Akriti Pharmaceuticals Pvt. Ltd.

Trusted Partner in Global Healthcare

EU-GMP

(UNDER PROCESS)

Research Manufacture Market

www.akritipharma.com

Company Profile

AKRITI PHARMACEUTICALS PVT. LTD. has evolved as a 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 exports to more than 30+ countries in Europe, CIS, Africa, South East Asia, SAARC, Latin America and Middle East region. This indicates our commitment to quality & global integration.

Akriti Pharma has PAN India operations & is present in Government Institutional sales of Finished Pharmaceuticals formulations with the team of highly emulsified & trained Professionals.

Our important operational areas are to manufacture, market & export various research based life saving medicines in Regulated and Semi-regulated markets. We provide an end to end solution to our pharmaceuticals partners globally.

Our Mission:

We strive for a happier, healthier tomorrow. We want to achieve leadership in pharmaceutical products and services across the globe, through excellence in technology-based research and development and compliance with regulatory requirements.

Our people 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 grow as an organization by enriching our people who are also our driving force and making them as competent professionals.




Manufacturing

Our state of art manufacturing facilities is situated at Jejuri, Maharashtra, India on two acres of land. There are two manufacturing units. One Unit is dedicated for Tablets, Capsules, Cream & Ointments.

Second Unit has manufacturing facility of Cephalosporin dry powder for Injection.

ORAL SOLIDS

Tablets
IR, ER, DR, CHEWABLE

Capsule
HARD GELATIN CAPSULES WITH PELLETS, POWDERS CAPSULES

TOPICAL • Ointment • Cream • Gel

STERILE • Injection

Plant Accreditations

- MOHAP UAE
- MOH Bahrain
- MOH Iraq
- WHO-GMP
- FMHACA Ethiopia
- TMDA Tanzania
- NDA Uganda
- PPB-Kenya
- NMRA-Sri Lanka
- MOH Uzbekistan
- BOMRA Botswana
- DNPM Guinea Conakry

Under Process

- MOH Saudi Arabia
- MCAZ Zimbabwe
- MOH Oman
- EU GMP

Product Development

- API sourcing
- Pre-formulation
- Formulation development
- Analytical method development
- Technology transfer & document support
- BA / BE study
- Dossier compilation / submission

R&D

Research & development

Formulation Development

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 equipments. 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, ACTD & CTD dossiers.

• Analytical Development

Our 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.

Regulatory Affairs

Regulatory Affairs

- Product / Dossier Development in CTD Format
- Dossiers Compilation & Duediligence
- EU CTD Dossier Filing Through National, DCP & MRP Procedure
- RFI and query responses, communication to regulatory agency on case basis
- In-house validated eCTD software
- Well versed with EU / UK MHRA / TGA / SAHPRA / ANVISA / HEALTH CANADA / RoW Regulatory submissions
- Regulatory Presence in 30+ Countries

Our Services offered to Regulated markets

AKRITI provides "end to end" solution to all its business partners from development to commercial supply

- Cost effective Product development
- Product development of Niche Drugs
- Facilitating commercial supplies (export capabilities)
- Project Management
- Product / Dossier development & Registration
- Execution of site transfers (one stop services) Contract Manufacturing

Site Evaluation

- Presence of a robust research infrastructure
- Past enrollment performance on similar studies

AKRITI has highly experienced team for product development to design formulations as per ICH Q8, Q9, Q10, QBD and expertise in designing formulations by using reverse engineering techniques with non-infringing formulations.

- **Pre-formulation**
- **Reverse engineering**
- **Process development (Cost effective)**
- **Analytical development and validations**
- **Characterisation of API, Excipients and Reference Product**
- **Prototype formula**
- **Process optimization**
- **Development as per** ICHQ8/Q9/Q10/QTP/CQA/RA/DOE
- **Process evaluation and validation**
- **Stability designing**

Akriti Pharma believes in producing products of niche therapeutic segments and working for development of following therapeutic categories with our technical expertise.

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

Global Presence

CIS Countries

- Turkmenistan
- Kazakhstan
- Uzbekistan
- Armenia
- Azerbaijan
- Tajikistan
- Ukraine

Asian Countries

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

African Countries

- Ethiopia
- Tanzania
- Uganda
- Kenya
- Rwanda
- Botswana
- Benin
- Togo
- Guinea Conakry
- Burkina Faso
- Cameroon

Latin American & Middle East Countries

- Costa Rica
- Guatemala
- Jamaica
- Guyana
- UAE
- Bahrain
- Iraq
- Kurdistan

Under Progress

- EU-GMP
- Saudi Arabia
- Zimbabwe
- Oman

Accreditations Available

MOHAP
UAE

MOH
Bahrain

EFDA
Ethiopia

TMDA
Tanzania

NDA
Uganda

PPB
Kenya

MOH
Iraq

DPML
Ivory Coast

NMRA
Sri Lanka

BOMRA
Botswana

MOH
Cambodia

DNPM
Guinea Conakry

MOH
Uzbekistan

WHO-GMP

Accreditations Under Process

EU-GMP

MCAZ
Zimbabwe

MOH
Oman

MOH
Saudi Arabia

Product List

CORPORATE OFFICE :
205 & 206, Thane Mint Indiabulls,
Behind Hiranandani Meadows,
Near Hyde Park, Thane (West),
Maharashtra, Mumbai- 400610, India

REGISTERED OFFICE :
117, Block No. 2, Emerald Plaza ,
Hiranandani Meadows,
Thane (West) Maharashtra,
Mumbai-400 610, India

MANUFACTURING UNIT :
Plot No. D-10 & D-11,
M.I.D.C. Industrial Estate, Jejuri,
Taluka - Purandhar (Saswad),
Dist. Pune – 412 303, Maharashtra, India

+91 22 21730204 / 21730960

jp@akritipharma.com

www.akritipharma.com