

www.omgene.com



to build healthier world...

About us

Omgene Life Sciences Private Limited, the R&D based Biopharmaceutical Research Company, incorporated in March 2011 and is operating in bio pharmaceutical space since it's foundation. 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 110+ 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 23 APIs (21 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.

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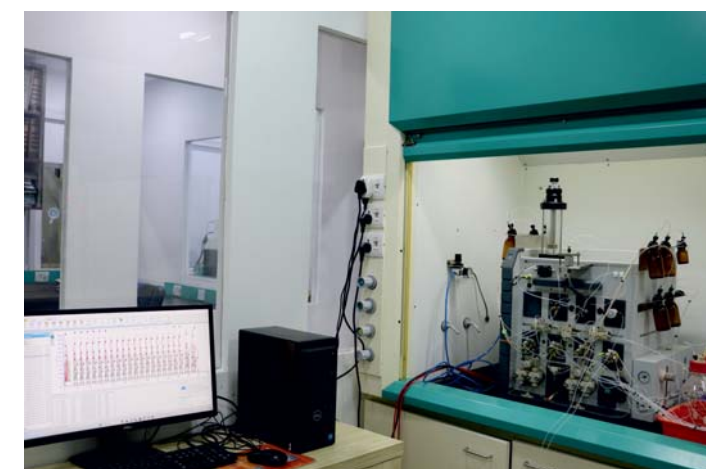
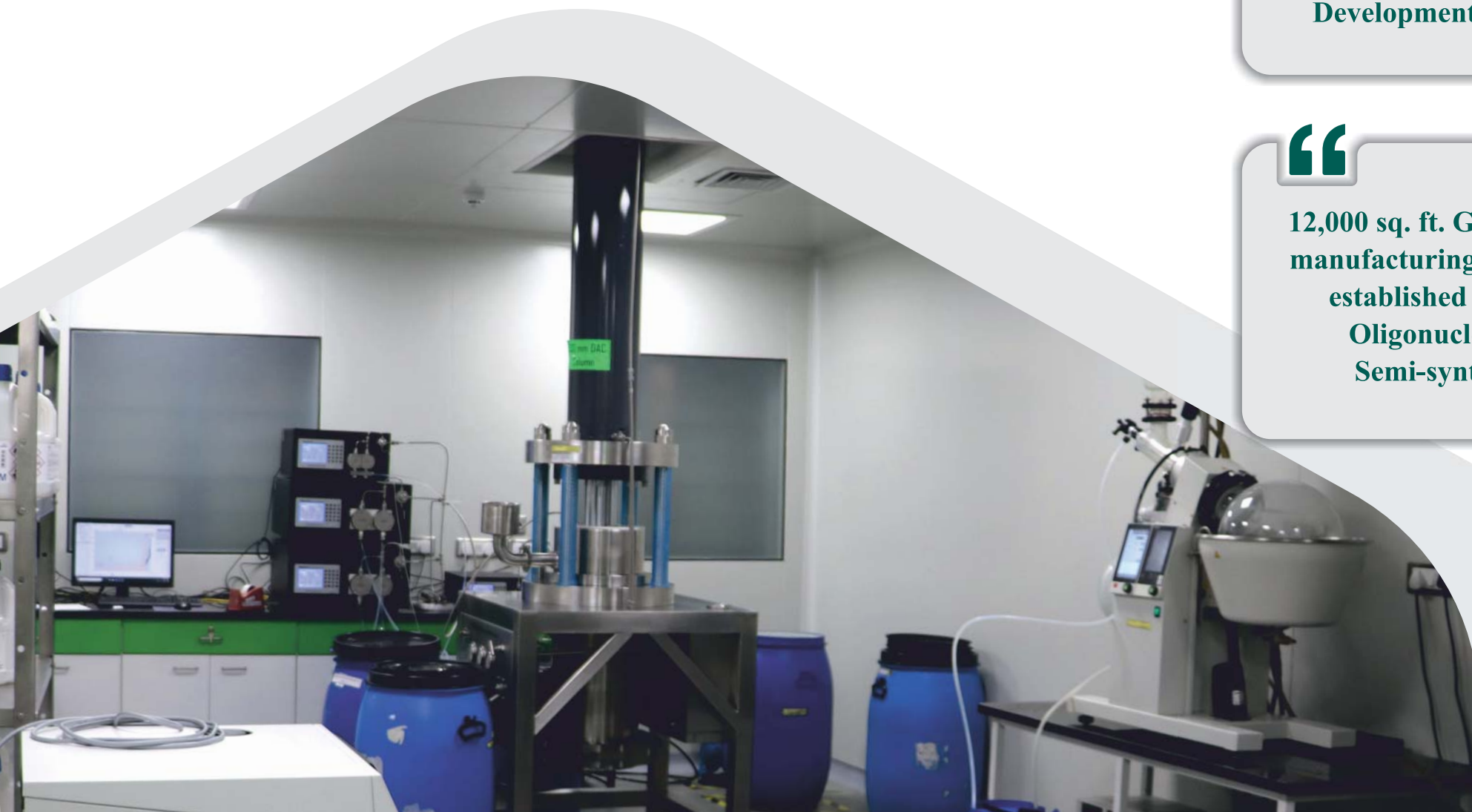
Omgene has 20,000 sq. ft. state of art DSIR approved R&D Facility comprising of the Chemical Synthesis, Formulation and Analytical Development Laboratories

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12,000 sq. ft. GMP commercial manufacturing facility (Unit I) established for Peptides, Oligonucleotides and Semi-synthetic APIs

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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 110+ highly skilled workforce.
- Expertise in development of peptides, Oligonucleotides, 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 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 lyophilized injectables, since 2020.
- Currently 22 molecules across various stages of formulation development.
- Have mg-to-kg scale setup and clean room GMP facility for peptide, Oligonucleotides and semi-synthetic API supplies (UNIT-I).

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)
18. Intermediates and processes to prepare Micafungin (WO2016056023A2)

Key Business Drivers

ACTIVE PHARMACEUTICAL INGREDIENTS

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

FORMULATIONS

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



Quality

- 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.
- 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, Oligonucleotides and Semi-synthetic 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 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, Ganirelix acetate, Terlipressin Acetate, Octreotide Acetate EP/USP, Cetrorelix Acetate, Glatiramer, Ganirelix Acetate, Goserelin acetate USP/BP, Triptorelin Pamoate USP, Triptorelin Acetate, Micafungin USP, Anidulafungin, Desmopressin Acetate USP/EP/IP, Atosiban Acetate IP, Exenatide USP, Teriparatide USP/EP/IP, Vasopressin USP/IP, Bivalirudin, Buserelin BP/IP, Atosiban IP, Somatostatin EP, Eptifibatide and Carbetocin.



UNIT-II:

Ongoing Expansion plans

- 12500 sq.mtr of Land acquired in Dahej SEZ for commercial API manufacturing, acquired approvals and civil work completed for infrastructure development.



UNIT-III:

Ongoing Expansion plans

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

