## WHY AZICO?

- API manufacturer with dedicated Regulated Markets focus, having no intention of competing with its customers in their domestic markets of FDF / Generics.
- High Quality APIs at competitive prices complying with stringent Regulatory requirements.
- Strong **Intellectual Property** Management and **Regulatory** back up.
- World class infrastructure
- Proactive management well supported by a strong committed team
- Rich pool of Scientific talent with expertise in the development of novel, non-infringing and cost-effective API's.
- Speed to market for customers and support their ANDA / Dossier by time bound development.
- Dedicated personnel for timely delivery and prompt response to all queries of the customers.
- Experienced **R&D** team, well qualified and equipped to develop most complex APIs and expertise to handle wide range of chemical reactions
- Absolute assurance of best quality APIs.
- Manufacturing capabilities ranging from gm level to multi-ton lots.



**We welcome contracts for**

- Development / manufacture of niche small volume APIs
- Development of APIs close to approval dates of brands
- Customer exclusivity base development of APIs
- Development of IP strategy for molecules which are yet to be approved and file process patents, polymorph / salt patents
- Custom Synthesis, Contract Manufacturing, Contract Research activities for Gram to Kilo and commercial level production

**Azico Pharmaceuticals Pvt. Ltd**

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# Azico Pharmaceuticals Pvt. Ltd.

*Just the right partner*

# INFRASTRUCTURE . . . WORLD CLASS

- **cGMP/USFDA** compliant manufacturing plant for commercial production with dedicated Clean Rooms designed & supported with ventilation system up to packaging of Finished Product.
- Pilot Plant cum commercial manufacturing block built in compliance with **cGMP/USFDA** guidelines with dedicated Clean Room Area up to packaging of Finished Product
- A separate dedicated facility having suitable containment system to produce Levothyroxine Sodium
- Well equipped R&D Laboratory supported with experienced team of Scientists
- Microbiology Lab
- Well equipped to handle reactions at the temperature -80°c to +250°C range
- Facility for Hydrogenation reactions under GMP conditions

# QUALITY

- **AZICO** is working towards implementation of high level standards of ***ISO 9001***, ***ISO 14001*** and ***OHSAS 18001*** norms so as to achieve certification by the respective competent authorities in the near future.
- The facility is suitable for Audits by ***USFDA*** / ***EMEA*** / ***PMDA*** and any regulatory agencies
- Stringent Quality checks and procedures in place at all levels of API manufacturing . . . from raw materials sourcing to sales and after sales service.
- The main objective for quality assurance and technical team of Azico is to carry out continual development of its process, procedures, people and products.
- Training is a continuous process at **AZICO** . . . at all levels.
- Quality System complies to ***ICH Q7 cGMP*** practices and requirements
- **AZICO** consciously works on In-process Control, Prevention of contamination, Change Control system, Complaints, Recalls / Rejections, System for controlling complaints and rejection and Regulatory Support to Customers.

Facility is suitable for Audits by **USFDA / EMEA / PMDA**

# RESEARCH & DEVELOPMENT

R&D is the focus area at **AZICO** and is handled by Technical Director who has 25 years of experience in development and scale up of Generic APIs mainly for regulated markets of USA & Europe. A team of skilled scientists continuously strive for excellence and efficiency in process development.

- R&D facility is equipped
  - To develop Generic APIs for Regulated markets of both Niche Small volume to moderate to high volume
  - With in-house R & D expertise in R&D leadership of Azico for development of Niche products
  - To handle reactions at the temperature -80°c to +250°C range
- Backward integration capabilities in Group companies
- Analytical R & D Laboratory for Generic API development, Process Research and Special Chemical Entities
- Experienced team of Chemists for carrying out Analytical Method Development & Validations. Preparation of specifications of key RMs, API intermediates and APIs as per ICH guidelines / FDA requirement. Successful Transfer as well implementation of analytical methods, specifications during and post trials / validations to team of manufacturing / QC/QA
- **AZICO** is equipped with state-of-the-art instruments for achieving high level of standards - **HPLC** with LCMS, **HPLC PDA Detector**, **HPLC Preparative** for impurity isolation, **HPLC** for routine analysis, **GC** Head Space, **GC** Regular etc,.