

# Acme Group



Acme Formulation



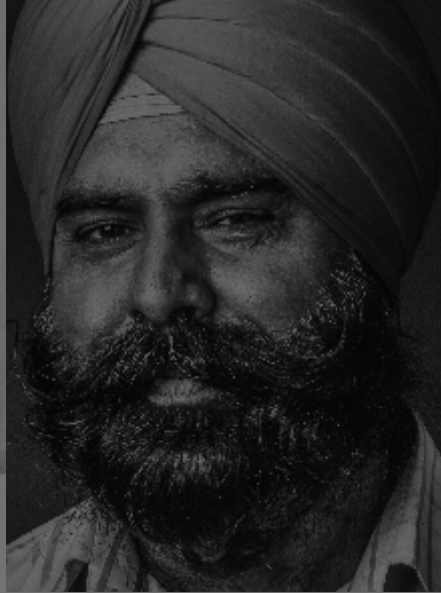
Acme Generics



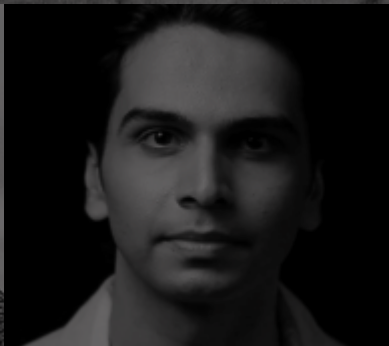
Immaculé



VERITAS  
RESEARCH

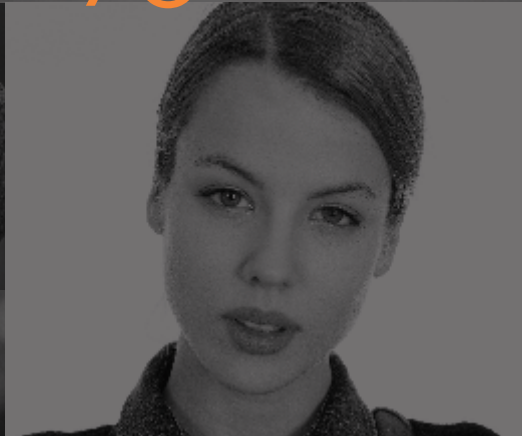


spreading health and hap





appiness across 75+ countries



## legacy of trust

Acme is a leading Contract Development and Manufacturing service provider to the pharmaceutical industry for Oral Solid and Sterile dosage form. Acme began its journey in 2005 and in a decade has transformed into a trusted partner and a complete solution provider. The Group has expanded into niche segments of Oral Hormones, both Sex Hormones and Levothyroxine, along with General Injectables - Liquids and Lyophilized, catering through three state-of-the-art manufacturing facilities.

Today it employs more than 2000 highly-skilled workforce at its facilities which are located in Northern India. The facilities are spread over an area of approx 500,000 sq ft having an annual capacity of 19.5 Billion Tablets, 2.5 Billion Capsules and 42 Million Ampoules / Vials.

In our journey over the past decade we have been audited and approved by various international regulatory agencies including USFDA, UK-MHRA, EU-GMP, ANVISA, PICS, INVIMA, TGA-Australia, Health Canada & WHO-Geneva. Apart from this the Group has approvals across major countries in Asia, Africa, CIS and Latin American Countries. 1<sup>st</sup> ANDA approval was received in August 2019 and it is positioned to register more than 30 ANDA in next 3 years. Acme's OSD site is scheduled to file its first ANDA in Quarter 1 of 2020.



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 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 in excess of USD 150 million, Acme proudly serves more than 25 customers including 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

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First OSD Facility  
Commences Operations  
(AF)

2008

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Hormonal Production  
Facility added  
(AF)

2012

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New Sterile FDF  
Facility added  
(IM)

2014

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New OSD  
Facility added  
(AG)

2015

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WHO Geneva Pre  
Qualification/ INVIMA  
approval received  
(AF)



## 2016

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UKMHRA / ANVISA /  
PICS approval (IM)  
EU-GMP approval (AG)

New R&D Centre at Bangalore  
commences operations

## 2017

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TGA,  
Health Canada  
(AG),(IM)

## 2019

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USFDA Successful PAI (IM)  
First ANDA approved  
2nd ANDA approval &  
5 new ANDA filing in Q4 2019

## 2020

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First US filing &  
USFDA PAI (AG)  
New ~10 ANDA  
filing (IM)

Acme Formulation : (AF)

Acme Generics : (AG)

Immacule Lifesciences : (IM)





## Acme Formulation



Acme Formulation

Oral solid dosage facility  
General and hormonal category

Facility area  
100,000 sq. ft.

Available dosage  
Tablets and capsules

Capacity  
3.5 billion tablets and 0.5 billion capsules per annum

Approvals  
EU-GMP (Hormone Block), WHO-Geneva, Tanzania, INVIMA, Nigeria, Ethiopia Ghana, Kenya, Yemen, Zimbabwe, Vietnam, Philippines, Zambia, Mozambique, Niger, Senegal, Sierra Leone.

## Acme Generics



Acme Generics

Oral solid dosage facility  
General tablets and capsules  
Levothyroxine tablets

Facility area  
300,000 sq. ft.

Available dosage  
Tablets and capsules

Capacity  
6 billion tablets from levothyroxine block  
10 billion tablets and 2 billion capsules from general block

Approvals  
EU-GMP/21 CFR Parts 210 and 211 by UL for OTC products exports to US, TGA Australia and Health Canada  
US ANDA filling in Q1 2020



Immaculé

# Immacule Lifesciences



## New sterile facility

Liquid injection and lyophilized vials

## Facility area

100,000 sq. ft.

## Available dosage

Liquid injections (vials and ampoules) and lyophilized vials

## Capacity

30 million liquid ampoules | vials  
12 million lyophilized vials

## Approvals

USFDA, UK-MHRA, ANVISA, TGA, PICs & INVIMA

# Veritas Research



Veritas Research is a leading Research and Development Company in the Pharma domain. It boasts of a team of over 30 professionals and thought leaders from various Global Pharma & CRO's. With State-of-the-art facilities including regulatory accepted hardware/ software applications, it has various secured networks across locations.

## Generic drug development (US, EU, Lat-AM and others)

- Solid Orals - IR, MR Tablets / Capsules
- Liquid orals - Solutions, Suspensions, Dry Syrups
- Topicals - Ointments/ Creams / Gels
- Ophthalmics – Suspension / Ointments / Solutions
- Parenterals - Liquid Injections – Vials, Ampoules, PFS,

## Innovative Generics [505 (B) (2)]

- Fixed dose combination immediate release tablets/capsules
- Fixed dose combination extended release capsules

## Innovative Drug Delivery Technologies

- Effervescent Formulation (Lubrication optimizations studies)
- Tablet in Tablet Formulation (Compression coating)
- Novel drug delivery systems including Liposomes

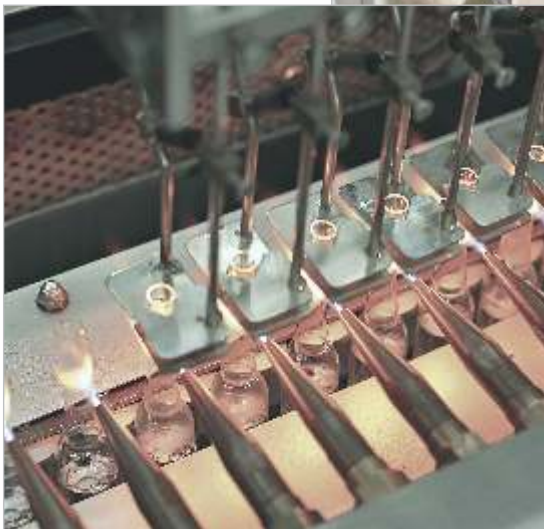
## Dedicated Oncology / High Potency Products Area with Isolators

- Dermatology product development Labs
- Process Development Laboratories
- Process Scale Up Facilities
- Analytical Testing Laboratories
- ICH Stability Chambers
- In-vitro binding

# accelerating wellness

R & D and Manufacturing facilities





# partnering success : our prestigious clients





# accreditations

 <p>U.S.</p>	 <p>UK</p>	 <p>HUNGARY</p>	 <p>Australian Government Department of Health and Ageing Therapeutic Goods Administration</p> <p>AUSTRALIA</p>	 <p>CANADA</p>
 <p>BRAZIL</p>	 <p>WHO</p>	 <p>UKRAINE</p>	 <p>COLOMBIA</p>	 <p>ZIMBABWE</p>
 <p>FMHACA ETHIOPIA</p>	 <p>TANZANIA</p>	 <p>UGANDA</p>	 <p>YEMEN</p>	 <p>GHANA</p>
 <p>PHILIPPINES</p>	 <p>THAILAND</p>	 <p>CHILE</p>	 <p>IVORY COAST</p>	 <p>KENYA</p>



# Products for Regulated Markets:

## Liquid Injections:

Tranexamic Acid Injection ---- Ampoule /  
500mg / 5ml, 1000mg / 10ml Vial

Cyanocobalamin Injection ---- Vial  
1mg / ml - 1ml, 10ml, 30ml

Succinylcholine Chloride Injection ---- Vial  
20mg / ml - 10ml

## Lyophilized Injections:

Clarithromycin for Injection ----- Vial  
500mg

Voriconazole for Injection ----- Vial  
200mg

Colistimethate for Injection ----- Vial  
1 MIU, 2 MIU

Teicoplanin for Injection ----- Vial  
200mg, 400mg

## Hormone Products:

### *Thyroid Portfolio*

Levothyroxine ---- Tablets  
12.5mcg, 25mcg, 50mcg, 75mcg, 88mcg, 100mcg,  
112mcg, 125mcg, 137mcg, 150mcg, 200mcg,  
300mcg

Liothyronine ---- Tablets  
5mcg, 20mcg, 25mcg, 50mcg

Propylthiouracil ---- Tablets  
50mg

Carbimazole ---- Tablets  
5mg, 10mg, 20mg

### *Gynaecological / Female Hormonal Products*

Misoprostol ---- Pills  
200mcg, 25mg

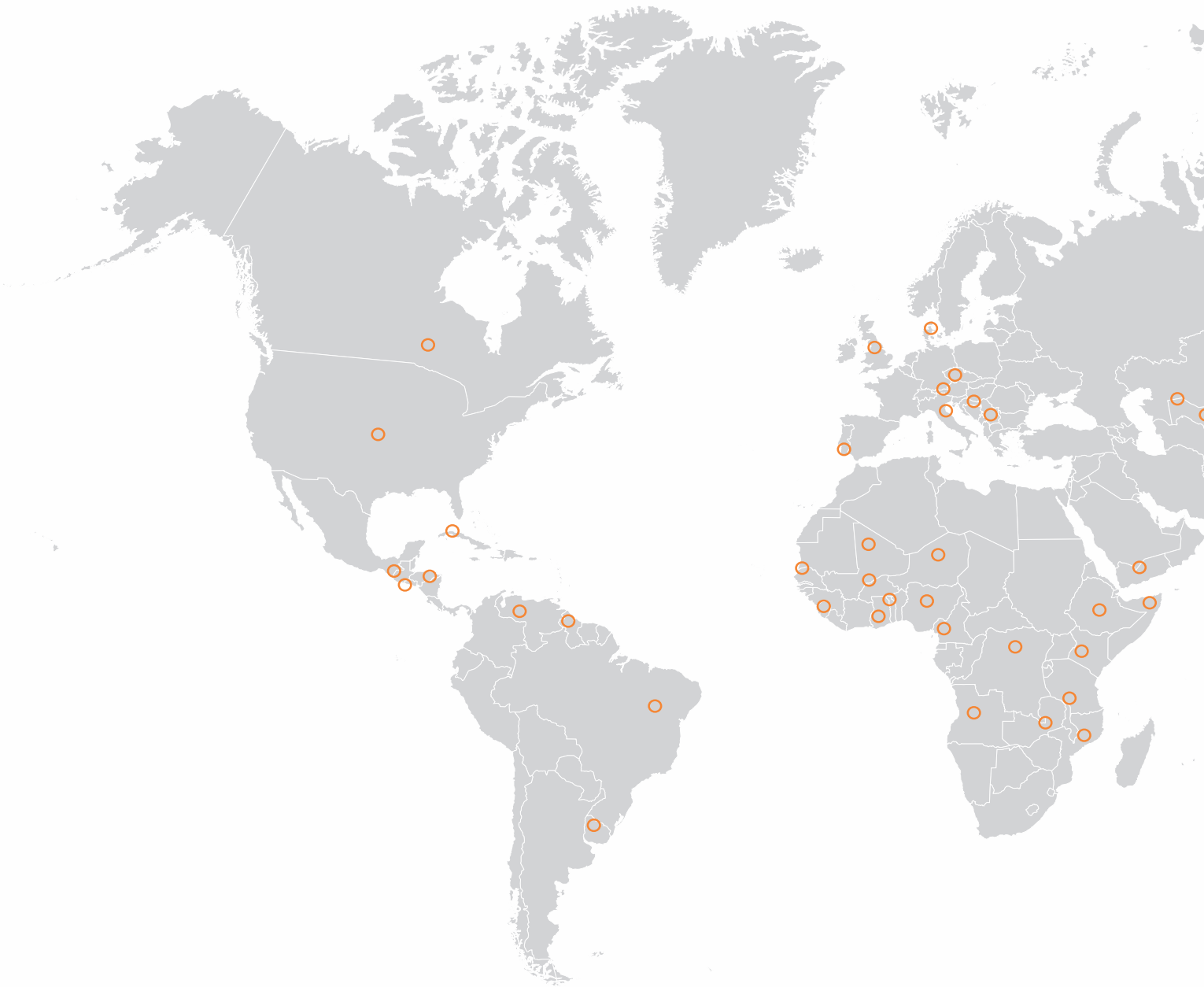
Mifepristone ---- Pills  
200mg

### *Oral Solid Products: (Tablets / Capsules)*

Methocarbamol ---- Tablets  
750mg



giant strides towards a global footprint





#### ASIA

Nepal, Sri Lanka, Philippines, Vietnam,  
Cambodia, Laos, Thailand, Yemen, Myanmar, Malaysia, Singapore

#### AFRICA

Ethiopia, Nigeria, Ghana, Tanzania, Kenya, Uganda, Zambia,  
Malawi, Nigeria, Sierra Leone, Madagascar, Angola, Zimbabwe,  
Mozambique, Cameroon, Senegal, South Sudan

#### NORTH AMERICA

US, Canada

#### EUROPE

United Kingdom, Hungary, Poland, Italy, Netherland,  
Portugal, Austria, Czech Republic, Denmark

#### CIS

Kazakhstan, Uzbekistan, Ukraine

#### SOUTH AMERICA

Brazil, Colombia, Guatemala, Nicaragua, Paraguay,  
Uruguay, Chile, Costa Rica, Venezuela, Peru

#### ANZ

Australia



Acme Formulation

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Acme Generics

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