eurofins | 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

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Formulation/Production

Equipment Description	Manufacture	Model
Encapsulating/Tableting		
Automated Encapsulator	IMA	Zanasi 40E
Single Station Tablet Press	Globe Pharma	MTCM-I
Rotary Tablet Press	Korsch	XL100
Quantos Automated Capsule Filler	Mettler Toledo	Q2
Profill Capsule Filler	Torpak	ProFiller 1100
Granulating		
Roller Compactor	Alexanderwerk	WP120
Mixing/Blending		
V-Blender	GlobePharma	MAXIBLEND & 1-2-3 PILOT
Top Down Mixer	Cole-Parmer	50006-01
Homogenizer	Silverson	L5MA
Comil	GlobePharma	197
Particle Size		
Nano (Wet Mill)	WAB Group	DynoMill Multilab
Jet Mill	Fluid Energy	00 and 0101
Spray Dryer	Buchi & GEA	B-290 & Mobile Minor
Zetapotential	Malvern Panalytical	Zetasizer Nano-ZS
Coating/Controlled Release		
Pan Coater	O'Hara Technologies	M10
Capsule Bander	Schaefer Technologies	LabTop Bander
Characterization		
Viscometer	Brookfield	LVDV2T
Bulk & Tap Density Tester	PharmaTest	PT-TD300
Hardness Tester	PharmaTest	PTB111EP
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
Wet Granulation	Vector	GMXB-Lab Pilot

Contact Us

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