

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 looking for world-class capabilities and scalable operations.

Guided by the founder's vision and purpose, the Acme group, over the years, has scaled new heights in the pharmaceutical value chain and today provides fully integrated contract manufacturing and development solutions to some of the top Indian and global pharmaceutical companies.

Acme strongly believes in fast growth combined with a focus on innovation and service. Currently, the group consists of three state-of-the-art, fast-growing companies, viz. Acme Formulation, Immacule and Acme Generics.

Powering the group are 2500+ highly skilled staff working in over 500,000 sq. ft manufacturing space across Northern India, producing 17 billion tablets, 3 billion capsules, 30 million Liquid vials/ampoules and 12 million Lyophilized vials. We specialize in niche segments of Oral Hormones, both Female Sex Hormones and Levothyroxine along with Liquid and Lyophilized injectables; and we are expanding our sterile 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.

In our journey 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. Apart from this, we have approvals across major emerging countries in Asia, Africa, CIS and Latin Countries. With 21 ANDAs approved, 18 ANDAs filed and under review and 50+ ANDA filing target for 2025, as a CDMO we continue our journey towards building a sustainable future.

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

Across our sites, our development teams are proficient in

- Pre-Formulation Studies: Chemical/ physical characterisation 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 to serve as a preferred business partner, and looks to the future with ever high 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~21 (IM/AG)
- ANDA Filings~18 (IM/AG)



2025

- ANDA Filing 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

20 ANDAs 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

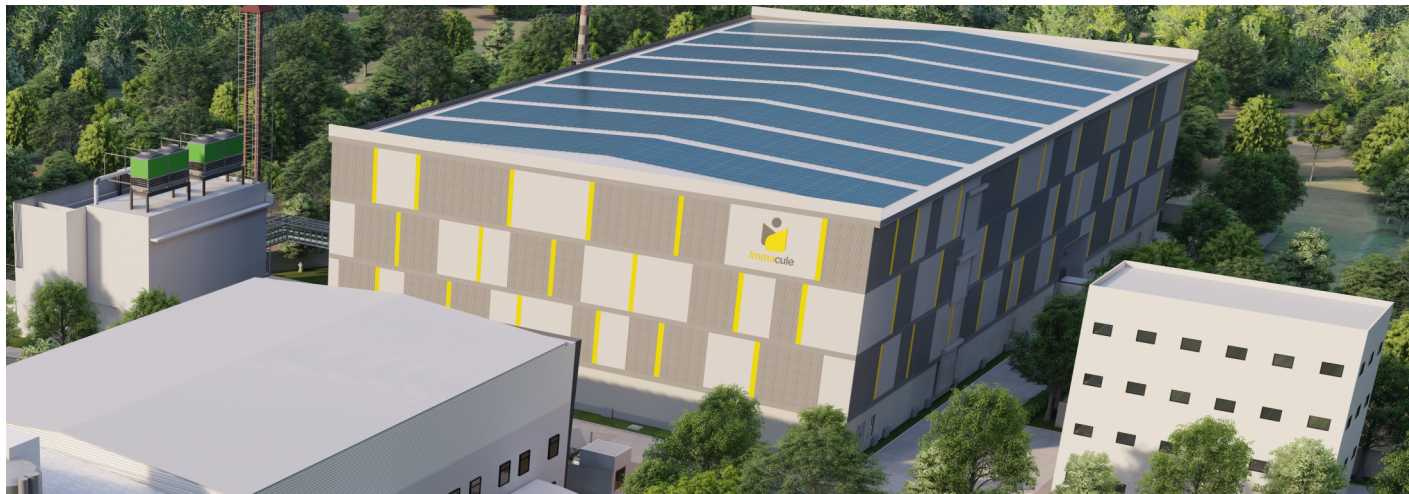
Nano Suspensions, Microsphere Technology

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

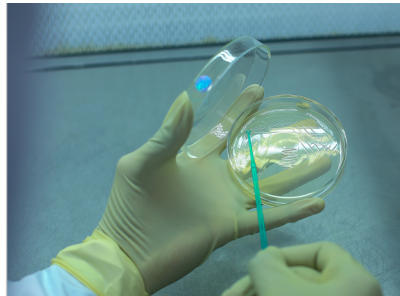
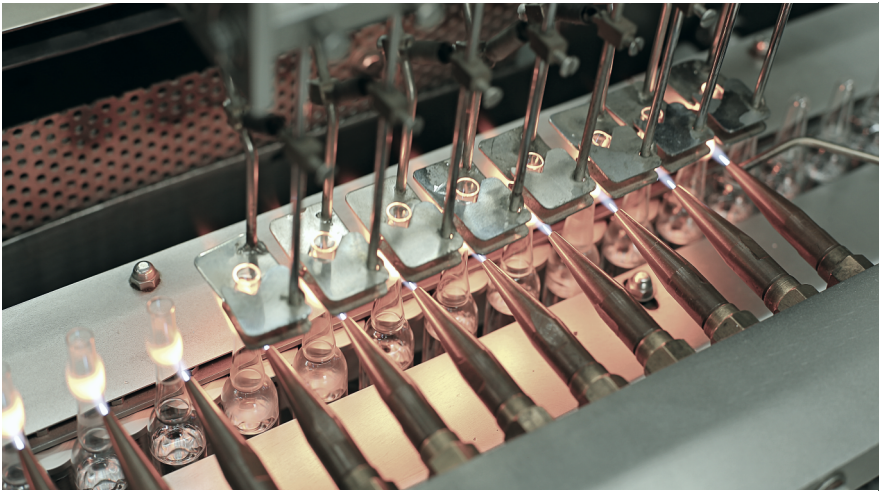
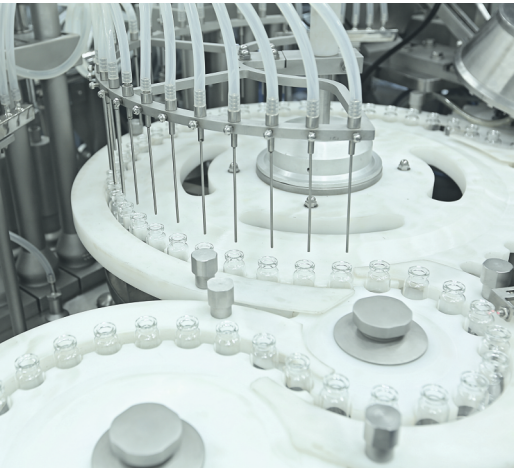
"Delivering Complex Generics with Unparalleled Regulatory Compliance"

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



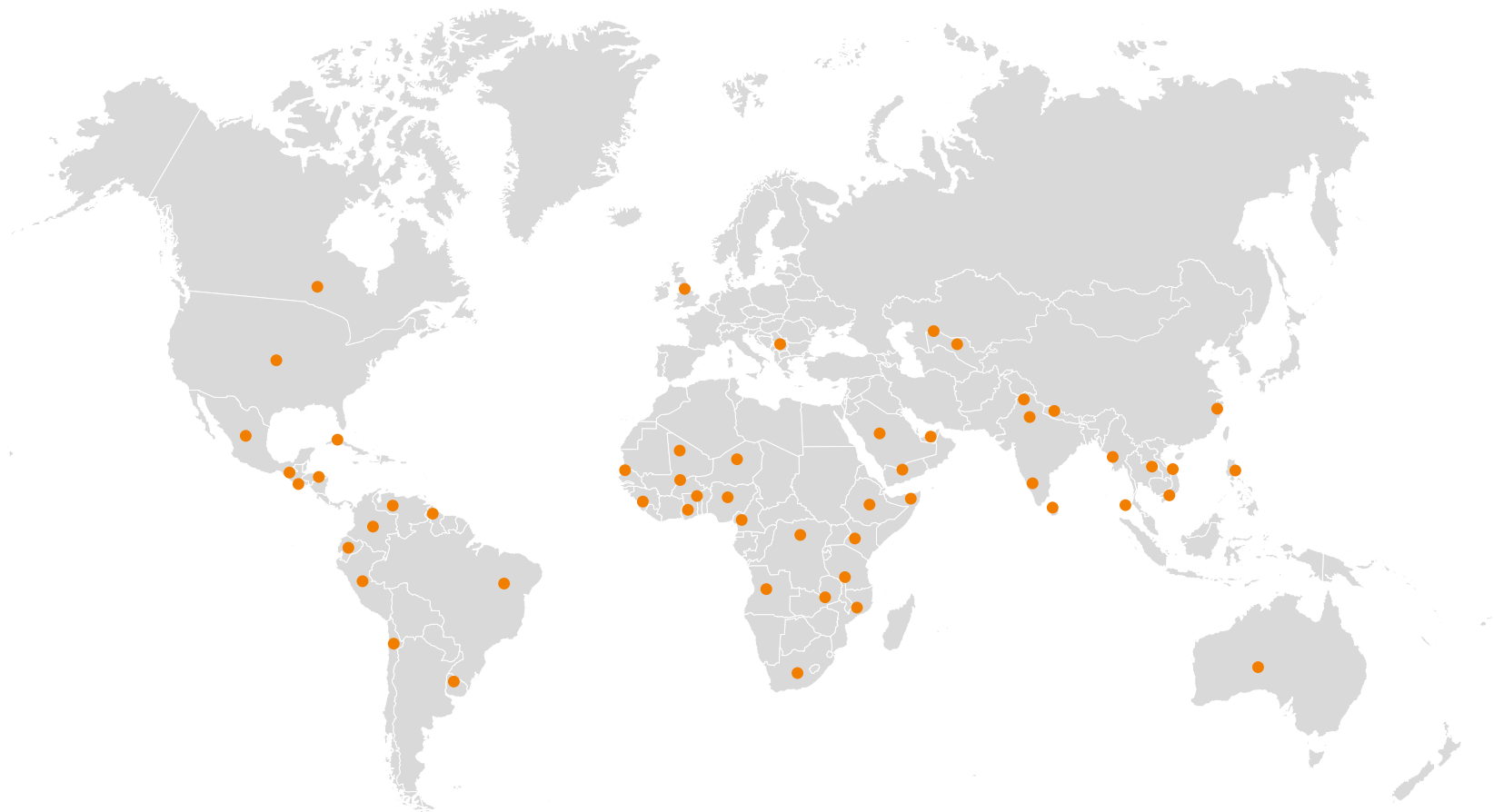
partnering success : our prestigious clients

 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	 COMBODIA	 GUINEA



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Acme Generics

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Immaculé

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