

One Stop Solution
Concept to
Commercialization

ACME GROUP



Acme Formulation



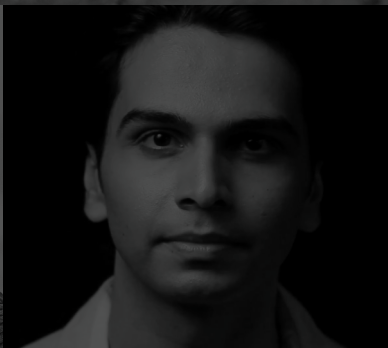
Acme Generics



Immaculé

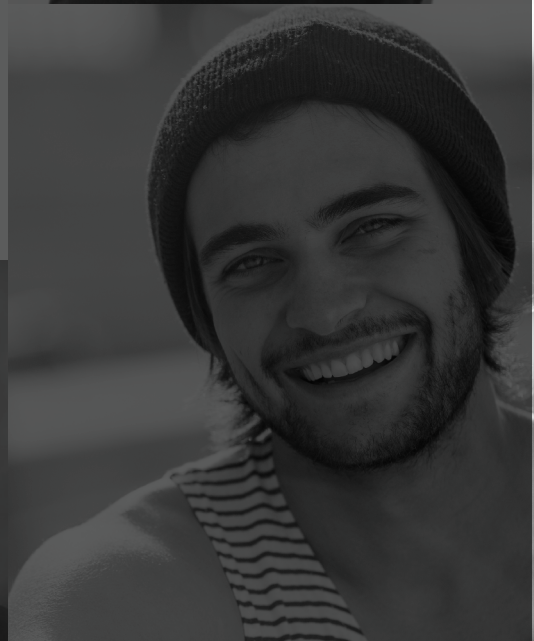


spreading health and happiness





Business 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 1 million sq. ft manufacturing space across Northern India, producing 17 billion tablets, 3 billion capsules, 30 million Liquid vials/ampoules and 12 million Lyophilized vials. The group has also expanded into niche segments of Oral Hormones, both Female Sex Hormones and Levothyroxine along with General Injectables- Liquid and Lyophilized.

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, the group also has approvals across major emerging countries in Asia, Africa, CIS and Latin Countries. With 15 ANDAs approved, 16 ANDAs filed and under review and 18+ ANDA filing target for 2024, as a CDMO we continue our journey towards building a sustainable future.

Acme looks to the future with ever higher goals and ambitions. Its unwavering focus on service and quality is strategically poised to grow even further in the years ahead.



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.





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)

Acme Formulation : (AF)

Acme Generics : (AG)

Immacule Lifesciences : (IM)

2020-22

- USFDA Approval renewed (IM)
- EUGMP Approval renewed (AG/AF/IM)
- ANDA Approvals~10 (IM)
- ANDA Filings~15 (IM)

2023-24

- Sterile Capacity expansion with investment of USD 100 million (Targeted Completion: May 2024)
- General Liquid/Lyophilized~60 million
- Oncology Liquid/Lyophilized~60 million
- Ophthalmics~30 million
- PFS/Cartridge~24 million (IM)
- ANDA Approvals~15 (IM)
- ANDA Filings~16 (IM/AG)
- USFDA Approval (AG)



2025

- USD 200 Million Revenue
- ANDA Filings Target~50+ (AG/AF/IM/IM)



Acme Formulation
Quality Delivered





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

2 Filed and Under Review

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

15 ANDAs Approved, 14 ANDAs under review, 18 + ANDA filing target for 2024

Approvals

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





Immacule Lifesciences

(Targeted Completion : May 2024)

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

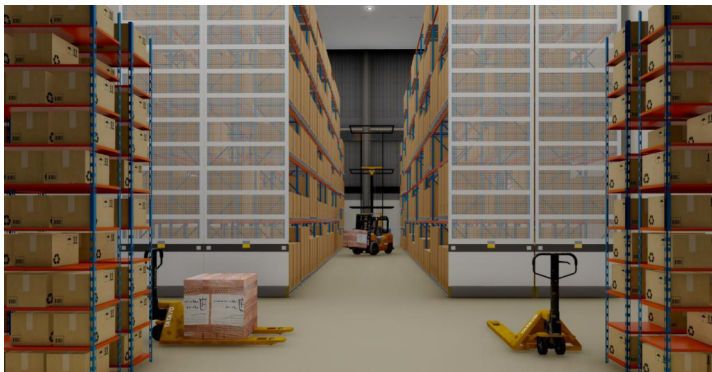
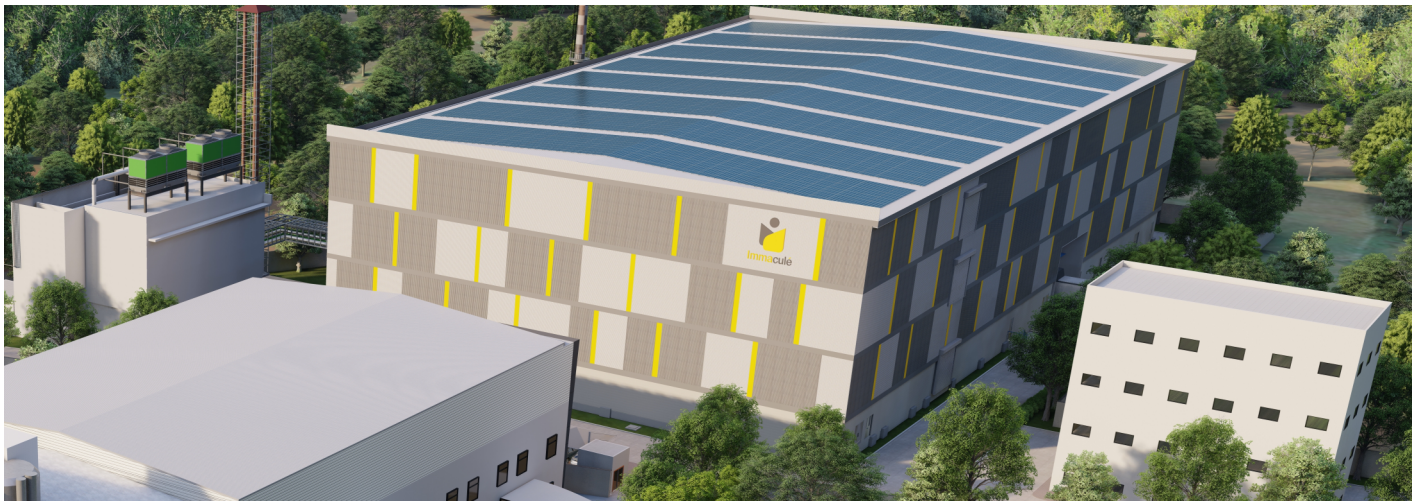
Temperature Sensitive Liposomes

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

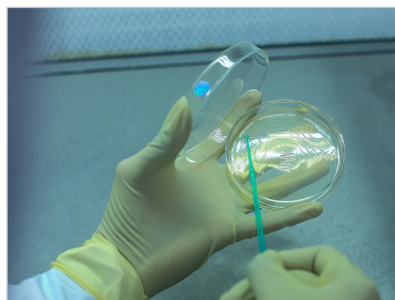
High Shear Granulators

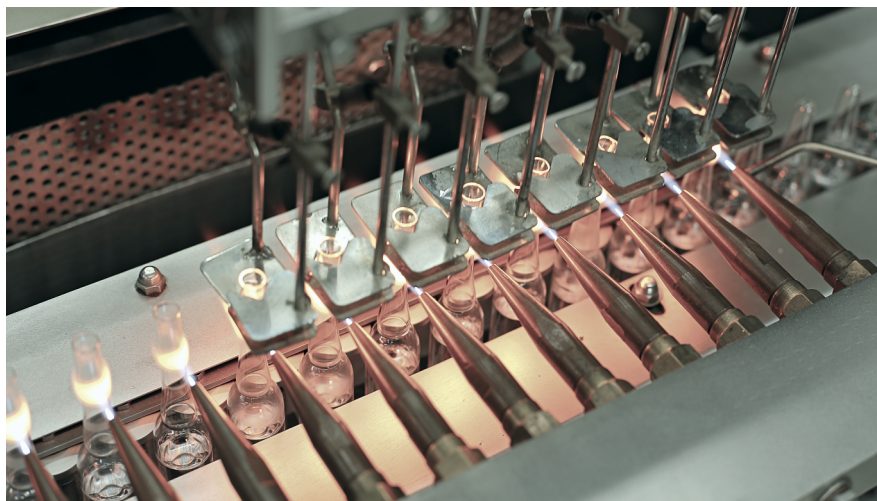
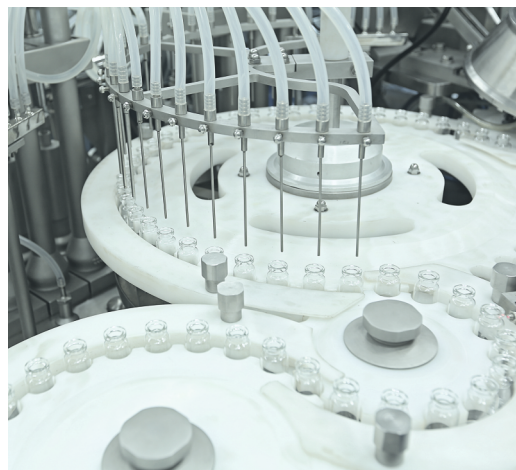
Microfluidizers



accelerating wellness

R & D and Manufacturing facilities





partnering success : our prestigious clients



 FRESENIUS KABI caring for life	 PROVEPHARM ACT TO IMPROVE LIFE	 BAYER	 aspen HOLDINGS	Baxter
 UNFPA	 dkt MOZAMBIQUE	 psi	 IDA FOUNDATION	 SFH
 PrecisionDose	 RKPHARMA INC.	 IVC BRUNEL HEALTHCARE	 accord The Evolution of Generics	 Alembic
 Navinta LLC	 Cipla	 SUN PHARMA	 MACLEODS	 LUPIN
 Mankind	 Strides	 zydus Dedicated To Life		



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

 <p>U.S.</p>	 <p>UK</p>	 <p>HUNGARY</p>	 <p>Australian Government Department of Health and Aged Therapeutic Goods Administration</p> <p>AUSTRALIA</p>	 <p>Health Canada</p> <p>CANADA</p>	 <p>ANVISA</p> <p>BRAZIL</p>	 <p>World Health Organization</p> <p>WHO</p>
 <p>MEXICO</p>	 <p>RUSSIA</p>	 <p>المملكة العربية السعودية South Food & Drug Authority</p> <p>SAUDI ARABIA</p>	 <p>SAHPRA South African Health Products Regulatory Authority</p> <p>SOUTH AFRICA</p>	 <p>Ministry of Health Sultanate of Oman</p> <p>OMAN</p>	 <p>UKRAINE</p>	 <p>MALAYSIA</p>
 <p>COLOMBIA</p>	 <p>THAILAND</p>	 <p>ZIMBABWE</p>	 <p>EFDA FEDERAL ETHIOPIAN DRUGS ADMINISTRATION</p> <p>FMHACA ETHIOPIA</p>	 <p>TFDA TANZANIA FOOD & DRUGS ADMINISTRATION</p> <p>TANZANIA</p>	 <p>PERU</p>	 <p>CHILE</p>
 <p>UGANDA</p>	 <p>VIETNAM</p>	 <p>PHILIPPINES</p>	 <p>KENYA</p>	 <p>DOML Direction de la Pharmacie, du Médicament et des Laboratoires de Contrôle</p> <p>IVORY COAST</p>	 <p>IRAQ</p>	 <p>KAZAKHSTAN</p>
 <p>GHANA</p>	 <p>MALAWI</p>	 <p>NIGERIA</p>	 <p>YEMEN</p>	 <p>SUDAN</p>	 <p>COMBODIA</p>	 <p>GUINEA</p>



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 Thanthewal, 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