AURIGENE
PHARMACEUTICAL SERVICES

Dr. Reddy's

CDMO Services

Built on the legacy of accelerating innovation and a vast track record in drug discovery, development, and manufacturing services, we collaborate with our customers to accelerate their molecule journey from lab to market.

- **Process Development**
- **Analytical Method Development and Validation**
- **Process and Powder Safety Assessment**
- **Solid Form Screening and Particle Engineering**
- **Non-GMP Pilot Facility**
- **Intermediates and API Contract Manufacturing in cGMP Facilities**

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URIGENE

Aurigene Pharmaceutical Services

is your CRO/CDMO partner for end-to-end capabilities across drug discovery, development and manufacturing of APIs, Intermediates and formulations. With more than two decades of experience, we offer integrated and standalone services for discovery chemistry, discovery biology, biologics, development and manufacturing services for clinical supplies, regulatory submission batches, and commercial manufacturing.

Why Aurigene CDMO Services?

25+

Years of Expertise

- 400+ projects from more than 100 global customers
- 700+ dedicated scientists
- End-to-end regulatory support

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USFDA approved cGMP facilities

India | UK | Mexico

- 4100+ m^3 capacity
- 1250+ reactors, including 100+ reactors with containment facility
- 5000+ MT of intermediaries manufactured per annum
- 2100+ MT of APIs manufactured per annum

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NCEs commercialized

- 15+ dedicated labs for process development along with analytical center of excellence
- Dedicated production blocks for peptides, continuous manufacturing, steroids, and PEG alcohol and derivatives
- Cryogenic reaction, High Potent and High-pressure reaction capabilities

End-to-end development services

Process development and optimization

Analytical development, method verification and validation

QbD studies and intermediate scale batch

Safety and hazard assessment

Solid form and salt screening

Tech transfer and GMP supplies

Specialized chemistry

- Peptides
- Carbohydrates
- mPEGs

Tech Platforms

- Flow chemistry
- High potent APIs
- Biocatalysis

Contained facilities

- Steroids
- High potent molecules (Cyto and non-cyto)

Scale-up facility

- 3 Kilo labs including a dedicated steroid line for intermediate scale

Phase appropriate development

- Enables faster clinical supplies

End-to-end IP and regulatory support

- Regulatory experience of filing and commercializing in 80+ countries

Drug substance development infrastructure - APIs and Intermediates

15 Process development labs

Scale-up labs: 3-kilo lab facilities

- Hyderabad- 50 and 20L
- Bengaluru- 50, 20, 10, 5L
- Hyderabad, potent lab- 50 and 20L

Peptide lab

Solid-liquid and hybrid phase synthesis

Analytical lab

Equipped with chromatography, characterization, spectroscopy, and thermal analysis

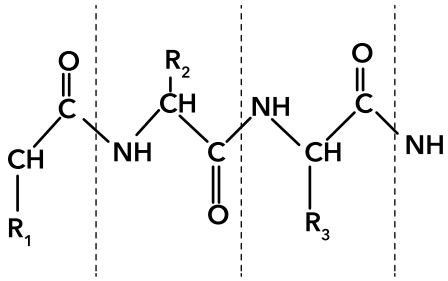
Flow chemistry lab

Equipped with vapourtec, coil reactors, knauer pumps, micro-reactors

High potent lab

Upto 50-gram scale operations of products up to OEL 0.1µg/m³

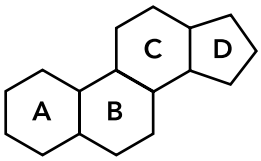
Development and manufacturing of specialized chemistry



Peptide

Integrated solution for complex peptides from discovery to manufacturing

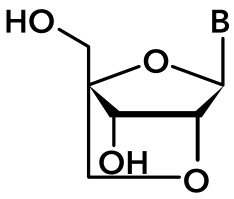
- 10+ years of experience with various class of peptides
- Microwave assisted as well as traditional SPPS
- 5000+ targets synthesized, 10+ clinical peptides



Steroid

4 decades of experience in developing and manufacturing steroids

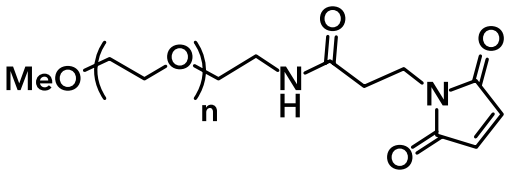
- Reactor volumes from 28L to 12KL
- 15+ steroidal molecule commercially manufactured



Carbohydrate

Technical expertise to handle the structural complexity of all forms of carbohydrates

- Experience with various forms of carbohydrates
- 2 decades of experience
- Reactor volumes from 60 L to 1600 L
- More than 50 intermediates/APIs



mPEG

Ability to develop and manufacture mPEG derivatives for varied applications

- 15+ years experience in mPEG
- Backward integrated to mPEG alcohol
- Technical expertise to meet the most stringent specifications
- 6+ commercialized activated mPEGs for big pharma clients

High potent APIs up to 0.1 µg/m³

Discovery to commercialization

Development facility - Hyderabad

- Can handle OEB 5 category up to 0.1 µg/m³
- Development up to 25 to 50 gms/ batch @ HPAPI lab
- Special equipment: Spray dryer with Isolator and micronisers
- Analytical method development and validation in dedicated AR and D lab

Commercial supplies - Hyderabad and Vizag

- Can handle OEB 5 category up to 0.1 µg/m³ across 3 dedicated GMP sites
- Multiple modules are available: 100 gms to 100 Kilos can be handled in the plant
- Special capability of micronisation and spray drying in Isolator is available to handle 3 to 5 Kgs/ batch
- All manufacturing sites are inspected with FDA and other regulatory bodies
- Dedicated HPAPI QC

Solid form screening and particle engineering lab

Crystallization and risk assessment lab will carry out a comprehensive solid-form screening, crystallization and development of API to meet the desired specifications.

- Salt screening
- Polymorph screening
- Solubility studies
- Crystallization development
- Process analytical technologies (PAT)
- Scale-up studies (mixing, filtration, drying, milling and micronization)
- Particle size distribution
- Spray drying for ASDs
- Diafiltration – TFF, crystallization

Drug Product (DP) Services

- We provide one stop solution for formulations ranging from early stage development to commercial manufacturing.
- We have expertise in developing and manufacturing all major dosage forms including oral solids, soft gelatin capsules, oral liquids, parenteral and topical dosage forms.
- Our cGMP manufacturing facilities are audited by international regulatory agencies including US FDA.

Tox or early phase formulations

- Pre-formulation studies
- Solubility and permeability enhancements
- Aq. and non-aq. solutions and suspensions
- Powder for reconstitution
- Liquid/lyo injections

Clinical formulations → **Commercial supplies**

Development, tech transfer and manufacturing of:

- Oral solids (potent and non-potent)
- Soft gelatin capsules
- Oral liquids
- Parenterals (cyto and non-cyto)
- Topicals (Ointments, creams, gels)

Aurigene offers phase appropriate development and manufacturing services









Our Global Manufacturing Footprint

Drug Substance cGMP Facilities

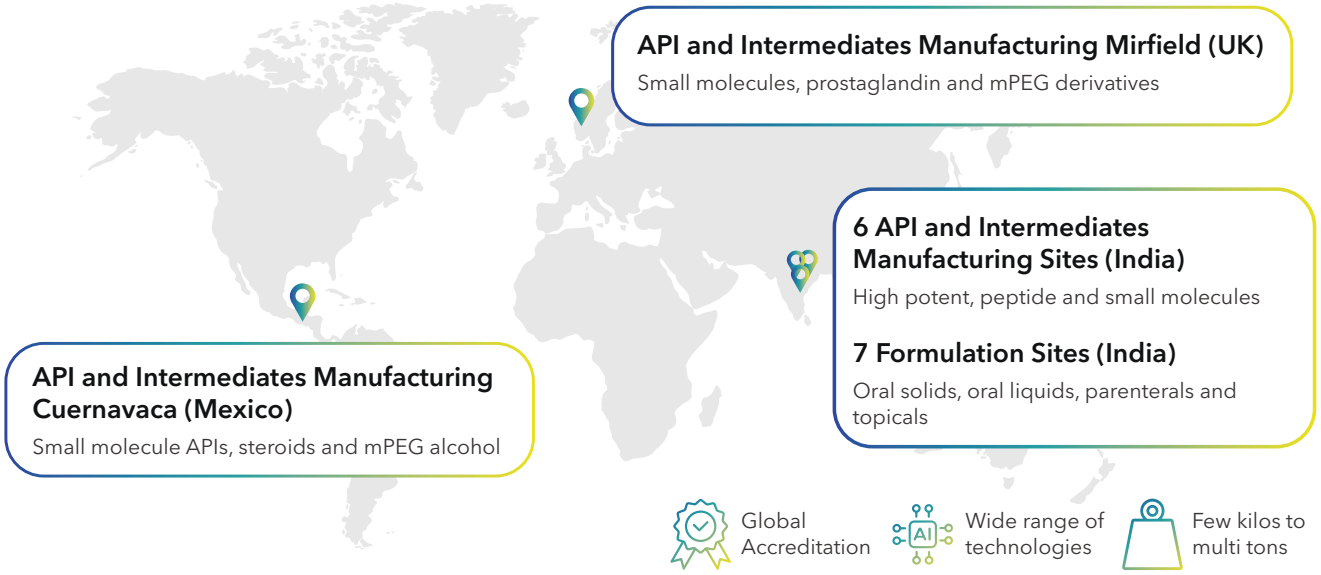
- **CTO-Mexico:** Large-scale small molecule APIs, steroids and mPEG Alcohol
- **CTO-Mirfield:** Small molecule, prostaglandin and mPEG derivatives
- **CTO-1, India:** High potent and small molecule APIs
- **CTO-2, India:** Small molecule APIs and Nutraceuticals
- **CTO-3, India:** Low and medium scale small molecule APIs
- **CTO-5, India:** Large-scale small molecule APIs
- **CTO-6, India:** Small molecule, peptide, spray drying and high potent
- **CTO-SEZ, India:** Small molecule, continuous manufacturing, spray drying and high potent

**CTO - Chemical Technical Operations*

Drug Product cGMP Facilities

- **FTO-2:** Regular OSDs (oral solid dosage forms)
- **FTO-3:** Regular OSDs
- **FTO-7:** Cyto parenterals and cyto and harmonal OSDs
- **FTO-9:** Non- cyto parenterals ophthalmics and BFS
- **FTO-11:** Parenterals cyto and non-cyto
- **FTO-PU1:** Regular OSDs
- **FTO-PU2:** Topicals, soft gelatin, and potent OSDs

**FTO - Formulation Technical Operations*



Accelerating Drug Innovation!

Discovery | Development | Manufacturing

Commitment to Sustainability and Social Responsibility

Driving Public Health, Innovation and Environmental Stewardship

Being committed to environmental stewardship

Making our products accessible and affordable to patients

Contributing to a fairer and more socially inclusive world

Enhancing trust with our stakeholders

Accreditations and awards

Aurigene as a wholly owned subsidiary of Dr. Reddy's Laboratories adopts the ESG goals of our parent company. Dr. Reddy's has been committed to sustainability for over two decades and has been honored with numerous accreditations and awards.

Dow Jones Sustainability Indexes

Retained the position on the DJSI (Dow Jones Sustainability Index)

Greenco Summit 2019

Environment Excellence Award from CII

Bloomberg

First Indian company featured in the Bloomberg Gender-Equality Index (GEI).

2023 ecovadis

Awarded Gold Medal by Ecovadis, a global sustainability ratings agency placing us in the top 5% of companies worldwide

Thank You

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https://www.aurigeneservices.com/

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