November 2023

Vishwa-Syntharo PharmaChem Private Limited

ISO 9001 Certified

Vishwa-Syntharo

- Vishwa-Syntharo PharmaChem Private Limited is a Joint Venture between Vishwa PharmaNexus Corporation of India and Syntharo Fine Chemicals of Germany
- The Joint Venture was established in September 2015 and the company registered in November 2015
- The Joint Venture seeks to leverage the advantages of both entities and the geographical and strategic location of both countries and provide Chemistry Research Services to companies across the globe

Background – Vishwa PharmaNexus

- The name "**Vishwa**" originates from the Sanskrit word: **Vishwasam** (Trust)
- Founded and whole-time managed by Dr. Sankara Subramanian with more than three decades of experience in leading pharmaceutical and chemical organizations in India
- Incorporated in **March 2010** for providing chemistry and related services to the pharmaceutical and fine chemical industry
- Moved operations to Sri Ramachandra University, Chennai, a premier Medical University in India with a collaboration with Harvard University, USA, in **October 2012** through a collaborative arrangement
- Entered into a Joint Venture with Syntharo Fine Chemicals, Germany in **September 2015**.

Background - Syntharo

- Incorporated near Hamburg in April 1998 for the sale of fine & specialty chemicals
- Over the years, the company has developed into manufacture of intermediates, which are needed primarily for the synthesis of agrochemical & pharmaceutical ingredients (APIs) and are used in cosmetic formulations
- **2008 - 2010**, located at the Chempark, Leverkusen
- In **July 2010**, relocated to the “Industriepark Troisdorf” (a former site of Dynamit Nobel) located between Cologne and Bonn
- Operate from a 8,000 sqft facility
- Manufacture technical solutions for the chemical industry from lab.-to commercial scale
- Customers include catalogue companies, R & D departments of research-intensive chemical companies
- Annual revenue: Mio EUR 4-5
- Apart from the German headquarter Syntharo has an office and warehouse in Germany:

  Syntharo Fine Chemicals USA, Inc. - New York, USA

  https://syntharo.com/

Mission & Vision

Vishwa-syntharo

Mission

Be a **TRUSTWORTHY** provider of products and services to the Pharmaceutical and Speciality / Fine Chemical industry in all its fields of operations

Vision

To be **GLOBALLY** renowned for excelling in Quality of Work, Integrity, Innovation, Business processes, Technologies developed, and Services offered

Quality Policy

At Vishwa-Syntharo PharmaChem we shall continuously strive to provide our customers the best and timely delivery of products and services, through:

- Adopting a Business Process Flow that satisfies applicable requirements;
- Continuous improvements to our business processes;
- Developing and using the most appropriate technology that is efficient, cost effective and has least impact on environment;
- Maintaining a transparent and timely communication chain with the customer;
- Deploying appropriate human resources for the projects and continuously upgrading their skill and efficiency levels through periodic training and mentoring.

Dr R Sankara Subramanian

Education:

B.Sc – Vivekananda College, Chennai; M.Sc – Loyola College, Chennai
Ph.D – IIT Madras (Chennai);
Post Doctoral – Univ. of Bath, UK

Previous work experience:

Recon Limited (now Hikal)	-Establishment of Research Laboratories -Process development for APIs
Shasun Chemicals & Drugs	- Head of R&D - Head of Corporate Quality Assurance & Regulatory Affairs - Strategic Business development - Structure and commission CRAMS activities
Sanmar Speciality Chemicals / ProCitius Research	- Establish and lead the API division through FDA inspection - Establish and manage the Contract Research division – ProCitius Research
ProVentus Life Sciences	- Co-investor - Restructure of business activities - Establish and manage API and CRAMS business activities

Lars Müller

Background:

Founder and Director of Syntharo Fine Chemicals GmbH since 2008

Others:

CEO, Chem-Trade & Consulting GmbH, 1998 – 2007

Raimund Müller GmbH & Co. KG, 1993 - 2006

Research Advisor

Prof K K Balasubramanian

Education: PhD: University of Madras

Post Doctoral: Wayne State University, Detroit
(Amino- and keto- sugars with Prof Carl Stevens)

Background: Dept. of Chemistry, Indian Institute of Technology Madras
(1971 – 2001)

Industrial : Executive Director, R&D, Shasun Chemicals and Drugs (2001 – 2011)

Currently: INSA Emeritus Scientist at Department of Biotechnology, IIT Madras

Expertise: Synthetic Organic Chemistry
Molecular rearrangements
Organic photochemistry & Electro-organic chemistry
Carbohydrate chemistry

Publications: 150

Students guided for PhD: 32

Key Awards: Lifetime achievement award CRSI Gold Medal 2012
Fellow of the Indian Academy of Sciences

Business Associate

Dr. K Vijayakumaran

Education:

M.Sc – University of Madras (Chennai);

PhD & Post Doctoral Research – University of Nancy (France)

Areas of Expertise:

Carbohydrate Chemistry	- Synthesis of mono and polysaccharides - Deuterated sugars
Oxidation reactions	Chromium based reagents in organic oxidation of complex organic molecules
Multi-step organic synthesis	Several compounds synthesized for laboratory chemical companies

Key Personnel .. 1

Name	Department	Ed. Qual.	Prior Experience	
Sasikumar Malayandi	Technology	M Sc Chemistry	- GVK Biosciences - Jubilant Chemsys - ProVentus Life Sciences	
Iyyasamy Sangudurai	Analytical	B Sc Chemistry	- Shasun Chemicals & Drugs - Strides Shasun Ltd - Venkatnarayana Active Ingredients	
Saruhasan	Technology	Diploma in Petrochemial Engineering	- Piramal Healthcare - Malladi Drugs & Pharmaceuticals - East Coast Organics - Alchymars ICM	

Key Personnel .. 2

Name	Department	Ed. Qual.	Prior Experience	
Mahesh Kuppam	Research & Development	M Sc Chemistry	- Fischer Chemicals - ProVentus Life Sciences - Syngene International	
Dhamodharan Devaraj	External Manufacturing	B.Tech Chem Engg	- EID Parry - Sun Pharmaceuticals	
Rajini Rajappan	Quality Assurance	M Sc Chemistry	- Syngene International - ProCitius Research (Sanmar Group)	
Vanitha Palanisamy	Project Management	M Sc Chemistry	- Joined as a fresh post-graduate - Five years with Vishwa-Syntharo PharmaChem	

Areas of Focus & Services

PROCESS DEVELOPMENT

Speciality Chemicals
Pharma Intermediates

COMMERCIAL MANUFACTURING

Speciality Chemicals

SCALE-UP

Kilo-lab

Process Development:

Development of a scalable process and providing technology package or products synthesized using the process developed. Processes can be scaled-up at the kilolab

Scale-up:

Scale-up of process provided or developed to supply multi-kilo quantities of target chemicals

Manufacturing (Commercial):

Commercial / Exclusive manufacture of Specialty Chemicals and Pharmaceutical Intermediates

Key Chemistry Capabilities

Asymmetric Synthesis	➢ Chiral alkylation ➢ Asymmetric Dihydroxylation, ➢ Sharpless Epoxidation
Oxidation	➢ Classical (Jones, $KMnO_4$, CrO_3, MnO_2 etc) ➢ Swern ➢ Moffat ➢ Corey-Kim ➢ Transition Metal Catalyzed
Reduction	➢ Metal Hydrides ➢ Homogeneous & Heterogeneous catalysed ➢ Transfer Hydrogenation ➢ Dissolving Metal Reduction
Others	➢ Fluorination (NFSI, DAST, selectfluor, deoxo-fluor) ➢ Carbonylation ➢ Cyanation
Organometallic	➢ Heck arylation ➢ Suzuki coupling ➢ Sonagashira coupling

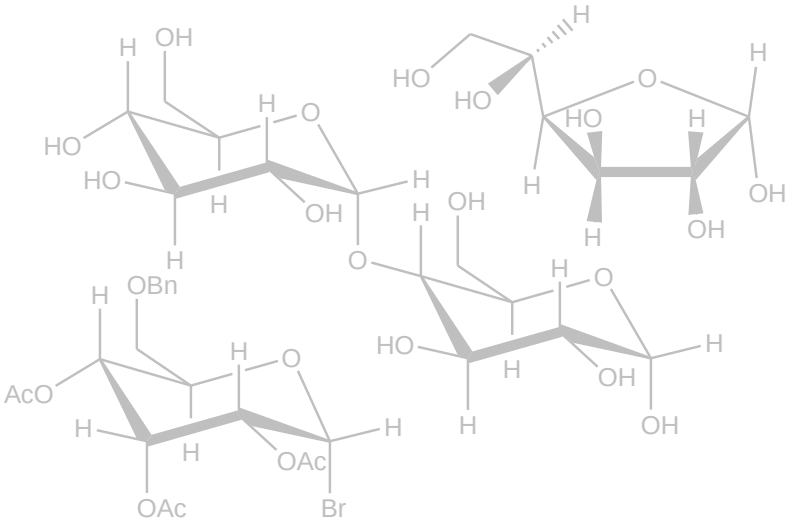
Common chemistries regularly performed is not included in above.

Chemistries that we do not handle: Reactions involving Phosgene; NaCN / KCN / HCN

Carbohydrate Chemistry

Basic monosachharides
Differentially protected and derivatized monosaccharides

Polysaccharides
Typically di- and tri- saccharides



Protected amino-sugars
Such as (D)-Glucosamine

Configurational inversion
Such as SN_2-displacement or oxidation-reduction sequence) to arrive at rare sugars

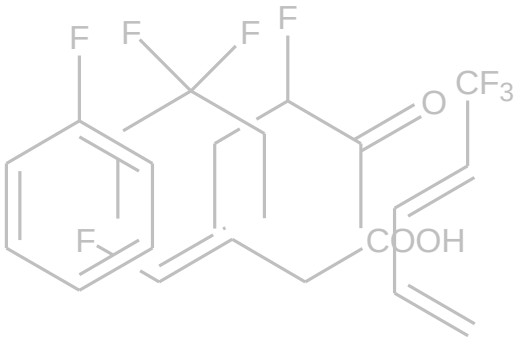
Carbohydrate-derived chiral synthons
Performing sequential chemical transformations on the chiral-pool derived from sugars to make chiral synthons

Fluorine Chemistry

Fluorinated chemicals

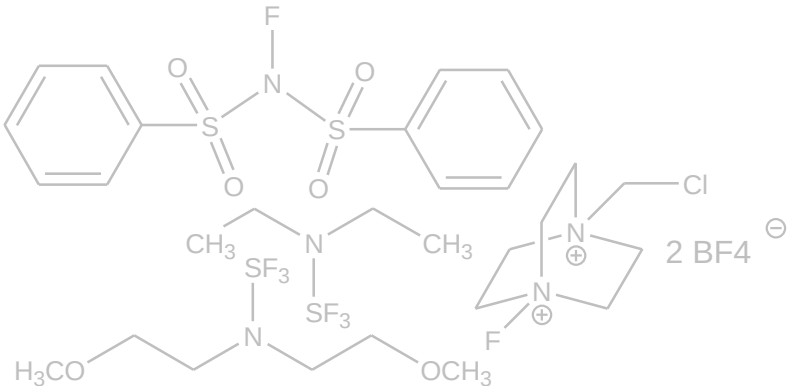
Custom synthesis of:

- Fluorinated chemicals
- Fluorinated NCEs



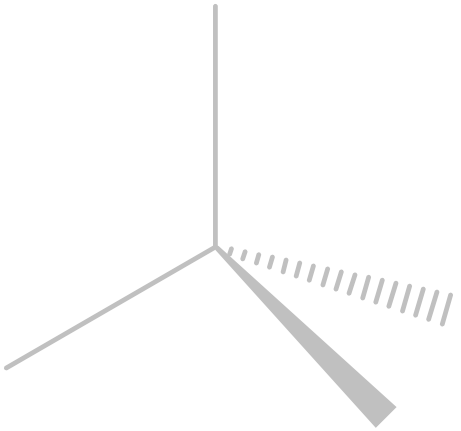
Typical fluorinating agents used:

- NFSI;
- DAST (at small scale only);
- Selectfluor; Deoxo-fluor
- KF / NaF



Chiral chemistry

- Resolution of compounds by chemical method
- Asymmetric / enantioselective synthesis
- Stero-selective synthesis using enzymes



Chiral purity estimated by:

- Chiral HPLC
- Optical rotation
- NMR using chiral shift reagents

Research & Development

Vishwa-syntharo

Fume Hoods:	5 (expanding to 12 soon)		
Rotary evaporator	Buchi		
Scale:	5 ml to 5 litres		
Temperature range:	- 70 to + 250 deg C		
Vacuum:	Diaphragm pump:	~ 5mm Hg	
	Oil vacuum pump:	~ 0.1 mm	
High pressure	250 ml SS 316 shaker (Amar Engineering)	Temp: Ambient to +250 C Pr.: Ambient to 30 Kg	2
	3 lit SS 316 (Shakti Engineering)	Temp: Ambient to +250 C Pr.: Ambient to 10 Kg	1
	7.5 lit SS 316 (PARR USA)	Temp: Ambient to +250 C Pr.: Ambient to 70 Kg	1
Capabilities:	❖ Column chromatographic purification ❖ Fractional distillation ❖ Cryogenic reactions ❖ Organo-metallic reactions		

HYD-004

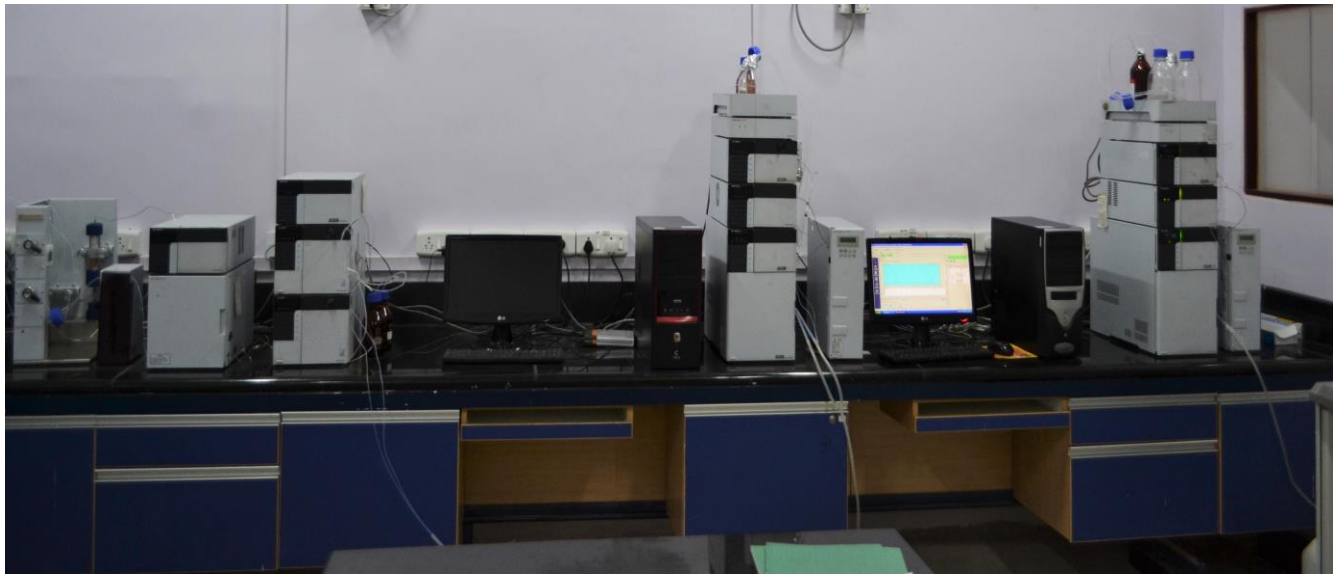
Analytical Inhouse

GC:	- Agilent GC 7820A with FID - Scion 436i GC with FID
HPLC (Analytical)	- Shimadzu LC-20AD (UFLC) with PDA Detector - Shimadzu LC-20AD (UFLC) with UV Detector
HPLC (Preparative)	Shimadzu LC-20AP
UV-Vis:	Agilent UV 8453
Auto-titrator:	SPECTRALAB Automatic Potentiometric Titrator (Model: AT38C)
Polarimeter (digital)	ATAGO AP-300
Melting Range	Stanford Research System - Optimelt
Water purification	Siemens Evoqua LaboStar TWF UV 7 (Capacity: 9 lit / hr)

Analytical Outsourced

FT-IR:	Perkin Elmer Spectrum IRES V 10.7.2 (Eurofin Labs)
NMR (Multi-nuclear)	Bruker 500 MHz (SRM University)
Residue on Ignition / Sulphated Ash	Neoscience Labs / Monarch Testing Laboratories
GC-HSS:	Agilent 7890B (Neoscience Labs)
GC-MS/MS:	Agilent 7000D (Neoscience Labs)
LC-MS/MS:	Agilent 6495 (Neoscience Labs) / Shimadzu LCMS 8040 (SPINCO)
ICP-OES	Thermo Fischer iCAP™ 7400 (Monarch Testing Laboratories)
ICP-MS	Agilent 7800 (Neoscience Labs)
Pesticide analysis	LC-MS / GC-MS (Neoscience Labs)
Microbiology	(Neoscience Labs)

Sample



Kilo-lab 1

Low-level fume hoods for 5 to 20 litre flasks - 2

Operating conditions:

Temperature: -70 to + 250 deg C

Vacuum: 1 mm Hg

Pressure: Ambient

GMP:

Ante-room, change-room and clean-room

Area classified as Class 100,000

GMP for N-1 compounds of APIs

Kilo-lab 2

100 Lit all glass unit	2
20 Lit fractional distillation (Glass)	1
20 Lit Rotary evaporator	1
Vacuum tray dryer (4 trays / 5 to 10 kgs) (SS 316)	1
Nutsche filter (PP)	1
Centrifuge (SS 316)	1
Pressure Nutsche Filter (SS 316)	1
Column Chromatography set up (Glass)	1

Operation conditions:

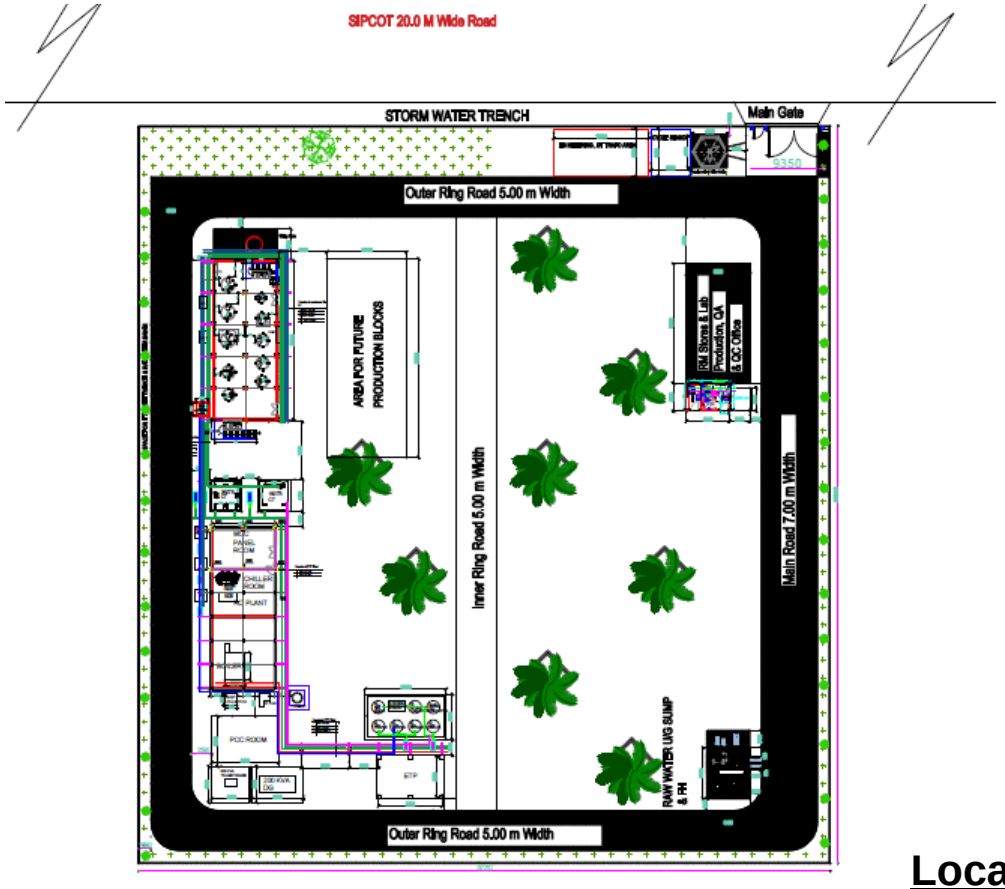
Temperature: -70 to + 250 deg C
Vacuum: 1 mm Hg
Pressure: Ambient

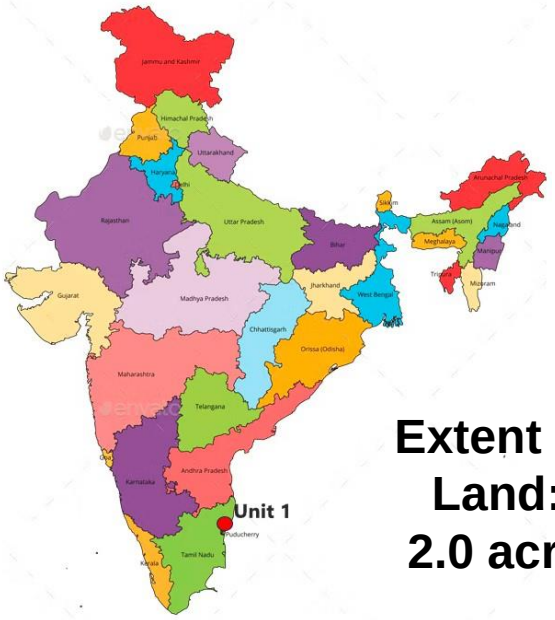
Area:

Ante-room
Air conditioned
Clean area (Not classified)

Can be converted to GMP for N-1 if required in ~ 3 months

Manufacturing Unit 1



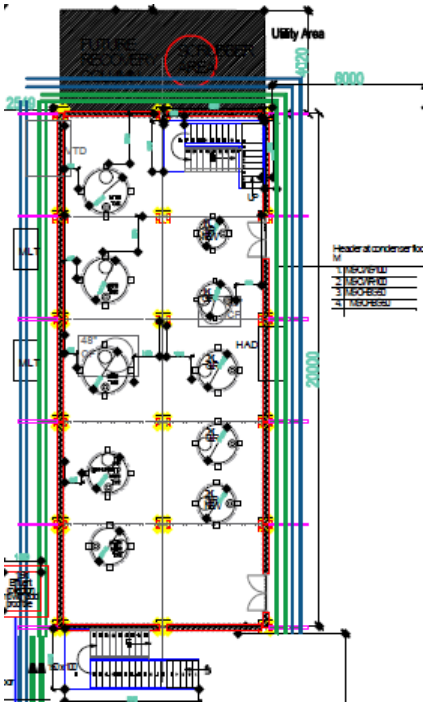


Extent of Land: 2.0 acre

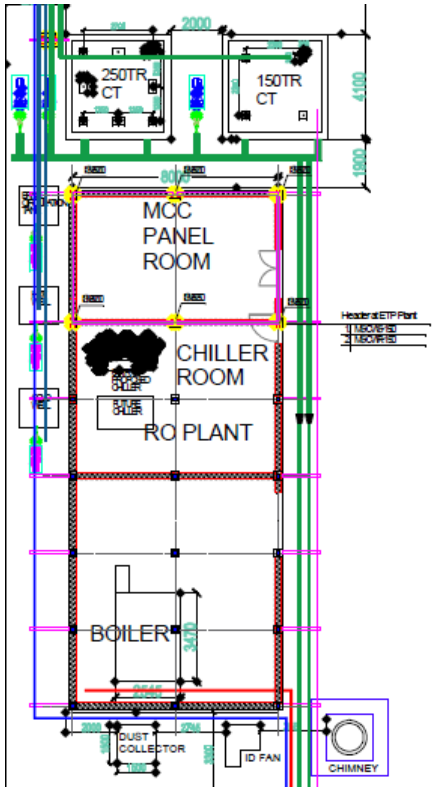
<u>Location</u>:
Plot. No. S-121,
Extended SIPCOT Industrial Park Phase-III
Ranipet,
Tamil Nadu-632405.

140 Km from Chennnai

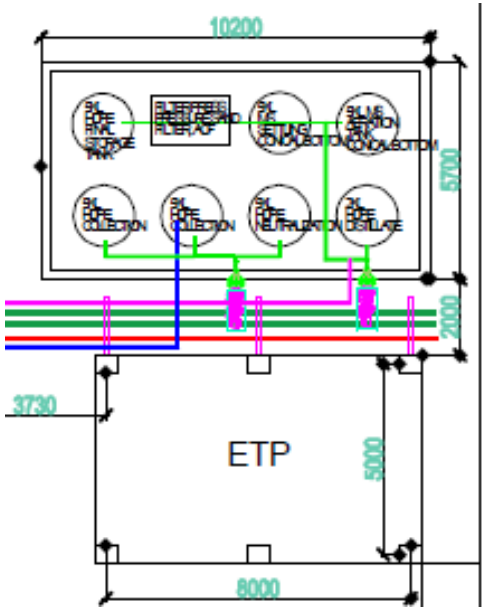
Manufacturing Unit 1 - Layout



Manufacturing Block 1



Utilities



Waste Treatment

Manufacturing Unit 1 - Reactors

Equipment ID	Capacity	MOC	Agitator Type	Primary Heat Exchanger (m^2)		Secondary Heat Exchanger (m^2)		Receiver	Steam	Remarks
	Kilo Litre			Cap (m^2)	Chilling	Cap (m^2)	Chilling	Kilo Litre		
R-01	2.00	SS 316	Anchor	12	CTW	10	CHW	0.5	Yes	
R-02	3.00	SS - 316	Turbine	16	CTW	12	CHW		Yes	Limpet Coil Reactor
R-03	3.00	SS - 316	Turbine	12	CTW	10	CHW	0.3	Yes	
R-04	3.00	SS - 316	Turbine	16	CTW	10	CHW	0.5	Yes	Jacketed Receiver
R-05	3.00	GLR	Anchor	16	CTW	---		0.5	Yes	Jacketed Receiver
R-06	2.00	SS - 316	Propeller	12	CTW	10	CHW	0.75	Yes	
R-07	2.00	GLR	Propeller	12	CTW	---		0.3	Yes	
R-08	2.00	GLR	Anchor	12	CTW	---		0.3	Yes	
R-09	1.00	GLR	Anchor	8	CTW	---		0.25	Yes	
R-10	1.00	SS - 316	Anchor	8	CTW	4	CHW	0.20	Yes	Jacketed Receiver
Total Cap.	**22.00**									

CTW	Cooling Tower Water	28 to 32 deg C
CHW	Chilled Water	+5 to +7 deg C
CHB	Chilled Brine	-10 to -5 deg C

Manufacturing Unit 1 – Ancillary Equipment

Equipment	ID #	Capacity	MOC	Remarks
Material Isolation				
Centrifuge	CF-01	48"	SS - 316	Top Discharge Four Legged
Centrifuge	CF-02	36"	SS - 316	Top Discharge Four Legged
Filter Press	FP-01	12" x 12"	PP	Open Filteration & Closed Filteration
Leaf Filter	LF-01	150 litrs	SS - 316	
Pressure Nutch Filter	PF -01	100 litrs	SS - 316	
Material Drying				
Vaccuum Tray Dryer	VTD-01	48 trays	SS - 316	SS Trays
Hot Air Dryer	HAD-01	48 trays	SS - 316	PP Trays

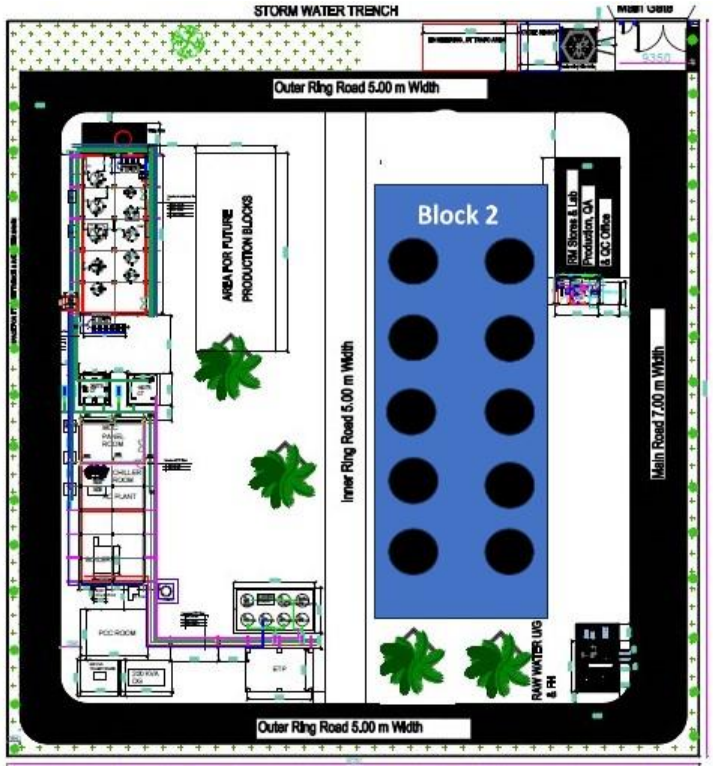
Manufacturing Unit 1 - Utilities

Equipment	Capacity	Nos	Remarks
Boiler	1 Ton	1	---
Chilling Plant	64 TR	1	Dual Mode
Cooling Tower	250 TR	1	---
	150 TR	1	---
Scrubber	2200 Cfm	PP FRP	
Reverse Osmosis(RO) Water	2,000 LPH	1	---
De-mineralised (DM) Water	1,000 LPH	1	---
Steam-jet Ejectors	55 m^3/hr	1	1 Water Jet & 2 Steam Jet
Watering Vac Pump	420 M^3/hr	1	720 mm Hg
Oil ring Vac Pump	5000 LPM	1	Double Stage
Diesel Generator	200 KVA	1	---
Raw Water Tank	50,000 Lit	1	---

Manufacturing Unit 1 – Block 2

Future Block 2 in Phase 2

- Based on need another block can be constructed
- 5 to 10 reactors of 5 to 8 KL Capacity
- Some utility enhancement may be required



Manufacturing Unit 1

Production block
1st Floor

Production block
Ground Floor

Production block
Second Floor

Scrubber System

Effluent Treatment

Aerial view

Manufacturing Unit 1

Analytical Instruments Lab
Quality Control

Wet Chemistry Lab
Quality Control

Reverse Osmosis
De-mineralised Water

Boiler – 1 TR
Wood fired

Chiller
62 TR

Manufacturing Unit 2

Production block

High Pressure Reactor / Hydrogenator

Location:

Plot No.8-15,
IP Athivaram, Ozili (M),
SPSR Nellore
Andrapradesh
524421

130 Km from Chennai

- **High Pressure Reactions**
- **Liquid Products**

Manufacturing Unit 2 - Reactors

Reactors	Capacity	MOC	No. of Reactors	Remarks
SS Reactor	1 KL – 3 KL	SS-316	10	---
Glass-lined reactor	1 KL – 3 KL	MSGL	4	---
Hydrogenator	1 KL – 2 KL	SS-316	2	55 KgSc – Op. Pr. 78 KgSc – Tested Pr.

Manufacturing Unit 2 – Ancillary Equipment

Equipment	Capacity	MOC	Remarks
Material Isolation			
Centrifuge	48"	SS - 316	---
Centrifuge	48"	SS - 316	---
Material Drying			
Fluidized bed dryer	200 Kg	SS - 316	---

Manufacturing Unit 2 – Utilities

Equipment	Capacity	Nos	Remarks
Boiler	2 Ton	1	Thermax
Chilling Plant	10 TR	1	Brine chiller
Cooling Tower	400 TR	1	---
Scrubber	---	1	Double stage
Reverse Osmosis(RO) Water	25 KLD	1	---
Air compressor	5000 CFM	1	---
High vacuum pump(Oil)	---	2	---
Storage tank	25 KL	1	MS, Vertical Tank
Storage tank	25 KL	1	MS, Vertical Tank
Storage tank	3 KL	1	FRP, Vertical Tank
Effluent RCC tank	25 KL	2	RCC, Above ground level

Manufacturing Unit 3

APIIC Industrial Estate, Gajulamandyam

Current Reactor capacities:

Glass Lined Reactor	2,000 Litres	1
	5,000 Litres	2
	6,000 Litres	1
Stainless Steel 316	2,000 Litres	2
	3,000 Litres	1
	6,000 Litres	2

Capacity can be added based on business needs

Quality Systems

- Vishwa-Syntharo is **ISO 9001:2015 certified**
- The site is registered with **U.S. Food and Drug Administration** (US FDA) for supply of nutraceuticals
- The documentation systems and business process flow meets **GMP** requirements

FDA

TÜV INDIA
ISO 9001 Certified

Statutory Details

100% Export Orient Undertaking:	Green Card 2944/MEPZ	November 2021
GST Registration:	33AAFCV2758N2ZU	July 2017
Import Export Code:	0415903157	December 2015
MSME:	TN02E0020838	August 2016
Factory License	KPM 12203	November 2019

Key Achievements ... 1

Product	Other Manuf.	Status	Customer
Commercial Scale			
Nutraceutical under patent	None	1,000 Kg lots	USA
Cross-linker for a novel catalyst	None	Under continuous production. 500 Kg / annum	EU
New Chemical Entity for polymer	None	100 Kgs produced Under trial. Commercial production in 2023	EU
Speciality chemical	None	200 Kg supplied	EU
Speciality chemical for cosmetic application	1 Indian	Under exclusive manufacturing	EU
Speciality chemical as a ligand for lanthanide and transition metal	2 Indian	1,000 Kg / month ramping upto 2,000 Kg / month	EU & USA
Five ligands for organometallics	China only	Process development complete	Korea, USA

Key Achievements ... 2

Product	Other Manuf.	Status	Customer
Speciality Chemical for Cosmetic use 1	None	Qualified through first commercial supply.	EU Major
Speciality Chemical for Cosmetic use 2	None	Qualification under progress	EU Major
Stabilizer for Novel API	None	500 Kg / annum	Japan
AWAITING REGULATORY APPROVALS			
Monomers for polymers (multiple monomers)	None	Supplied qualification lots	US MNC
AWAITING CUSTOMER APPROVALS			
Polymerization catalyst	1	Qualification complete. Capacity: 2,000 Kg / month	Petrochemical

TECHNOLOGIES LICENSED			
Key Raw Material for API (Import substitution)	None	3,000 Kgs / month	Indian US FDA / EU approved Pharma
Key Raw Material for API (Import substitution)	5	7,000 Kgs / month	Indian US FDA / EU approved Pharma

CONTACT

Vishwa-Syntharo PharmaChem Private Limited

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