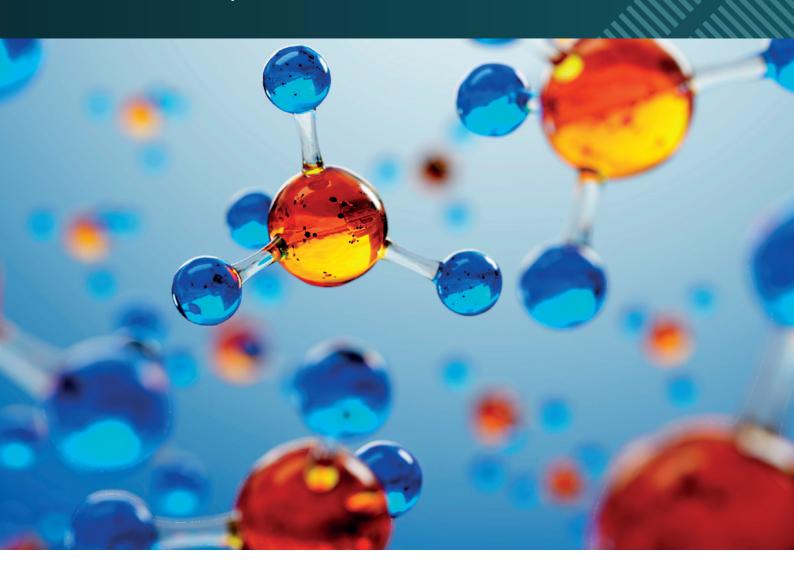


Small Molecule Pharmaceuticals

Toolkit for the characterization of small molecule pharmaceuticals



Early phase discovery and development Preclinical development Clinical & Scale-up Manufacturing **Process optimization** 0 QA/QC 0 **Process development** Target ID Hit-to-lead: Lead Hit ID & validation 🧶 & validation optimization Formulation development **Formulation optimization** 0 **Post-market extensions Instruments** PEAQ-ITC, Morphologi 4(-ID) Mastersizer 3000+ WAVEsystem, Zetasizer Empyrean **Aeris** Epsilon 4 **Spraytec Creoptix GCI** MicroCal Advance X-ray diffraction X-ray Automated Image Laser diffraction X-ray fluorescence Laser diffraction Laser diffraction technology technology (development) diffraction (QC) Analysis Dynamic light (aerosols) (in process) Grating-Coupled Isothermal scattering (Morphologically-Interferometry Titration (Discovery, QC) Directed Raman Spectroscopy) (Discovery) Calorimetry (Discovery) Measure binding Measure particle Detect crystal Measure component Measure component Measure Measure Measure Detect Detect crystal Detect crystal Measure particle Measure aerosol and droplet Measure particle Identify elements to: crystal kinetics Thermodynamics size distribution structures to: structures in structures to specific particle specific particle size size distributions particle size size distributions in order to: size distributions of particle size Meet USP <232>, of molecular and concentration structures non-ambient size and shape and shape distributions distributions of distributions powders, slurries and assess solid of powders and Measure Optimize <735> and ICH Compare device and interactions of micro- and to screen conditions to: form for: distributions of of powders and slurries to: powders and of powders. suspensions in-line Q3D for detection binding affinity solid form formulation performance nano-suspensions for solid slurries and at-line and on-line for: powders to: suspensions to: suspensions to: Measure binding Assess Quality Assess of elemental as part of in vitro Suitable for Detect to assess form and its suspensions affinity stability of assurance Assess filterability Assess in vitro filterability of Assess impurities bioequivalence assessments Quality control biophysical contaminants stability stability of: for: dissolution solid form of reaction slurries bioequivalence reaction slurries Quality control Understand how droplet and Quickly screen for Quality assurance screening Target assays rate Quality and in depth Characterize Assess flowability Assess dissolution Assess trace elements aerosol particle size change Process control control characterization Lead compounds amorphous and packing rate flowability and Assess during device actuation Detect residual Process optimization of molecular form stability of Quality density of powders packing density Assess stability Understand the impact Drug delivery catalyst interactions of powders suspensions systems Detect process of suspensions of formulation changes Screen for from hit to lead induced attrition on device performance • Detect foreign toxic and wear Aid device selection particles elements High sensitivity • 96-well plate • Size range 0.5 µm • Size range 0.01 μm – 3500 μm • Size range 0.1 μm – 2000 μm Size range Highly customizable: Turnkey Detection of • Size range 0.1 µm $(k off 10 s^{-1})$ configuration solution for: – 1300 µm elements from – 2500 µm • Size: 0.3 nm Multiple X-ray wavelengths Precise dispersion control Rapid data acquisition Fluorine to Fast analysis • 2°C - 80°C – 10 µm Structure Precise dispersion (10 KHz) Configurable to • Multiple detector options and configurations Wet and dry accessories Americium. determination control measure powders. • 2 × 96/384-• 10 µg min • Zeta potential: Droplet size evolution Multiple sample mount options • Dynamic imaging accessory including ICH suspensions and well plate sample mass 3.8 nm - 100 µm Phase Wet and dry during actuation Q3D classes 1, · High sensitivity and throughput emulsions configuration identification dispersion • 370 µL sample • Minimum volume Automated device actuation 2A, 2B and 3 • ATEX 0, 1, 2, 20, 21 Phase Crude samples Ontional Raman volume • Size: 3 uL Easy synchronization • LLD 1 ppm – 100% and 22 compliant quantification spectrometer • Up to 42 tests **PLATINUM** of device actuation · Zeta potential: Automated clean per 24Hr and data acquisition 20 µL and sterilize inplace capability N/A N/A USP <729> USP <941> USP <941> USP <776>, <787>, USP <429>, <729> USP <232>, <233>, ISO 13320:2009 ISO 13320:2009 <788>, <1787> ISO 22412:2017 ICH Q6A ATEX 0, 1, 2, 20, ICH Q6A ICH Q6A ICH Q6A <735> ISO 13779-3 ISO 13779-3 ISO 13322-1:2004 ISO 13320:2009 ICH Q3D 21 and 22

Smart Manager - technology suite for telemetry and remote monitoring

OmniTrust – common software for the regulated environment

21 CFR Part 11 compliant



About Malvern Panalytical

Malvern Panalytical is a global leader in the analytics of material and life sciences. We unleash the power of small things to make big things happen for our customers.

Our vision is to make the world cleaner, healthier, and more productive.

We partner with our customers to make their solutions possible through the power of precision measurements, our expertise, trusted data, and insights.

Our people are partners in discovery. We collaborate with our customers and with each other to discover new possibilities and achieve breakthroughs.

Our culture is a healthy, high-performance culture shaped by our values: Own it, Aim High and Be True.

We're committed to Net Zero in our own operations by 2030 and in our total value chain by 2040.

With over 2300 employees across the globe, we are part of Spectris plc, the world-leading precision measurement group.

Malvern Panalytical. We're big on small™

Malvern Panalytical provides the global training, service and support you need to continuously drive your analytical processes at the highest level. We help you increase the return on your investment, and ensure that as your analytical requirements grow, we're there to support you.

Our worldwide team of specialists adds value to your business processes by ensuring applications expertise, rapid response, and maximum instrument uptime.

- Proactive local and remote support
- Full and flexible range of service agreements
- Compliance and validation support
- Onsite or classroom-based training courses
- e-Learning training courses and web seminars
- Digital services, including MyStore and My Customer Support Portal
- Sample analysis, method development, and applications consultancy



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