



Demystifying Complex Generics...



About us

Omgene Life Sciences Private Limited, the R&D based Biopharmaceutical Research Company, incorporated in March 2011 and is operating for around 13 years in bio pharmaceutical space. Omgene was established by a highly skilled and experienced Technocrat working in pharmaceutical field, Dr. A.L. Prasad (Founder, Promoter and Managing Director), having around 30 years of industrial track-record, is leading the R&D team comprising 100+ highly skilled workforce.

Omgene is a fast-growing Indian Bio-Pharmaceutical company engaged in developing, manufacturing, and marketing of Peptide API, Semi-synthetic API, Synthetic API, Oligonucleotides and Recombinant molecules. We are also involved in formulation development of liquid and lyophilized powder injectables, complex generics and oral peptide delivery to provide critical care in affordable price with high quality medicines.

Around 18 patents are filed, and 100+ API & 395 intermediates were developed since inception.

We have successfully commercialized 19 APIs (17 peptides and 2 semi-synthetic molecules) from our API manufacturing facility (UNIT-I).

Our Mission is to offer critical disease management at a revolutionary price, while show casing Indian capabilities in R&D of Peptides and Niche Generic products. We are also working with Vision to be among the leading players in the field of R&D while contributing towards healthcare at an affordable price.



6000 sq. ft. GMP commercial manufacturing facility (Unit I) established in 2022 for Peptides and Semi-Synthetic APIs.

of the Chemical Synthesis, Formulation

and Analytical Development Laboratories







Key Strengths

The company has consistently demonstrated unfettered imagination and dynamism in meeting all the challenges for complex molecules and our proud strengths are:

- Core leadership team brings 100+ years of combined experience across pharma API R&D and formulation development.
- Have a team of 100+ highly skilled workforce.
- Expertise in development of peptides, semi-synthetic & synthetic APIs and its intermediates.
- Expertise in synthesizing long peptide chains up to 40 amino acid chains.





100+ API/ 395+ intermediates developed since inception and various other APIs are under development.

- Working on development of formulations of complex generics, depot formulations, Oral solid Dosage forms, Oral Peptides delivery, liquid and lyophilised injectables, since 2020.
- Currently 22 molecules across various stages of formulation development.
- Have mg-to-kg scale setup and cleanroom GMP facility for peptide and semi-synthetic API supplies (UNIT-I)

Key Business Drivers

Active pharmaceutical ingredients

- Peptides
- Semi-Synthetics
- Complex Synthetic Molecules
- Recombinant Peptides
- Oligonucleotides

Formulations

- Lyophilized Injectables
- Stable Peptide Injectable solutions
- •Microspheres / NDDS (Leuprolide Lyophilized microspheres, Octreotide lyophilized microspheres)
- Oral Peptide delivery (Semaglutide tablets, Linaclotide Capsules)

Patents

- 1. Synthetic process of Romidepsin (WO2016084100A3; IN3757/MUM/2014)
- 2. Methods of making Carfilzomib (WO2016069479 A1; S201462068928P)
- 3. Process to prepare Anidula fungin (WO2016056022 A3; EP3464319A4; N3175/MUM/2014)
- 4. Process to prepare Micafungin sodium (WO2016056023 A3; EP3226885A4; IN3174/MUM/2014)
- 5. Preparation of Sugammadex Sodium. (US10494450; IN2089/MUM/2015; JP2018518589A; EP3303413A4)
- 6. Preparation of Vortioxetine (IN20182100185)
- 7. Preparation of Lifitegrast (IN20182100185)
- 8. Process to prepare Midostaurin (IN201821017401)
- 9. Process to prepare Deutetrabenazine (PCT/IN2019/050070; IN201821003879)
- 10. Process to prepare Degarelix Acetate (WO/2019/202613; IN2019050319)
- 11. Method for preparing GLP-1 analogue by solid-phase peptide synthesis (IN201921036266)
- 12. Anovel process for preparation of Remdesivir (IN202021051952)
- 13. Process of making Mebendazole form A (Granted Patent No: 416049, 201721019939)
- 14. A process for the preparation of parathyroid hormone analog (IN202121019400)
- 15. Anovel process for synthesis of carbetocin octapeptide (IN202121003027)
- 16. An improved process for the preparation of saroglitazar calcium (IN202221019842)
- 17. The process for preparation of bempedoic acid and their novel intermediates (IN202121054268)
- 18. Intermediates and processes to prepare Micafungin (WO2016056023A2)

• Committed to deliver quality products to our customers, meeting remarkably their expectations in terms of specification, delivery, technical support, regulatory compliance and competitiveness.

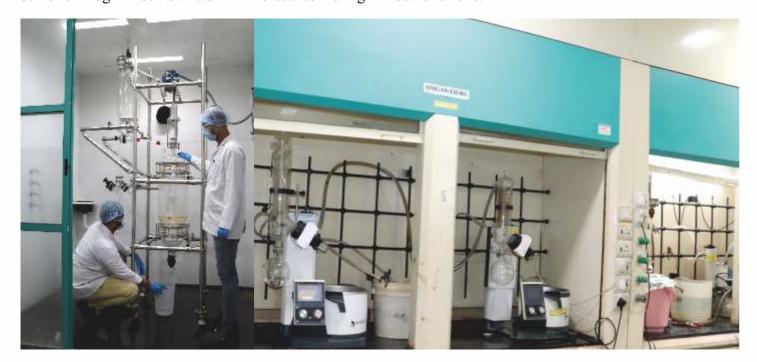
- Combination of excellent technical competency and our experienced team of experts, yield high quality products.
- Technology transfer teams are well placed for Quality outputs.

Quality

• Sophisticated Instruments are available to provide all essential stage-wise support to clients.

Generic API R&D Facility

- Qualified Scientists and Team Leaders to support development of API, Intermediates, and Impurities.
- Well equipped high-end infrastructure supports for purification and controlling Quality of APIs.
- Strong capabilities in development and transfer of technology to manufacture Peptides APIs from gram scale to kilogram scale and small molecules from gram scale to tons.



Formulation R&D facility for complex generics

Omgene offers formulation development services across diverse dosage forms with Qualified Scientists, Team Leaders, and facility to support development of:

- Complex generic and Depot formulations.
- Oral peptide delivery.
- Liquid Injectables and Lyophilized formulations.



GMP manufacturing units

UNIT-I:

- UNIT-I manufacturing facility at Makarpura, Vadodara for commercial peptide and semi-synthetic APIs is in function since 2022.
- FDA Approval is available for commercial supply of Leuprolide Acetate USP, Degarelix Acetate, Terlipressin Acetate, Octreotide Acetate EP/USP, Cetrorelix Acetate, Glatiramer, Ganirelix Acetate, Triptorelin Pamoate, Triptorelin Acetate, Micafungin, Anidulafungin, Desmopressin Acetate USP/EP/IP, Atosiban Acetate IP, Exenatide USP, Teriparatide USP/EP/IP, Vasopressin USP/IP, Bivalirudin, Buserelin BP/IP and Goserelin BP.



UNIT-II: Ongoing Expansion plans

• 12500 sq.mtr of land acquired in Dahej SEZ for commercial API manufacturing, EC approval obtained, and civil work started for infrastructure development.



UNIT-III: Ongoing Expansion plans

• 22,594 sq.mtr. of land acquired in Gavasad Vadodara, NA, GPCB, Town planning completed for Formulation manufacturing facility.









