First Time US Pharmaceuticals (India) Pvt. Ltd.

Quality Policy

Developing and providing pharmaceutical products and services of assured quality with outstanding level of commitment to integrity, reliability, delivery and continuous improvement at competitive price in compliance with relevant laws and regulations.

V-Blender

RMG

FBP

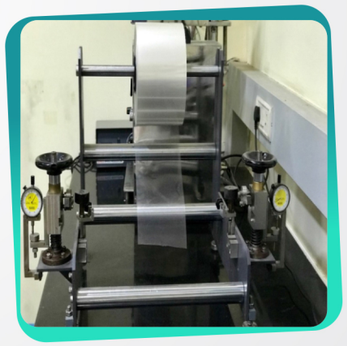
FBD

Compression

Auto Coater

Multi Blender

Multi Mill



Draw Down Coater

FTUP Team :

- Efficient Technical Team with Enormous Experience
- Gel of Experience with high Educational Qualifications
- Substantial Experience in entire Formulation Development, Pre/Post Approval changes, Analytical Development, Analytical Validation, Manufacturing and Regulatory Submissions

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PROFILE

An innovative entrepreneurial healthcare company with focus on services assuring quality and timeliness.

First Time US Pharmaceuticals (India) Pvt. Ltd. (FTUP) is a US FDA approved facility and a subsidiary of USpharma, a listed US company established in 2013 under the leadership of Dr. Manesh Dixit, a professional and an entrepreneur.

FTUP is established in India with a strong vision of providing one stop high quality and cost effective solution of pharmaceutical development, testing and manufacturing in Compliance with the global regulatory requirements.

Our facility, equipment, infrastructure, and procedures are in accordance with the 21 CFR 210, 211 and EU cGMP requirements. FTUP's facility is registered and self-identified with US FDA, further, FTUP also has a Public testing license from Indian FDA.

We work in a highly competitive field, so we're constantly investing in technology and research to make sure we stay ahead of the curve. Our commitment to quality guarantees our success and your satisfaction. "

Why FTUP

FTUP provides an integrated solution to the Pharmaceutical Industry from product identification to the product launch. We are focused on delivering pragmatic, commercially viable and long term sustainable solutions through our services. We have expertise from different functional areas of the pharmaceutical industry to keep our customers always ahead and avoid unexpected situations. .

SERVICES

FTUP provides all-in-one solution to pharmaceutical companies from product development to regulatory approval of product under one roof.

Formulation Development

- Formulation Development including Quality by Design (QbD) studies, Product Development Report and Quality Overall Summary
- Technology Transfer
- Process Optimization, Process Validation
- Expertise in development of Solid Orals, Topical and Transdermal Formulations

Analytical

- Analytical Method Development and Validation and Verification by HPLC
- Residual Solvent Method Development and Validation by GC
- Elemental Analysis Method Development and Validation by ICP-MS
- Development and Validation of Genotoxic Impurities
- Impurities Profiling and Characterization
- Method Development, Validation of Topical & Transdermal formulations
- Analytical Method Transfer
- Physico-Chemical Characterization
- Drug Excipients Compatibility Study
- Polymorphism and Particle Size Analysis
- Stability and Release Testing

Regulatory & Compliance

- Review and compilation of ANDA and EU-CTD dossier
- Pre and Post Approval Activities
- Regulatory Life Cycle and Strategies
- SPL Submissions
- Assistance for US-FDA Compliance requirements
- Regulatory Consulting Services

IPR

- Guidance for Patent Infringement / Non-Infringement
- Patent Analysis and Litigation Assistance

Contract Manufacturing and Services

- Contract Manufacturing
- Controlled Substance Formulation and Manufacturing in USA
- Process Optimization Service
- Product Launch Assistance in USA
- Distribution in USA

ICP-MS

GC-HS

HPLC Room

Dissolution

UV

IR

Multiwave Pro

Micro Balance

Texture Analyser

Wet Lab

Stability Chambers

Photo-Stability Chamber