eurofins

CDMO

SOLID STATE RESEARCH & DEVELOPMENT SERVICES

💡 WHO WE ARE

With more than 15 years of experience in physicochemical characterization of solid state APIs, advanced intermediates as well as screening for different API solid forms, our team of scientists at Eurofins CDMO provide quality-by-design approach for small molecule APIs at different phases of pharmaceutical development. Our SSRD Services are integrated within API development programs as well as within the Finished Dosage Forms (FDF) services or can be offered as a stand-alone service.
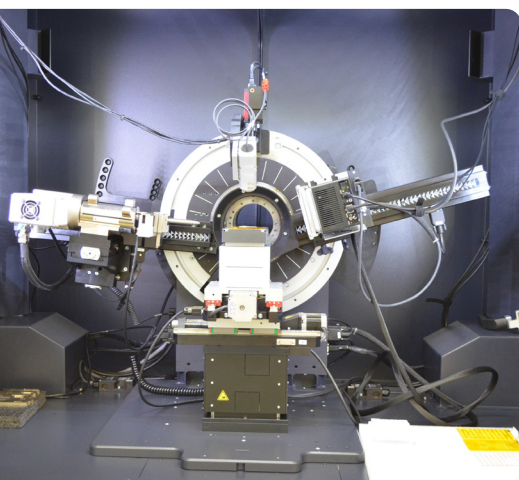
💊 SERVICES

Physicochemical Characterization

A thorough characterization of the physical and chemical properties of the API is a regulatory requirement and a vital step in drug development. Our state-of-the-art instrumentation combined with the expertise of our highly qualified scientists provides a thorough understanding of physicochemical characteristics of the API as well as advanced intermediates.

Powder X-Ray Diffraction, Bruker, D8 Discover

Our complete physicochemical characterization of the APIs include:
- Powder X-Ray Diffraction (PXRD)
- Particle Size Distribution (PSD)
- Dynamic Vapor Sorption (DVS)
- Differential Scanning Calorimetry (DSC)
- Thermogravimetric Analysis (TGA)
- Loss on Drying (LOD)
- Refractive Index Measurement (RI)
- Scanning Electron Microscopy (SEM)
- Energy Dispersive X-Ray Spectroscopy (EDS)
- Attenuated Total Reflection IR Spectroscopy (ATR-IR)
- Raman Fiber-Optic Spectroscopy
- Nuclear Magnetic Resonance (NMR)
- Polarized Light Microscopy (PLM)
- Solubility

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Polymorph Landscape Screening

The discovery of API polymorphism at all stages is considered highly significant not only for API scientific advancement but also for NDA filing and your IP strategy. Through our polymorph landscape screening services, we investigate isolation and crystallization of the API in a number of solvents with different properties and under a variety of conditions to identify and characterize new solid forms (polymorph, hydrate, solvate).

High-Throughput Screening, Unchained Labs

Utilizing High-Throughput Screening (HTS) technologies, our routine screening requires minimum amount of API while performing a large number of crystallization experiments resulting in a significant reduction in cost. Our routine polymorph screening employs several crystallization techniques including:

- Slurry
- Cooling
- Anti-solvent
- Evaporation
- Grinding
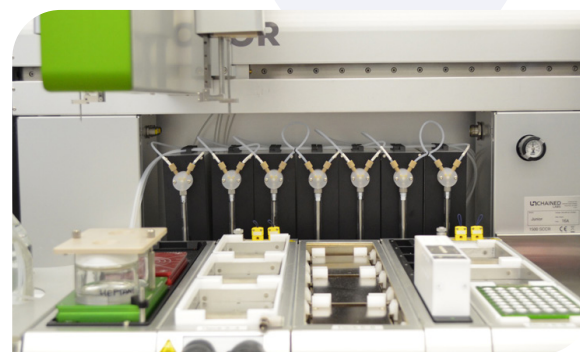
Salt & Co-Crystal Screening

Salt and co-crystal screening are reliable solutions in modern drug development to address some undesirable properties such as low solubility, chemical instability and high hygroscopicity in APIs. Using High-Throughput Screening (HTS) technologies, we investigate formation of salts or co-crystals with pharmaceutically acceptable salt and co-formers in different solvent mixtures. This screening approach provides us with a quick identification of lead candidates which then will be prepared for complete characterization.
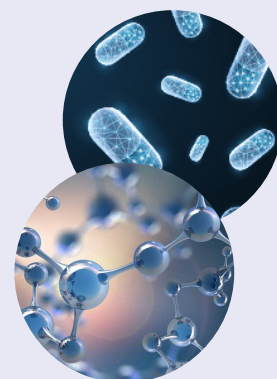
Solubility & Intrinsic Dissolution Screening

Starting materials, intermediates and API's solubility are essential information required to optimize different steps in a manufacturing process. Utilizing high-throughput robotic technology and in-house analytical capabilities, we offer fast and accurate solubility screenings in a large number of solvents while using minimum quantity of material and solvents.

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Chiral Resolution

Diastereomeric crystallization is a chiral resolution technique based on differences that diastereomers or diastereomeric salts of enantionmers exhibit in their physicochemical properties such as different properties. Utilizing High-Throughput Screening (HTS) technologies, we are able to identify these differences in a variety of different solvents and choose best solvent candidates to develop our diastereomeric crystallization. The crystallization process itself is monitored by in-line monitoring technologies (e.g. FBRM) through the development stage to maximize selectivity and yield.

Crystallization Engineering

Taking a quality-by-design approach, we offer knowledge-based crystallization process development to achieve robust and scalable crystallizations that yield reproducible high quality solid. A thorough understanding of the solid form accompanied with solubility data is the base of our crystallization process development.

Using our in-house state-of-the-art instrumentation, we collect all of the crucial solubility data (e.g. solubility, cloud curves, metastable zone width) and monitor crystallization process in real time (e.g. FBRM) as well as offline (e.g. PXRD, PSD).

A fast and efficient knowledge transfer between our solid state and process development scientists ensures a polished crystallization process that is focused on:
- solid form control
- chemical purity and residual solvents
- particle size distribution control
- efficiency and yield

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Equipment Description	Manufacture	Model
Screening for Discovery		
High Throughput Screening	Unchained Labs	Freeslate Junior
Characterization		
DVS (Dynamic Vapor Sorption)	Surface Measurement Solutions	DVS Resolution
DSC (Differential Scanning Calorimetry)	TA Instruments	Q200
TGA (Therogravimetric Analysis)	TA Instruments	Q200
LOD (Loss on Drying)	Mettler Toledo	-
NMR (Nuclear Magnetic Resonance)	Bruker	AVI 300
Particle Size Distribution	Malvern Panalytical	Mastersizer 3000
Refractive Index Measurement	Mettler Toledo	Excellence R4
Attenuated Total Reflection IR Spectroscopy	Thermoscientific	Nicolet iS5
Raman Fiber-Optic Spectroscopy	B&W Tek	BWS465
Powder X-Ray Diffraction	Bruker	D8 Discover
Powder X-Ray Diffraction	Bruker	D2 Phaser
Microscopy		
SEM (Scanning Electron Microscopy)/ EDS (Energy Dispersive X-Ray Spectroscopy)	Thermoscientific	Phenom ProX
Polarized Light Microscopy	Motic	BA310
Hot Stage Microscopy	Mettler Toledo	Hot Stage System HS82
Crystal Engineering & Optimization		
Solubility Measurement	Technobis	Crystal16
FBRM (Focused Beam Reflectance Measurement)	Mettler Toledo	ParticleTrack G400

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