and supply to global markets. This facility will be operational by end of 2024.

Formulation R&D Capabilities

- State of the art Pharmaceutical R&D lab
- Parenteral & Oral Solid Dosages Formulations (Oncology and Non-Oncology)
- Dedicated areas with isolator to handle potent molecules.
- Aqueous / Non-Aqueous Injections
- Lyophilized Powder for Injections
- Tablets/ Hard Gelatin Capsules

Major R&D Infrastructure	Make	Capacity
Peristaltic pump for filling (inside BSC)	Watson Marlow (Flexicon PF6)	0.2mL to 9999 mL
Lyophilizer (inside BSC)	Martin Christ / Epsilon 2-6D LSC plus	Shelf area: 0.2m ² / 350 vials based on 24mm vials (10R)
Integrated granulation line (in Isolator)	SAAN	0.6 Kg to 1.5 Kg
Compression machine (in Isolator)	RIVA MINIPRESS	2400 - 4200 tablets / hour
Capsule filling machine (in Isolator)	UNIQUE ENGINEERING	3600 caps/hour
Coating machine	FREUND VECTOR	0.5 Kg to 2.5 Kg

Pilot cGMP Manufacturing (For Investigational, Clinical & Bio Studies)

- Pilot cGMP manufacturing facility consists of both Injectable and OSD formulations, suitable for lower batch size.

Dosage form	Installed capacity per annum
Tablets	~ 20 Million
Capsules	~ 20 Million
Injections	Liquid ~ 0.80 Million
	Lyophilized ~ 0.75 Million

Equipment	Make	Capacity
Injectable Section		
Compounding and filtration vessel	Propac	10 L and 50 L
Filling and sealing line	i-Dositechno	30 vials per min (1800 vials / hr)
Lyophilizer	Lyomac	3.24sq mts. (5500 vials based on 10 ml vial / 24 dia)
Autoclave	Fedegari	530 lts.
External washing machine	Klenzaid	2000 vials / hour
Terminal sterilizer	Pharmalab	324 L
OSD section		
Integrated Granulation line	GEA	0.75kg to 1.75kg
Single pot processor	Bosch	0.75kg to 1.75kg
Bin Blender	GEA	0.75kg to 2.0kg
Compression machine	Key international	10 station / 24000 tablets / hr
Capsule filling machine	Dott-Bonapace / INCAP	6000 capsules per hr.
Coating machine	LB-BOHLE	0.5kg to 5.0kg



Manufacturing - Oncology Products

Oncology manufacturing facility consists of both Injectable and OSD formulations, suitable for higher batch size.



Installed Capacity Per Annum	
Tablets	~ 100 Million
Capsules	~ 100 Million
Injections	Liquid ~ 5 Million
	Lyophilized ~ 5 Million

Infrastructure	Make	Capacity
Injectable section		
Compounding and filtration vessel	Propac	50L, 200L and 1000L
Integrated Vial Filling line	BOSCH	120 vials per min
Lyophilizer	Martin Christ	10 sq mts. (20,000 Vials)
Autoclave	Fedegari	1075 lts.
OSD section		
Integrated Granulation line	GEA	4.5 Kg to 36 Kg
Integrated Single pot processor	BOSCH	11.25 Kg to 26.25 Kg
Bin Blender	GEA	30 litres to 200 litres
Compression machine	GEA	21 station / 60 RPM / 75600 tablets / hr
Capsule filling machine	MG2	70000 Capsules / hour
Coating machine	LB BOLHE	3 Pans (10L, 25L and 50L) / 5Kg to 30Kg

Quality Control

QC Laboratory	Make	Microbiology Laboratory	Make
HPLC & GC	Agilent	Sterility test Isolator	Tailin
UV spectrophotometer	Agilent	Steritest symbio isl pump	Millipore
Autotitrator - Aqueous and Non Aqueous	Metrohm	Autoclave	Fedegari
Autotitrator - KF Titrator	Metrohm	KTA	Lonza
Coulometer	Metrohm	Vitek -2 identification system	Biomeriux
Polarimeter	Rudolph	Air sampler	Sun technology
Refractometer	Rudolph	Deep freezer	Allyone
FTIR	Perkin Elmer	Precision Balances	Mettler
DSC	Perkin Elmer	Bio safety cabinets	Klenzaid
Analytical Balances	Mettler	EZ pump	Millipore
Liquid Particle Counter	Shreedhar inst	Colony counter	BVN
Osmometer	Rosalina	Walk in incubator	Allyone
		Depyrogenation oven	Allyone

Quality control Lab is equipped with all modern instruments like HPLCs, GCs, FTIR, UV-VIS\ spectrometer etc. for routine testing of Raw materials, Packing materials, Semi-finished, Finished products and stability testing for OSD and Injectable Oncology products. Micro biology lab is equipped to perform all the applicable microbiological tests including method development and validation e.g. Sterility testing under isolator, BET, MLT, Water and product testing for OSD and Injectable products.



Regulatory filing & Accreditations

- Oncology Formulations Facility is approved by Indian Drug Control Authority & WHO.
- EU approval of Oncology facility is likely by Q2-2023 from BfArM-Germany (Site transfer of approved Marketing Authorizations of Injectable products is completed)
- USFDA Approval of Oncology facility is likely by Q2-2023 (ANDAs filed for OSD and Injectable products)



Global Registrations

REGION	COUNTRY	
ASIA	ALGERIA	MOROCCO
	AUSTRALIA	NEW ZEALAND
	CHINA	PHILIPPINES
	EGYPT	S. AFRICA
	HONG KONG	SAUDI ARABIA
	INDONESIA	SINGAPORE
	JORDAN	TAIWAN
	KOREA	THAILAND
	KUWAIT	TURKEY
	LEBANON	UAE
	MALAYSIA	VIETNAM

REGION	COUNTRY	
Europe & Russia	AUSTRIA	IRELAND
	BELGIUM	ITALY
	BULGARIA	NETHERLANDS
	CROATIA	NORWAY
	DENMARK	POLAND
	ESTONIA	PORTUGAL
	FINLAND	ROMANIA
	FRANCE	RUSSIA
	GERMANY	SPAIN
	GREECE	SWEDEN
	HUNGARY	SWITZERLAND
	SLOVENIA	UK

REGION	COUNTRY
North America	USA
	CANADA
Africa	FR. W. AFRICA
	SOUTH AFRICA
LACan	ARGENTINA
	BRAZIL
	C. AMERICA
	PERU
	CHILE
	COLOMBIA
	MEXICO

Product Pipeline : Oncology

Sterile Oncology Products	
1	Carboplatin Injection
2	Gemcitabine for Injection
3	Topotecan HCl for Injection
3	Azacitidine for Injection
4	Docetaxel Injection
5	Epirubicin Injection
6	Irinotecan Injection
7	Oxaliplatin Injection
8	Pemetrexed for Injection
9	Paclitaxel Injection
10	Bortezomib for Injection
11	Bendamustine for Injection
12	Cisplatin Injection
13	Cytarabine Injection
14	Carmustine for Injection
15	Melphalan for Injection
16	Cabazitaxel Injection
17	Carfilzomib Injection

Oral Solids Oncology Products	
1	Capecitabine Tablets
2	Imatinib Tablets
3	Sunitinib Capsules
4	Pazopanib Tablets
5	Abiraterone Tablets
6	Anastrozole Tablets
7	Letrozole Tablets
8	Dasatinib Tablets
9	Gefitinib Tablets
10	Temozolamide Capsules
11	Lenalidomide Capsules
12	Pomalidomide Capsules
13	Bicalutamide Tablets
14	Thalidomide Capsules
15	Sorafenib Tablets
16	Lapatinib Tablets



Strategic Business Alliance & Partnership

For Pharmaceutical Development, Manufacturing & Supply of products across the globe.

In our relentless pursuit to enhance patient reach, we are open for alliance & collaboration for the following

- * **Product Development**
- * **Co-development & Manufacturing**
- * **In-Licensing /Out Licensing, B2B**
- * **Marketing & Co-marketing**
- * **Sales & Distribution**
- * **Joint Venture**

Contract Development & Manufacturing (CDMO)

'Research & Development of drug Formulations, with cGMP compliant Pilot Manufacturing Facility for Clinical/ Investigational Injectable & Oral Solids'

'World-Class USFDA & EU GMP Compliant Sterile & Non-sterile Oncology Product Manufacturing'

R&D expertise in latest Pharmaceutical development design approach applying "Quality-by-Design" principles, ensuring design efforts translate into a more successful product development, scale-up, EB execution, and global regulatory submissions.

State-of-the-art R&D facility with extensive knowledge & experience in development of multiple dosage forms comprising Tablets, Capsules, Injectable (Liquid, Lyophilized, PFS, Complex Injectable, Semisolid formulations).

Collective expertise of existing R & D personnel handling drug design and development for highly regulated markets like USA, Europe, UK, Australia, Canada and other geographies, on over 300 formulations right from concept to regulatory filing and approval, hands on experience in developing F2F, Para IV and Non-infringing formulations

Sterile and Non-sterile formulation products manufacturing at world class facility for Oncology.

Aseptic processing under Isolator and cRAB technology integrated with BOSCH Filling line with an operating capacity of 7 million Vials & PFS per annum with a filling range from 1 ml to 50 ml vial sizes.

Lyophilisation using Martin Christ Lyophiliser with an automated loading and unloading of vials under Isolator

Oral Solids processing under isolator containment equipped with GEA granulation line, compression machine, LB Bohle Coating machine, MG2 Capsule filling machine and CVC Bottle Packing line with an annual operating capacity of 180 million tablet and capsules.



Oncology manufacturing & supply with responsibility, commitment & integrity

USFDA FEI No. 3021389808

*Designed, Operated & Compliant
to meet the regulatory standards as per*



World Health
Organization



MHRA
Regulating Medicines and Medical Devices



BfArM



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration





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