OmGene

Life Sciences Pvt. Ltd.

Demystifying Complex Generics...

to build healthier world...

Reach Us

333-334, GIDC Makarpura, Vadodara, Pin: 390 010, Gujarat, India
info@omgene.com
www.omgene.com

ABOUT US

Omgene Life Sciences Private Limited is a Research and Development (R&D) based organization, which was incorporated in March 2011 and has been operating for around 12 years in bio-pharmaceutical research. The R&D team is led by an experienced technocrat, Dr. A.L. Prasad, who has around 30 years of Industrial track-record and has a team of around 100 persons.

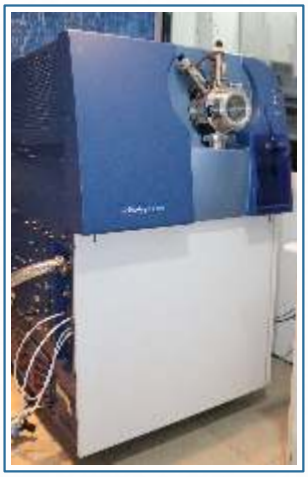
At Omgene, we are involved in niche product development research for preparation of Peptide Active Pharmaceutical Ingredients (API), semi-Synthetic API, Synthetic API, Recombinant molecules and formulation development of complex generics for critical care like treatment of cancer, infertility, obesity, diabetes & different renal problems. Around 18 patents are filed and 100+ API & 395 intermediates were developed since inception and are successfully commercialized.

We have successfully commercialized 10 APIs (8 peptides and 2 semi-synthetic molecules) from our present In-house GMP manufacturing facility (GMP-1).

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.

> *Omgene has 20,000 sq. ft. of state of art DSIR approved R&D Facility comprising of Chemical Synthesis, Formulation and Analytical Development Laboratories*

> *6000 sq. ft. GMP commercial manufacturing facility established in existing facility for Peptides and Semi-Synthetic APIs.*



KEY STRENGTHS

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

- Working for development of advanced complex generics core leadership team brings +100 years of combined experience across pharma API R&D and, formulation development.
- Have a team of 90+ highly skilled workforce; 51 Masters and 5 PhD holders.
- Expertise in development of peptides, semi-synthetic & synthetic APIs and its intermediates.
- Expertise in synthesizing long peptide chains – up to 40 amino acid chains.

CAPABILITIES

- **100 API/ 395 intermediates developed since inception and 13 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.
- Have mg-to-kg scale setup and cleanroom area for small volume API quantity supplies (GMP1).

KEY BUSINESS DRIVERS

API

• Peptides • Semi-Synthetics • Complex Synthetic Molecules • Steroids
• Fermentation and Recombinant Peptides • Sugar derivatives

Formulations

• Lyophilized Injectables • Stable Peptide Injectable solution
• Microspheres / NDDS • Oral Peptide delivery

PATENTS

1. Synthetic process of Romidepsin (WO2016084100 A3; IN3757/MUM/2014)
2. Methods of making Carfilzomib (WO2016069479 A1; S201462068928P)
3. Process to prepare Anidulafungin (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. A novel 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. A novel 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)

QUALITY

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

•Combination of better technical competency and our experienced team of experts, yield high quality products.

• Technology transfer teams are well placed for Quality outputs.

• 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.

• Nice 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 unit

• GMP 1 commercial manufacturing facility: Cleanroom facility within existing premises for supply of low volume API quantities.

• Small scale manufacturing of some peptide and semi-synthetic APIs.

• FDA Approval is available for commercial supply of Leuprolide Acetate USP, Degarelix Acetate, Terlipressin Acetate, Octreotide Acetate USP, Cetrorelix Acetate, Glatiramer, Ganirelix Acetate, Triptorelin Acetate, Micafungin, Anidulafungin, Desmopressin Acetate, Atosiban Acetate, Exenatide, Teriparatide, Vasopressin.

Future Expansion plans

• 12500 sq.mtr of Land identified in Dahej SEZ , provisional order issued, procurement formality to be completed and company to apply for accelerated EC approval (GMP2).

• 22,594sq.mtr. of land acquired in Vadodara, NA, GPCB, Town planning completed and to start the civil work soon (GMP3).