

One Stop Solution
Concept to
Commercialization

ACME GROUP



Acme Formulation



Acme Generics



Immaculé



spreading health and hap



piness 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 have expanded 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 38 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)

Acme Formulation : (AF)

Acme Generics : (AG)

Immacule Lifesciences : (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)

2024-25

- 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~38 (IM/AG)
- ANDA Filings~18 (IM/AG)
- ANDA Approval Target 50+ (AG/AF/IM)
- EU GMP Approval renewed (AF/IM)
- Health Canada Approval renewed (AG)



CONTINUOUS
GROWTH



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

1 approved, 1 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

37 approved, 17 under review

Approvals

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





Immaculé 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

Fedagari / Telstar : Autoclave / VHP / Terminal Sterilizer

Bram Cor : Vapor Compression Distiller

DDE : Compounding and Holding Vessels / PUPSIT

WAB : DYNO-MILL

Lighthouse / Bonfiglioli : HSO Analyzer / CCIT / RH

Eurovent Certified AHUs

Swiss Log : Sample Transfer System

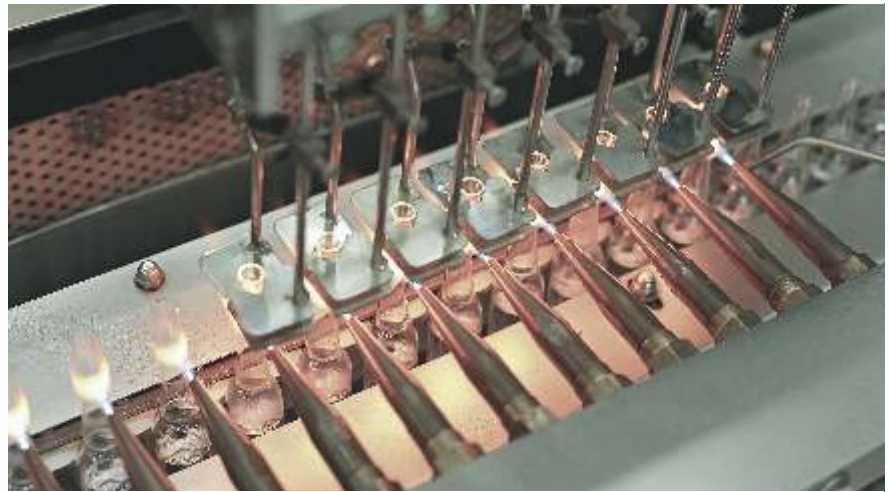
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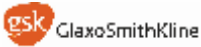
accelerating wellness

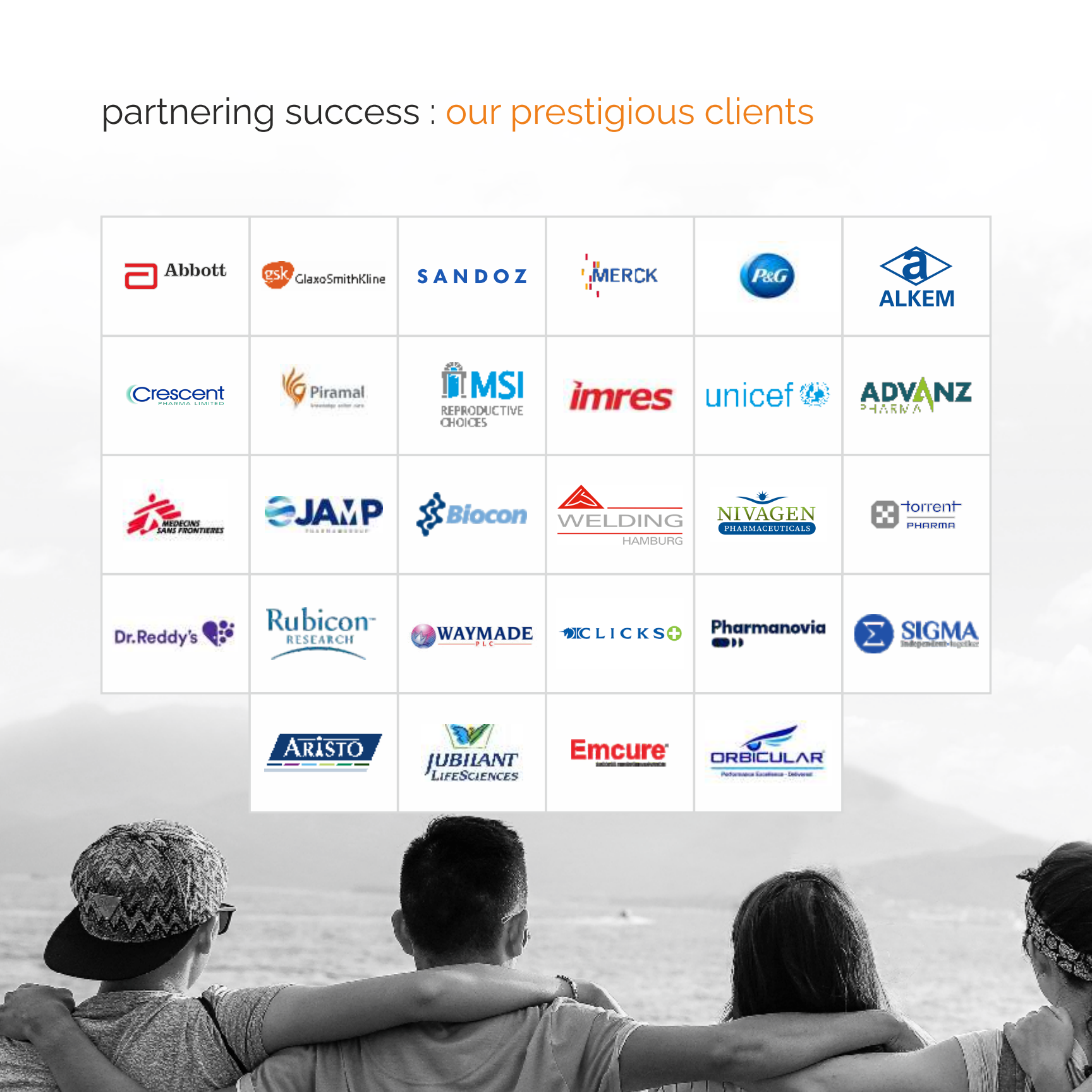
R & D and Manufacturing facilities





partnering success : **our prestigious clients**



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



giant strides towards a global footprint



- **AFRICA:**
Ethiopia, Nigeria, Ghana, Tanzania, Kenya, Uganda, Zambia, Malawi, Sierra Leone, Madagascar, Angola, Zimbabwe, Guinea, Mozambique, Cameroon, Senegal, South Sudan, South Africa, Ivory Coast.
- **ANZ:**
Australia, New Zealand.
- **ASIA:**
Nepal, Sri Lanka, Philippines, Vietnam, Cambodia, Laos, Thailand, Myanmar, Malaysia, Singapore, China, Taiwan.
- **CENTRAL & SOUTH AMERICA**
Brazil, Colombia, Guatemala, Nicaragua, Paraguay, Uruguay, Chile, Costa Rica, Venezuela, Peru, Ecuador, Mexico, Bolivia.

- **CIS & OTHERS:**
Kazakhstan, Uzbekistan, Ukraine, Russia, Georgia.
- **EUROPE:**
United Kingdom, Hungary, Poland, Italy, Netherlands, Portugal, Austria, Czech Republic, Denmark, Germany, Finland, Sweden, Spain, Latvia, Ireland.
- **Middle East:**
UAE, Saudi Arabia, Yemen, Iraq, Oman, Kuwait.
- **North America:**
US, Canada.

accreditations

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



Acme Formulation

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Acme Generics

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