

One Stop Solution
Concept to
Commercialization

ACME GROUP



Acme Formulation



Acme Generics



Immaculé

spreading health and happiness across 75+ countries

legacy of trust

The Acme Group began its journey in 2005 with a bold mission of becoming a leader in the contract manufacturing space and a preferred business partner for pharmaceutical companies seeking world-class capabilities and scalable operations.

Guided by the founder's vision and purpose, the Acme Group has scaled new heights in the pharmaceutical value chain over the years. Today, it provides fully integrated contract manufacturing and development solutions to some of the top Indian and global pharmaceutical companies. Acme is driven by a belief in fast growth combined with a focus on innovation and service. The group currently consists of three state-of-the-art, fast-growing companies: Acme Formulation, Immacule Lifesciences, and Acme Generics.

Powering the group are 2,500+ highly skilled staff working across over 1 million sq. ft. of manufacturing space in Northern India. We produce 17 billion tablets, 3 billion capsules, 30 million liquid vials/ampoules, and 12 million lyophilized vials annually. Our expertise lies in the niche segments of oral hormones, including female sex hormones and levothyroxine, along with liquid and lyophilized injectables. We are also expanding our sterile manufacturing capacity to produce an additional 60 million general liquid and lyophilized vials, 60 million liquid and lyophilized vials for oncology, 30 million three-piece ophthalmic containers, and 24 million pre-filled syringes and cartridges annually.

Over the past decade, we have been audited and approved by various international regulatory agencies, including USFDA, UK-MHRA, EU-GMP, Health Canada, TGA Australia, ANVISA, INVIMA, and WHO Geneva. In addition, we have received approvals across major emerging markets in Asia, Africa, CIS, and Latin America. With 22 ANDAs approved, 18 ANDAs filed and under review, and a target of 50+ ANDA approvals by 2025, we continue our journey towards building a sustainable future as a leading CDMO.

At Acme, we offer Quality, Speed, and Value by combining our technical competencies with cost-effective solutions.

Across our sites, our development teams are proficient in:

- Pre-formulation Studies: Chemical/Physical Characterization and Drug/Excipient Compatibility
- Formulation Development
- Analytical Method Development and Validation
- Stability studies covering all ICH zones, including container-closure compatibility studies

Commercial Manufacturing

With an investment of over USD 150 million, Acme proudly serves many of the world's leading companies. With an unwavering focus on service and quality, Acme is strategically positioned as a preferred business partner and looks to the future with even higher goals and ambitions.



dream.believe.achieve

moving from strength to strength

2005-10

- First OSD Facility commences operations (AF)
- Hormonal Production Facility commenced (AF)

2011-16

- New Sterile FDF Facility commenced (IM)
- New OSD Facility commenced (AG)
- WHO prequalification and INVIMA Approval (AF)
- UK MHRA / ANVISA / PICS Approval (IM)
- EUGMP Approval (AG)
- New R&D centre commenced

2017-19

- TGA, Health Canada Approval (AG)
- USFDA Approval with Zero 483 (IM)
- ANDA Approvals~02 (IM)
- ANDA Filings~05 (IM)

2020-23

- USFDA Approval renewed (IM)
- EUGMP Approval renewed (AG/AF/IM)
- ANDA Approvals~15 (IM)
- ANDA Filings~15 (IM)
- ANDA Approval~1(AG)
- USFDA Approval (AG)
- USD 150 million invested to expand Sterile Capacity (IM)

2024

- Sterile Capacity expansion to commence operations
- General Liquid/Lyophilized~60 million
- Oncology Liquid/Lyophilized~60 million
- Ophthalmics~30 million
- PFS/Cartridge~24 million (IM)
- ANDA Approvals~22 (IM/AG)
- ANDA Filings~18 (IM/AG)



2025

- ANDA Approval Target~50+ (AG/AF/IM/IM)

- Acme Formulation : (AF)
- Acme Generics : (AG)
- Immacule Lifesciences : (IM)



Acme Formulation

Acme Formulation

Oral Solid Dosage Facility

General and Hormonal category

Available Dosage

Tablets and Capsules

Facility Area

150,000 sq. ft.

Capacity

1 billion female sex hormone tablets

3 billion tablets, and 1 billion capsules from General Block

Approvals

EU-GMP (Hormone Block), WHO-Geneva, Colombia INVIMA, Tanzania, Nigeria, Ethiopia, Ghana, Kenya,

Yemen, Zimbabwe, Vietnam, Philippines, Zambia, Mozambique, Niger, Senegal, Peru, Chile, Ukraine



Acme Generics

Oral Solid Dosage Facility
General Tablets and Capsules/Levothyroxine Tablets

Available Dosage
Tablets and Capsules

Facility Area
300,000 sq. ft.

Capacity
6 billion tablets from Levothyroxine Block
7 billion tablets and 2 billion capsules from General Block

ANDAs
1 approved, 1 under review, 10+ filing target for 2025

Approvals
USFDA, EU GMP, Health Canada, TGA Australia, MOH Russia, Kazakhstan, NDA Uganda

Research & Development
We have an in-house Research and Development wing with 50+ professionals. and capabilities to develop complex generics and potent products

- Generic drug development (US, EU and other emerging markets)
- Innovative Generics (505 (B)(2))
- Innovative Drug Delivery Technologies
- Dedicated Oncology/High Potency Products Area with Isolators



Immacule Lifesciences

Sterile Product Facility

Liquid and lyophilized Injectables

Facility

USFDA approved state-of-the-art 21 CFR compliant, built with an investment of USD 50 million

Available Dosage

Aseptic / Terminally Sterilized Vials (1mL-100mL) / Ampoules (1mL-10mL)

COC / COP Plastic Vial Handling

Capacity

12 million Lyophilized Vials

30 million Liquid Ampoules/Vials

ANDAs

21 approved, 17 under review, 18+ filing target for 2025

Approvals

USFDA, UK MHRA, Hungary OGYEI, TGA Australia, Health Canada, Brazil – ANVISA, WHO Geneva,

SAHPRA, Mexico – COFEPRIS





Immacule Lifesciences

Sterile Product Facility

Oncology Liquid/Lyophilized Injectables, Ophthalmic, Pre-Filled Syringe/Cartridge, General Liquid/Lyophilized Injectables

Facility Area

250,000 sq. ft.

Capacity

Oncology Liquid/Lyophilized Injectables: 60 million

General Liquid/Lyophilized Injectables: 60 million

Ophthalmic: 30 million

Pre-Filled Syringes/Cartridges: 24 million

"Mastering Complex Injections: Precision, Quality, Diversity"

High Viscosity Formulations, Long-acting Release Formulations

Peptide Conjugates & Complex Cyclic Peptides

Temperature Sensitive Liposomes

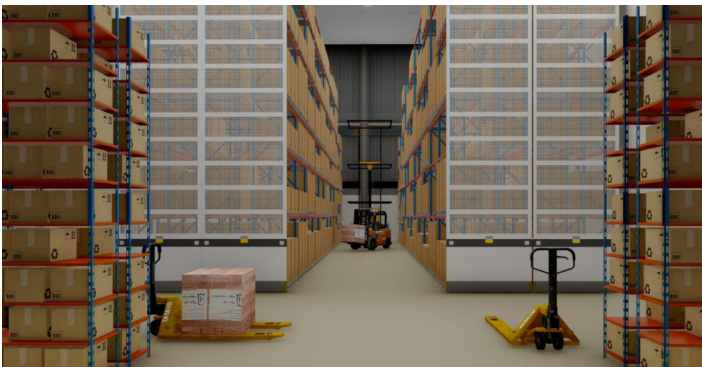
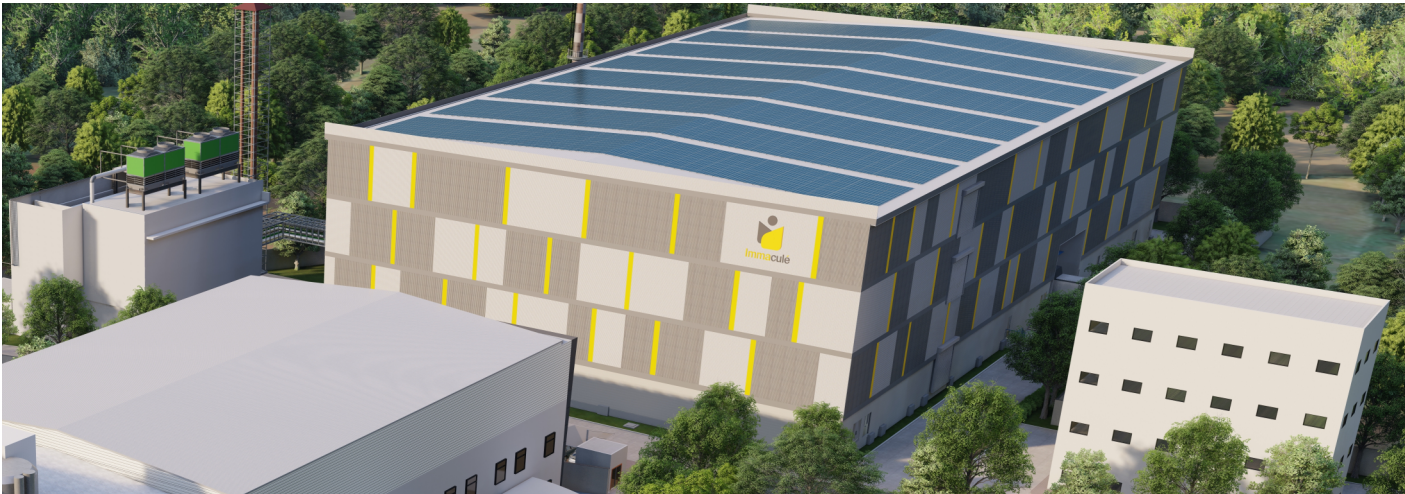
Nano Suspensions, Microsphere Technology

Sustained Release Formulations

GMP Accreditations Planned

USFDA, EU GMP, UK MHRA, PIC/s, TGA Australia, Health Canada, WHO Geneva, ROW and Emerging Markets





"Trusted Technology Investment: Paving the Way for Superior Products"

Bausch and Stroebel /Hull : Liquid & Lyophilized Vials

Groninger: Ophthalmic Solutions

Syntegon: Pre-Filled Syringes / Cartridges

Oncology Block

Ima Life : Liquid & Lyophilized Vials

Supporting Equipment

Fedegari : Autoclaves/ VHP

Bram Cor : Vapor Compression Distiller

"Delivering Complex Generics with Unparalleled Regulatory Compliance"

Ultrasonic Homogenizers

Tangential Flow Filtration (TFF) Systems

Nano-Milling Tools

Dissolution Testing Devices

Mass Spectrometers

Dynamic Light Scattering Instruments

Rotary Autoclave

Particle Size Analyzers

Turbidimeter

Rheometers

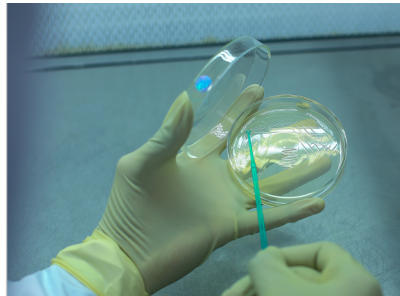
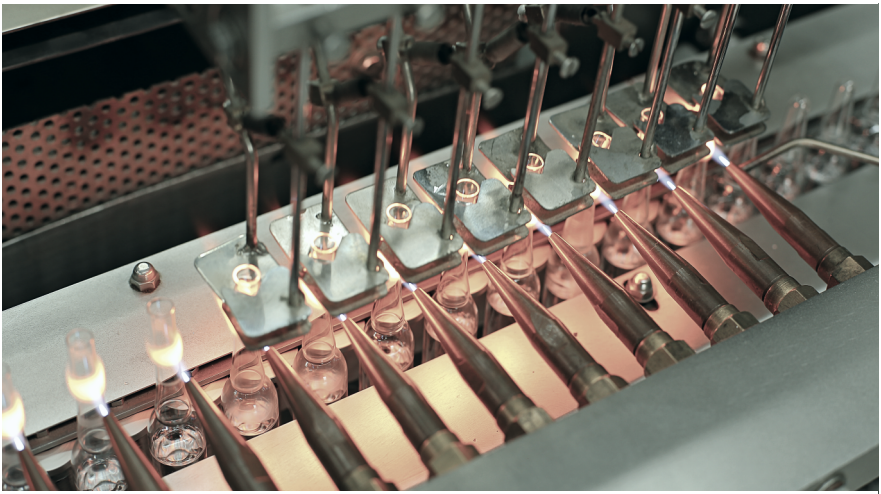
High Shear Granulators

Microfluidizers



accelerating wellness

R & D and Manufacturing facilities



partnering success : our prestigious clients

 Abbott	 gsk GlaxoSmithKline	 SANDOZ	 MERCK	 P&G
 Crescent PHARMA LIMITED	 Piramal knowledge action care	 MSI REPRODUCTIVE CHOICES	 imres	 unicef
 MEDECINS SANS FRONTIERES	 JAMP PHARMA GROUP	 Biocon	 WELDING HAMBURG	 NIVAGEN PHARMACEUTICALS
 DR. REDDY'S	 Rubicon RESEARCH	 WAYMADE PLC	 CLICKS+	 Pharmanovia
 ARISTO	 JUBILANT LIFE SCIENCES	 Emcure SUCCESS THROUGH INNOVATION	 torrent PHARMA	 SIGMA Independent together

 FRESENIUS KABI caring for life	 PROVEPHARM	 BAYER	 aspEN HOLDINGS	 Baxter
 UNFPA	 dkt MOZAMBIQUE	 psi	 IDA FOUNDATION	 SFH
 PrecisionDose	 RKPHARMA	 IVC BRUNEL HEALTHCARE	 accord The Evolution of Generics	 Alembic
 Navinta LLC	 Cipla	 SUN PHARMA	 MACLEODS	 LUPIN
 Rising PHARMACEUTICALS	 Mankind	 Strides	 zydus Dedicated To Life	 EPIC PHARMA



giant strides towards a global footprint



- AFRICA
Ethiopia, Nigeria, Ghana, Tanzania, Kenya, Uganda, Zambia
Malawi, Sierra Leone, Madagascar, Angola, Zimbabwe,
Mozambique, Cameroon, Senegal, South Sudan, South Africa,
Ivory Coast
- ANZ
Australia
- ASIA
Nepal, Sri Lanka, Philippines, Vietnam, Cambodia,
Laos, Thailand, Myanmar, Malaysia, Singapore
- CENTRAL & SOUTH AMERICA
Brazil, Colombia, Guatemala, Nicaragua, Paraguay,
Uruguay, Chile, Costa Rica, Venezuela, Peru, Ecuador,
Mexico
- CIS & OTHERS
Kazakhstan, Uzbekistan, Ukraine, Russia, Georgia
- EUROPE
United Kingdom, Hungary, Poland, Italy, Netherlands,
Portugal, Austria, Czech Republic, Denmark, Germany
- MIDDLE EAST
UAE, Saudi Arabia, Yemen
- NORTH AMERICA
US, Canada

accreditations

 U.S.	 UK	 HUNGARY	 AUSTRALIA	 CANADA	 BRAZIL	 WHO
 MEXICO	 RUSSIA	 SAUDI ARABIA	 SOUTH AFRICA	 OMAN	 UKRAINE	 MALAYSIA
 COLOMBIA	 THAILAND	 ZIMBABWE	 FMHACA ETHIOPIA	 TANZANIA	 PERU	 CHILE
 UGANDA	 VIETNAM	 PHILIPPINES	 KENYA	 IVORY COAST	 IRAQ	 KAZAKHSTAN
 GHANA	 MALAWI	 NIGERIA	 YEMEN	 SUDAN	 CAMBODIA	 GUINEA



Acme Formulation

**Acme
Formulation Pvt. Ltd.**

Ropar Road, Nalagarh,
Distt. Solan, (H.P.) - 174 101
Board Lines : +91 1795-228501-02
Direct Lines : +91 1795-228506
E-mail : viralshah@acmeformulation.com



Acme Generics

**Acme
Generics Pvt. Ltd.**

Plot No.115, HPSIDC Industrial Area,
Davri, P.O. Gurumajra, Tehsil Nalagarh,
Distt. Solan (H.P.) -174 101
Board Lines : +91 1795-248301-02
Direct Lines : +91 1795-248306
E-mail : viral@acmegenerics.in



Immaculé

**Immaculé
Lifesciences Pvt. Ltd. India**

Village Thanthawal, Ropar Road,
Nalagarh, Distt. Solan, (H.P.)-174 101
Board Lines : +91 1795-228601-02
Direct Lines : +91 1795-228606
E-mail : viral@immacule.in
www.immacule.in

Corporate Office : Plot No 132, Sector 82, JLPL Industrial Area, Sahibzada Ajit Singh Nagar, Punjab 160055, Ph. : +91 172 350 6244