

CDMO

CLINICAL DEVELOPMENT & CGMP MANUFACTURING SERVICES

Eurofins CDMO is an FDA-approved contract development and manufacturing organization (CDMO) focused on API and Drug Product development and manufacturing services for complex small molecules. IND enabling development of poorly soluble compounds and clinical manufacturing strategies are a core strength at Eurofins CDMO. Our Drug Product team works closely with clients to match project objectives and science to deliver the right formulation on time.

OUR SERVICES

Pre-Formulation

A wide range of IND enabling drug product services are provided at Eurofins CDMO. Our PhD scientists have extensive experience in material characterization, analytical chemistry and strategies for developing poorly soluble compounds. Our Pre-Formulation laboratory is fitted with a suite of specialized equipment focused on solubility, absorption and In-Vitro/In-Vivo correlation studies.



Our capabilities include:

- Solubility & Absorption Studies Pion Inc. Suite of Equipment (μDISS, μFLUX, Macro DISS)
- Salt and Polymorph Screening; Excipient selection and screening
- Prototype Stability ICH Stability (Temperature, Humidity and Photo)
- GLP Formulation Support Formulation Preparation and Analysis
- Stability Indicating Assay and Cleaning Method Development
- Physical Characterization

Formulation Development

Our Formulation Scientists and Process Engineers are experts in poorly soluble compounds and high containment operations. Our formulation development lab and pilot plant suites are specifically designed for high containment and outfitted with cGMP matching technologies. We follow a data driven approach to clinical formulation development.



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cGMP Manufacturing Services

Our Operations team has extensive experience in cGMP clinical drug product manufacturing. Our state-of-the-art facilities and cGMP compliant systems are specifically designed for quick-to-clinic operations. Eurofins CDMO's team of Engineers, Technology Transfer specialists, and Scientists specialize in process transfer and scale-up strategies, providing a seamless transition of programs from development through cGMP manufacturing.

cGMP Manufacturing Services Capabilities

- High Containment Operations
- cGMP Clinical Manufacturing (Oral Dosage Forms)
- Nanomilling Wet Milling
- Micronization Jet Milling
- API-in-Capsule
- Encapsulation and Tableting
- Liquid and Suspensions
- · Amorphous Dispersions
- cGMP Stability and Drug Product Release
- cGMP Storage and Distribution

Formulation Services Capabilities

- Particle Size Reduction Wet Nanomilling, Jet Mill Micronization
- Method Development and Validation
- GLP Formulation Support
- Liquid and Suspensions
- Excipient Compatibility
- Poorly Soluble Compounds
- Amorphous Dispersions
- Prototype Stability



CDMO

Formulation/Production

Encapsulating Tableting Automated Encapsulator IMA Zanasi 40E Single Station Tablet Press Globe Pharma MTCM-IA Rolary Tablet Press Korsch XLI.00 Quantos Automated Capsule Filler Metter Toledo 0 Profill Capsule Filler Torpak Profiller Departed Profiler Profill Capsule Filler Torpak Profiller Departed Profiler Roller Compactor Alexandenwerk WP120 Mixing Slending WP120 WAXIBERD & 1-2-3 PIL07 Top Down Muser Cole-Parmer S000-0-01 Hornogenizer Silverson LSMA Comil GlobePharma 197 Particle Size Nano (Wet Mill) WAB Group DynoMill Multitable Privated Profiler Jer Mill Fluid Energy Ox and ox 10 Spray Orger Buchi & GEA B. 290 & Mobile Minor Zetapotential Mabrem Panalytical Zetasizer Nano 25 Coargule Bander Schaefer Technologies LabTop Bander Characterization Province Profiler <	Equipment Description	Manufacture	Model
Single Station Tablet Press Globe Pharma MTCM-14 Rotary Tablet Press Korsch ALL00 Quantos Automated Capsule Filler Torpak ProFiller 1100 Frofill Capsule Filler Torpak ProFiller 1100 Cranulating Weber Webre Roller Compactor Allexanderwerk Webre Weblender Globe Pharma MAXIBLEND & 1-2-3 PlL01 Top Down Mixer Cole-Parmer 50000-01 Homogenizer Globe Pharma 1900 Comil Globe Pharma 1907 Particle Size Webres Dynomill Multilab Jet Mill Fluid Energy Dynomill Multilab Jet Mill Fluid Energy On and 101 Zetapotential Makern Panalytical 2etasizer Nano 25 Engrap Controlled Release Buchi & GEA B.290 & Mobile Minto Part Coeter O'Hara Technologies Mal Casquelle Bander Shaefer Technologies Mal Elva Experiment PharmaTest PT-11100 Bulk & Tap Density Tester Pha	Encapsulating/Tableting ————————————————————————————————————		
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Friability Test PharmaTest PTF 100 Miscellaneous & Support Equipment Induction Sealer Enercon LM5070-01 Pouch Sealer Accu-Seal 675 Weight Sorter CI Precision SP-B40 Metal Detector Loma Systems IQ4 Deduster CapPlus TD-400 Upcoming in 2022 Fluid Bed Granulation/Drying Vector VFC Lab 3XL	Bulk & Tap Density Tester	PharmaTest	PT-TD300
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Upcoming in 2022 Fluid Bed Granulation/Drying Vector VFC Lab 3XL	Metal Detector	Loma Systems	IQ4
Fluid Bed Granulation/Drying Vector VFC Lab 3XL	Deduster	CapPlus	TD-400
Fluid Bed Granulation/Drying Vector VFC Lab 3XL	Upcoming in 2022		
Wet Granulation Vector GMXB-Lab Pilot	Fluid Bed Granulation/Drying	Vector	VFC Lab 3XL
	Wet Granulation	Vector	GMXB-Lab Pilot

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