Our Services offered to Regulated markets

CONTRACT MANUFACTURING

- We can carry out site variation
- Prepare validation batches
- Generate stability data
- Manufacture and supply the product at Competitive rates

CONTRACT R&D AND PRODUCT DEVELOPMENT FOR EUROPEAN MARKET

- To develop formulation as per customer requirement
- Perform BE studies
- Perform stability studies
- Develop and compile registration dossier in eCTD formats

DOSSIER OUT-LICENSING & SUPPLY OF THE PRODUCT

- File for registration in European countries
- On dossier approval, manufacture & supply commercial batches

Quality Control:

QC

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The Quality Control system is an integral part of cGMP and ensures that the necessary and relevant tests are done and that neither the material not the products are released for use or supply, until their quality has been judged to be satisfactory. The Quality Control Laboratory is responsible for sampling and testing of all starting materials, and packaging materials in accordance to the predetermined specifications and established procedures. In case of raw materials, 100% sampling is carried out for identification and composites samples are tested as per the specifications. The QC Laboratory is also responsible for testing of in-process and finished product samples. The stability studies are carried out at Quality Control Laboratory. The Microbiological testing includes Assays for vitamins, sub-culturing of different micro-organisms, Viable Environmental Monitoring of Non Aseptic areas and Sampling & Analysis of different grades of water. The Quality Control laboratory is fully equipped with most sophisticated and modern analytical instruments for chemical and instrumental analysis. e.g.

High Performance Liquid Chromatography (HPLC)	Autoclave for Sterilization & Destruction
Ultra violet Spectrophotometer (UV)	Incubators
Auto Titrators	Hot Oven
Dissolution Test Apparatus	Laminar Air Flow
Infra Red Spectrophotometer (FTIR)	

The microbiology laboratory is fully equipped with required instruments and facilities to test microbiological quality parameters. e.g.

The analytical and calibration assistance is taken from approved scientific / analytical testing laboratory.

Quality Assurance & Quality Management System:

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The Quality Management System is governed by the Principles and Requirements as defined in the Schedule M of Indian Drugs and Cosmetics Acts 1940, as well as cGMP.

The Quality management system is established with an understanding that "Product Quality as well as performance quality" are crucial in the long term survival of the organization.

The Quality management system stresses upon key aspects viz., process capability operating system acceptance supply and quality motivation. The purpose of the Quality Policy is to ensure the compliance of Quality systems and procedures so that the Finished Drug Products manufactured at site meets all the required specifications ensuring the identity, strength, safety and purity of products.

The Quality Control Department is independent from manufacturing and authorized to take appropriate decisions on quality matters of Raw material / Packaging material/ Finished products or any other issues related to quality.

Countries Where we Operate...

CIS Countries

- Armenia
- Azerbaijan
- Belarus
- Kazakhstan
- Kyrgyzstan
- Moldova
- Georgia
- Russia
- Uzbekistan
- Tajikistan
- Turkmenistan
- Ukraine

African Countries

- Ethiopia
- Kenya
- Uganda
- Ghana
- Nigeria
- Senegal
- Ivory Coast

Asian Countries

- Cambodia
- Hong kong
- Myanmar
- Philippines
- Srilanka
- Thailand
- Vietnam

Latin American & Middle East Countries

- Bolivia
- Costarica
- Trinidad & Tobago
- Jamaica
- Chile
- Yemen

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Akriti Pharma believes to produce products of niche therapeutic segments and working for development of following therapeutic categories with the help of our R & D and F & D.

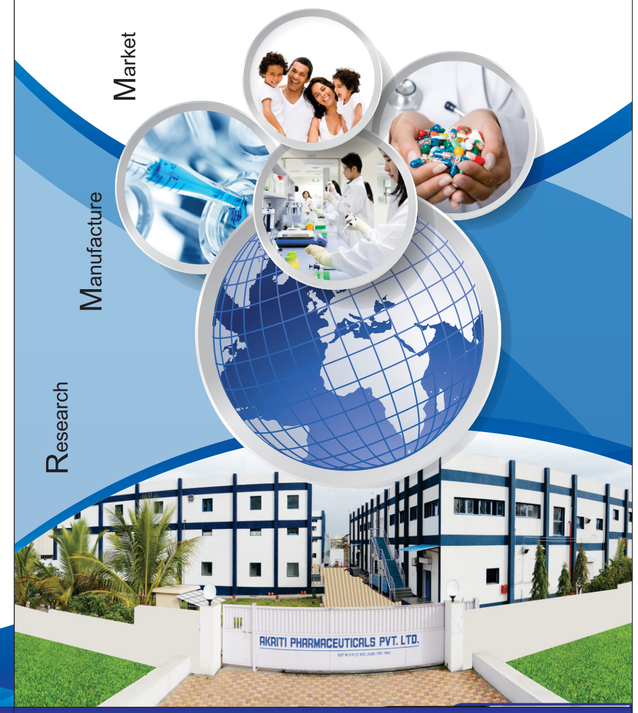
1) Immunosuppressant
2) Antiretroviral
3) Latest Antihypertensive
4) Latest Antidiabetic
5) Latest Anti bacterial
6) Life style products

Akriti Pharmaceuticals Pvt. Ltd.

Trusted Partner in Global Healthcare

EU GMP

APPROVED FACILITY



Company Profile

Page 2

AKRITI PHARMACEUTICALS PVT. LTD. is an emerging global pharmaceutical company that manufactures & markets a broad range of Pharmaceutical Formulations. Our operation ranges from R&D, manufacturing & marketing of finished pharmaceutical formulations. The head office of Akriti Pharma is based in Mumbai-INDIA.

Market & Customer Base

Akriti Pharma is actively involved in its global operations like CIS, African, South East Asian, SAARC, Latin American and Middle East Countries. Akriti Pharma has developed its marketing setup in European Countries also.

Akriti Pharma's domestic marketing team comprises of highly qualified & trained professionals. Akriti Pharma markets its finished branded pharmaceutical formulations in Domestic market.

We are a rapidly and dynamically growing up entity in the world of Pharmaceutical formulations. Our important operational areas are to manufacture, market & export of various research based niche Products & life saving medicines in regulated and semi-regulated markets

Our Mission:

We strive for a happier, healthier tomorrow. We work on total customer satisfaction to achieve leadership in pharmaceutical marketplace, products and services across the globe, through excellence in technology, based on research and development , compliance with regulatory requirements.

Our human resources continue to be the most valuable asset in this pursuit of leadership and the prime driving forces for our growth.

Our Vision:

Our vision is to be a leading pharmaceutical company in India and become a significant global player.

We aim to be present in regulated and semi-regulated markets of the world.

We strive to enrich our people – our driving force, by making them as competent professionals for consistent growth of our organization

Manufacturing

The manufacturing unit is situated at Jejuri, Maharashtra, India on two acres of land. The factory is having two manufacturing units. One Unit has manufacturing facility of Tablets, Capsules, Cream & Ointments. Second Unit has manufacturing facility of Cephalosporin dry powder for Injection.

Capacities & Capabilities

- General Oral Solid Tablets
  - 250 Million / Year
- General Oral Solid Capsules
  - 80 Million / Year
- Ointment / Cream / Paste
  - 8 Million / Year
- Cephalosporin Dry Powder Inj.
  - 120 Million / Year

- Film Coated Tablets
- Enteric Coated Tablets
- Chewable Tablets
- Dispersible Tablets
- Effervescent Tablets
- Immediate Release Solid Dosage Form (IR)
- Sustained Release Tablets (SR)
- Modified Release Tablets (MR)

Upcoming Manufacturing Facility

Cephalosporins

- Tablets
- Capsules
- Dry Syrup

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Accreditation in Process

- MOH SUDAN 1
- TFDA TANZANIA 2
- MOH YEMEN 3

Regulatory Affairs

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REGULATORY AFFAIRS

* Well experienced regulatory affairs team with more than 15 years of experience in Regulated Markets
* Regulatory Affairs is well versed with regulatory guidelines of European countries
* Regulatory Affairs is adept in compiling of ACTD & eCTD Dossiers
* Regulatory Affairs team is highly competent to registered the products in European countries

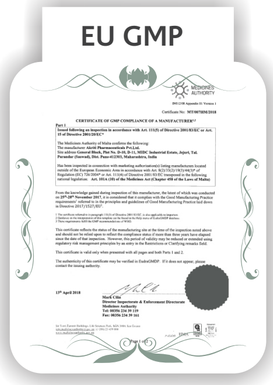
Intellectual Property Management Cell (IPMC)

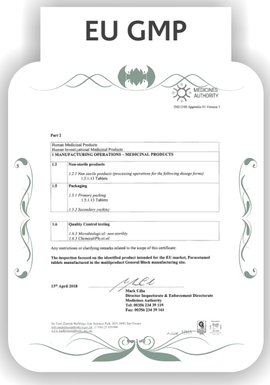
* Akriti IPMC house is well experienced & skilled team with technical knowledge in Pharmaceutical Sciences
* Akriti IPMC is skilled in patentability analysis, filing national & international patent applications
* IPMC has personnel capable in infringement analysis & validity analysis of third party patents
* IPMC is an indispensable support for elucidation of R&D product pipeline and product filing strategies

Akriti has set up Formulation, research & development to develop safe and effective therapeutic options for undiscovered and unmet medical needs. Our R&D Center conforms to international quality standards and houses advanced and up to date equipment. It has one of the most advanced infrastructures for both basic and applied research. Design of experiments (DOE) and statistical analysis have been applied widely to formulation development, and are useful in process optimization and process validation. Akriti development arm has dedicated teams of highly qualified scientists working on patent navigation, specializes in creating alternate and patentable processes for generic formulations, process development, scaling-up, tech transfer and registration of generic products with eCTD dossiers. Our analytical development team is capable to develop methods of analysis lay down specifications and work out quality assurance norms in relation to all the above activities.

The R&D facility is geared towards development of technologically challenging products. We strive to develop cost-effective, high-quality formulations to make the life of the patient better.

Accreditations Available





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