TOOBA PHARMACEUTICALS PRIVATE LIMITED

In The Business Of Human Wellbeing

Innovation | Professionalism | Ethics | Best Practices

MANUFACTURES

API BULK DRUGS & INTERMEDIATES

WHO-GMP CERTIFIED

ABOUT US

Tooba Pharmaceuticals Private Limited [TPPL] is a WHO GMP Certified manufacturer of API Bulk Drugs and Intermediates, with state-of-the-art manufacturing facility.

TPPL retains its strong roots in R&D to explore and develop generics using newer technologies in an environment friendly manner.

TPPL, headquartered in Chh.Sambhajinagar, Maharashtra is a majer urban center and an industrial hub, home to several pharmaceutical industries. Well connected with major metropolitan are as with in the state and beyond, there's a ready access to markets and raw materials.

The manufacturing plant is situated in the Paithan Industrial area, erected as per the GMP norms laid down by FDA.

STRENGTH

- **TPPL is in the process of filing four DMFs in regulated market.**
- **TPPL has developed patentable technologies. Recently we have filed patent for Glycopyrronium Bromide. (Application No.: 202021022784)**

  TPPL has gathered around technocrats with cumulative research experience for almost 90 years and nave acclaimed more than 200 patents to their credit. So it is fully poised to meet challenges in developing non-infringing routes for various molecules. As far as regulatory experience is concerned this technical team in past was responsible for filing dozens of DMFs for regulated markets meeting stringent quality requirements.

  Excellent QA/QC facilities with all required instruments for compliance of Quality Standards.
- **TPPL believes in developing the product from innovative processes by using mostly Indian Raw Materials.**
- **TPPL endorses the Government of India's vision and mission of developing the products with indigenous sources-'Be Vocal About Local'.**

VISION

Striving for developing innovative processes consistent with highest quality standards in an environment friendly and cost-effective manner.

MISSION

- TPPL will focus tirelessly on developing novel processes applying contemporary know-how, Inculcating culture of innovation in its technical team, focus will be maintain on consistency and integrity of processes through continuous development, validation and documentation.
- Human resource development and honing their competencies through training and inclusiveness.
- Environment friendliness and safety shall be part of TPPL culture.

VALUES

- Rely on Research and Innovation
- Adopt Environment Friendly Technologies and Processes
- Integrate Quality in everything that we do. Let the best of Ethics be the guiding principle of all our business operations
- Develop a Corporate image that evokes confidence and delight
- Provide a Safe Work Environment for our personnel
- Seek Business Growth through efficient production distribution and management
- Adopt Corporate Social Responsibility that espouses the above, in addition to fulfilment of our social, legal, statutory and environmental responsibilities in word and spirit.

FINISH BLOCK

INTERMEDIATE BLOCK

PRODUCTS

AVAILABLE APIs

Sr. No.	Product	Grade	CAS No.
01	Trazodone Hydrochloride	BP/USP/Ph.Eur./IP	25332-39-2
02	Tamsulosin Hydrochloride	BP/USP/Ph.Eur./IP	106463-17-6
03	Mexiletine Hydrochloride	USP/Ph.Eur./IP	5370-01-4
04	Glycopyrrolate	USP/IP	596-51-0
05	Glycopyrronium Bromide	Ph.Eur	51186-83-5
06	Baclofen	BP/Ph.Eur./IP	1134-47-0
07	Carbimazole	BP/Ph.Eur./IP	22232-54-8
08	Modafinil	USP/Ph.Eur	68693-11-8
09	Nitrofurantoin (Monohydrate/ Anhydrous /Macrocrystal)	IP/Ph.Eur/USP	67-20-9
10	Etoricoxib	USP/IP/IH	202409-33-4
11	Magnesium Aspartate	USP/Ph.Eur./BP/IP	18962-61-3
12	Primidone	USP/IP/BP/Ph.Eur	125-33-7

CEP Filings: Next 2 Years

Trazodone Hydrochloride	25332-39-2
Glycopyrronium Bromide	51186-83-5
Etoricoxib (ASMF)	202409-33-4
Baclofen	1134-47-0
Tamsulosin Hydrochloride	106463-17-6
Primidone	125-33-7
Mexiletine Hydrchloride	5370-01-4

In Progress APIs

Cytisincicline / Cytisine	485-35-8
Xanomaline	131986-45-3
Daridorexant	1792993-84-0
Naratriptan	121679-13-8
Pyridostigmine Bromide	101-26-8
Moxonidine	75438-57-2
Cyclizine Hydrochloride	303-25-3
Clotrimazole	23593-75-1

INTERMEDIATES

Sr. No.	Intermediate Name	CAS No.	Used in API
1	1-(3-Chlorophenyl)-4-(3-chloropropyl)piperazine hydrochloride	52605-52-4	Trazodone HCl
2	(1,2,4) Triazolo[3-a]pyridin-3(2H)-one	6969-71-7	Trazodone HCl
3	Trazodone Base	19794-93-5	Trazodone HCl
4	5-[(2R)-2-Aminopropyl)-2-methoxybenzenesulfonamide	12101-81-2	Tamsulosin HCl
5	Tamsulosin Base	106133-20-4	Tamsulosin HCl
6	1-(2,6-Dimethylphenoxy)-2-propanone	53012-41-2	Mexiletine HCl
7	Methyl Phenyl Glyoxalate	15206-55-0	Glycopyrrolate
8	a-Cyclopentylmandelic acid	427-49-6	Glycopyrrolate
9	Methyl a-Cyclopentylmandelate	19833-96-6	Glycopyrrolate
10	N-Methyl-3-pyrrolidinol	13220-33-2	Glycopyrrolate

TOOBA'S GLIMPSES:

ADMIN BUILDING

R&D

STABILITY CHAMBERS

HPLCs

FINISH BLOCK

POTENTIOMETER

CMO/CDMO SERVICES:-

Tooba Pharmaceuticals Private Limited (TPPL) is a trusted Contract Development and Manufacturing Organization (CDMO) offering end-to-end solutions for Active Pharmaceutical Ingredients (APIs) and Intermediates.

Established in 2007, we provide comprehensive services to global innovator pharmaceutical companies, supporting them from laboratory scale to pilot and commercial manufacturing scales through our state-of-the-art, WHO-GMP certified facility. Our offerings include end-to-end support — from process development and technology transfer to validations and regulatory filings.

Our comprehensive service portfolio covers the entire product lifecycle, including:

- Process development and optimization
- Technology transfer
- Process validation
- Regulatory documentation and filing support

We take this opportunity to express our ability to deliver high-quality, cost-effective, and timely solutions powered by our dedicated team of scientists and technical experts.

CRO / R&D CRAMS SERVICES:-

Tooba Pharmaceuticals Private Limited (TPPL) as a CRO/R&D CRAMS service provider, offers end-to-end research and development solutions to the global pharmaceutical industry. We specialize in process optimization, analytical and method development, impurity profiling & control, and troubleshooting, enabling faster and more efficient drug discovery and manufacturing.

TPPL's CRO services focus on developing safe, economical, and patentable API processes based on green chemistry principles. Our expertise extends to telescoped synthesis and regulatory dossier support (ASMF/CEP), backed by proven innovation in molecules such as Trazodone, Mexiletine, Glycopyrrolate, Tamsulosin, Nitrofurantoin, etc.

With a strong emphasis on innovation, quality, and regulatory compliance, TPPL has earned the trust of pharmaceutical companies worldwide. We deliver cost-effective, sustainable, and high-quality solutions, ensuring every project meets global standards and client expectations — helping our partners bring their molecules to market faster and more efficiently.

OUR SERVICE OFFERINGS INCLUDE (BUT ARE NOT LIMITED TO):

- Synthetic route identification, development and optimization
- Synthesis of niche building blocks, scaffolds, and intermediate compounds for analog generation
- Development of commercially viable and competitive alternate manufacturing routes
- Reduction of costs and process complexity to develop cost-effective and sustainable processes
- Optimization of reaction conditions to enhance yield and purity
- Integration of Green Chemistry principles to minimize by-products, waste, and environmental impact
- Focus on developing import-substitute routes to strengthen supply chain independence
- Pre-clinical and clinical compounds on multi-gram to multi-kilogram scale
- In-house preparation of Impurities and Working Standards
- Analytical Method Development and Validation
- Impurity Profiling
- Genotoxic Evaluation and Validation
- Polymorph Studies
- NDMA Risk Assessment
- Elemental Impurity Assessment
- Kilo and Pilot Scale Manufacturing
- Technology Transfer
- Stability Studies
- Documentation Support for Regulatory Filings and Approvals

KEY CAPABILITIES & INFRASTRUCTURE:-

- Technocrats with a cumulative research experience of almost 90 years
- Processes developed for over 100+ products by our expert team
- 200+ patents credited to our scientists and researchers
- TPPL has developed patentable technologies. Recently we have filed patent for Glycopyrronium Bromide (Application No. 202021022784).
- Dedicated Process Safety in Laboratories
- Wide range of reactors including Stainless Steel, Glass-Lined, and Glass Assemblies
- R&D Lab: 1–20 L glass assemblies for rapid process development
- Pilot Plant: 100–200 L glass assemblies for efficient scale-up
- Manufacturing capacity ranging from 1 kg to multi-tonne scales
- Hydrogenation facility available
- Photochemical Reactor available
- Capability for high-temperature reactions (up to 200°C) and high-vacuum distillations
- Exclusive Finished Block equipped with AHUs and HEPA filters for API manufacturing
- Backward integration of key raw materials to ensure supply chain reliability
- Integrated project management and planning for end-to-end process execution
- Multiple fume hoods in synthetic laboratories with efficient exhaust systems
- 2-litre high-pressure hydrogenator for specialized reactions
- Capability to perform organometallic reactions using metal catalysts
- Facilities to maintain reaction temperatures from below 0°C to +200°C
- High-vacuum distillation systems (up to 0.1 mm Hg)
- Rotary evaporators (Rota Vap) for solvent recovery and concentration
- Access to the latest scientific literature and databases for informed research and innovation

A BRIEF SUMMARY OF WORKING PROCEDURE

- **R&D Focus:**

TPPL's Research and Development (R&D) is primarily focused on the manufacturing of Active Pharmaceutical Ingredients (APIs) and Intermediates.

- **Expertise and Experience:**

TPPL's R&D team comprises technocrats with a cumulative research experience of nearly 90 years and over 200 patents to their credit.

The team is well equipped to develop non-infringing, innovative synthetic routes for a wide range of molecules.

- **Quality Assurance:-**

Company management directly monitors the quality, Quality is of supreme importance in Tooba Pharmaceuticals and supported by people at all levels, in all functions. Our Quality Assurance (QA) and Quality Control (QC) teams conduct rigorous testing, validation, documenting and monitoring to ensure that every product meets the highest standards of purity, efficacy, and safety. Our facility is WHO-GMP and ISO 9001 certified and fully compliant with current Good Manufacturing Practices (cGMP). Most importantly the management is well versed with the chemical technology & regulatory requirements know how.

MAIN ELEMENTS OF THE WORKING PROCEDURE

GREEN CHEMISTRY:-

- Adoption of Green Chemistry principles to promote environmentally sustainable processes.
- Reduction in the use of hazardous reagents and optimization of solvent recovery and energy efficiency.
- Active efforts to reduce water consumption, minimize effluent generation, and implement Zero Liquid Discharge (ZLD) practices from the very first day of process development.
- Commitment to developing cost-effective, eco-friendly, and globally compliant synthetic processes.

DATA INTEGRITY:-

- At Tooba Pharmaceuticals Private Limited (TPPL), we uphold the highest standards of data integrity and confidentiality across all our operations. Every piece of data generated during research, development, and manufacturing is maintained to be accurate, complete, consistent, and traceable throughout its lifecycle.
- Our documentation strictly follows the ALCOA+ principles. All records are manually maintained under controlled conditions, verified through regular reviews, audits, and cross-checks to ensure reliability and compliance.
- We recognize the critical importance of client confidentiality in contract research and manufacturing. All client information, project data, and intellectual property are handled with the utmost discretion and security, ensuring full protection of proprietary information.
- Through continuous personnel training, adherence to standard operating procedures (SOPs), and a culture rooted in integrity and trust, TPPL ensures that every project meets global quality and ethical standards while safeguarding our clients' confidence.

SAFETY : -

- Safety integrated into every stage of R&D — from laboratory synthesis to pilot-scale operations.
- All personnel are equipped with Personal Protective Equipment (PPE) and follow Safety SOPs.
- Robust safety protocols for chemical handling, instrument operation, and waste management.
- Processes designed to protect operators, the environment, and product integrity.

PATENT AND LEGAL COMPLIANCE:-

- R&D team adept at developing non-infringing synthetic routes for APIs and intermediates.
- Strong focus on techno-commercial feasibility while ensuring compliance with international patent regulations.
- Strategic innovation and comprehensive patent assessment ensure smooth operation in regulated markets.

COST-EFFECTIVENESS:-

- Continuous R&D focused on both existing and new products to ensure techno-commercial viability.
- Development of efficient, scalable synthetic routes that align with project timelines.
- Process optimization, yield enhancement, and resource efficiency are core to maintaining competitive costs.

GENOTOXICITY :-

- Early identification of genotoxic impurities using literature data, risk assessments, and predictive toxicology tools.
- Development and validation of analytical methods to detect genotoxic impurities at trace levels.
- Compliance with ICH M7 guidelines to ensure the highest safety standards for human use.

NDMA (NITROSAMINE CONTROL):-

- Design of R&D processes to prevent the formation of nitrosamine impurities.
- Use of safe starting materials, improved process design, and comprehensive risk assessments for every product.
- Routine analytical testing for nitrosamine levels to meet stringent global safety and regulatory standards.

MAKE IN INDIA INITIATIVE :-

- Development of manufacturing routes from basic chemical scaffolds to ensure quality control and reduce import dependency In-house synthesis of impurities for complete control over the development process.
- Commitment to the Government of India's "MAKE IN INDIA" initiative by utilizing indigenous raw materials and technologies.
- TPPL endorses the Government of India's vision and mission of developing the products with indigenous sources-'Be vocal about local'.

INFRASTRUCTURE

Sr. No.	FACILITY	EQUIPMENT
1	R&D	Autoclave/Hydrogenetor, Photochemical Reactors, Glass Assemblies etc.
2	QA/QC	HPLC, HS-GC with auto injector, Polarimeter, FTIR, UV, Karl Fischer , Potentiometer, etc.
3	Intermediate Block	Stainless Steel Reactors, Glass Lined Reactors, Glass Assemblies, Centrifuge, Tray dryer, Multi Mill, Sifter etc.
4	Finish Block	Glass lined reactors, Glass Assemblies, Vacuum Tray Dryer, Nutsche Filter, Centrifuge, Multi Mill, Sifter, Water purification Plant, Positive pressure AHUs. RCVD etc.
5	Engg. & Maint. (Utility)	Boiler, Cooling Tower, Chillier, Vacuum Pumps, Air compressor, etc.
6	Solvent Yard	
7	Packaging store	
8	Stores	
9	Administration Block	
10	Common Area	
11	Effluent Treatment Plant	

FACILITIES

- Multi storeyed Intermediate Block
- Multi storeyed Finish block
- Stainless Steel Reactors and Glass Lined Reactors
- Glass Assemblies
- Centrifuges
- Sparkler Filters
- Vacuum Tray Dryers
- Multi Mills and Vibro Sifters
- Wet Lab Facility
- Stability Chambers
- Control Sample Room
- Instrumentation Lab

EYE SOOTHING
LUSH GREEN AREA

REACTION CAPABILITIES

- Hydrogenation
- Grignard reaction
- Steam Distillation
- Photochemical Reaction
- Condensation
- Acylation
- Alkylation

APPROVALS & CERTIFICATIONS:

- WHO GMP Certified
- Environment Clearance
- Consent to Establish & Operate
- GMP Certified
- EU GMP/UK DMF/EDQM (In Progress)
- ISO 9001:2015
- ISO 45001:2018
- ISO 14001:2015
- Factory License
- GLP Certified

MAKE IN INDIA

WHO-GMP CERTIFIED · FDA MAHARASHTRA · GMP · ISO 9001:2015 · GLP

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