

Small batches, powerful medicines: Recipharm expands high potency offering

- *Recipharm extends its high potency capabilities at Leganés, Spain, to GMP pilot scale.*
- *The same equipment can produce both clinical and small-scale commercial batches, for compounds up to OEB 5, avoiding a further technology transfer.*
- *The offering builds on around 250 tonnes per year of commercial high potency capacity on the same site.*

Recipharm, a leading global contract development and manufacturing organisation (CDMO), today announced that it has extended its high potency offering at its Leganés site in Spain to GMP pilot scale, giving customers a single high containment route from development to commercial supply.

Greg Behar, CEO at Recipharm, said: "High potency compounds are a fast-growing part of the industry's pipeline, from oncology to rare diseases, and with new high containment facilities taking more than two years to come online, specialist capacity is struggling to keep pace. We are moving ahead of that demand. At Leganés, customers can bring their high potency programmes to one partner, from the first pilot batches all the way to commercial supply, helping them get these medicines to patients sooner."

Customers increasingly want smaller, more flexible capacity that can follow a product from the clinic to its first commercial batches. At Leganés, the same pilot scale equipment can produce both clinical and small-scale commercial batches for high potency oral solid dose (OSD) products. When larger volumes are needed, products scale up to the site's commercial lines without moving to another site, reducing risk at scale-up and supporting dossier filings.

The new pilot scale suite is built around dry granulation, with high potency tableting and coating in the same containment area. Dry granulation is particularly well suited to high potency drugs: it preserves API stability without moisture or heat, improves containment and operator safety, makes efficient use of scarce or high value materials, and is solvent free. The suite is supported by Recipharm's proprietary ReciPredict™ platform, which uses material science, modelling and simulation to optimise formulation and process design, reducing API consumption by up to 70% during development and scale-up, an important saving where API is scarce and costly.

The new capabilities build on Leganés' commercial high potency operations, which handle compounds up to OEB 5 with a capacity of around 250 tonnes per year. The site also manufactures and packages conventional and film coated tablets and capsules, with full serialisation and in-house quality control laboratories. It is approved by the US FDA, AEMPS (EU GMP) and Japan's PMDA.

Recipharm's high potency network extends beyond Leganés. Across its sites, Recipharm also offers OEB 3 and OEB 4 OSD manufacturing, as well as OEB 4 sterile fill and finish of pre-filled syringes, liquid vials and pre-filled cartridges, supporting advanced injectable products.

With Leganés at the heart of its high potency network, Recipharm is equipped to take customers' most demanding high potency programmes from development to market.

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For more information

About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) employing over 4,500 employees worldwide. Recipharm provides manufacturing services of pharmaceuticals in various dosage forms, including sterile fill & finish, oral solid dosage and biologics; clinical trial material development and manufacturing services; and pharmaceutical product development. Its Recipharm Advanced Bio segment works with customers to develop and commercialise advanced therapy medicinal products (ATMPs): pre-clinical to clinical development, commercial development and manufacture for new biological modalities, encompassing technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, nucleic acid-based mRNA and plasmid DNA production.

Recipharm manufactures several hundred different products to customers ranging from big pharma to smaller research and development companies. Headquartered in Switzerland, it operates development and manufacturing facilities in France, Germany, India, Italy, Portugal, Spain, Sweden and the US.

For more information about Recipharm, please visit www.recipharm.com and www.recipharm-ab.com

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