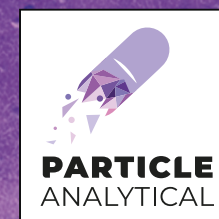


ANALYTICAL TECHNIQUE	INSTRUMENT	SPECIFICATION	APPLICATION
<b>Laser diffraction</b>	Malvern Mastersizer 2000 and 3000 with dry and wet dispersion module	Mastersizer 2000: 0.02-2000 $\mu\text{m}$ Mastersizer 3000: 0.01-3500 $\mu\text{m}$	Control of particles during manufacturing and final product quality/performance. Particle size and volume.
	Sympatec with VIBRI dry dispersion module	Particle size distribution (PSD) in the range: 0.5-10000 $\mu\text{m}$ (Ph. Eur. 2.9.31)	Detection of batch-to-batch variations and agglomeration.
<b>Optical Microscopy</b>	Malvern Panalytical Morphology G3	Magnification and specifications related to the sample size. (Ph. Eur. 2.9.37)	Provides verification and complementary information of laser diffraction results.
<b>Particle Counting</b>	Particle Measuring System APSS-2000	Particle count, size and volume distribution by light obscuration. Range: 2-125 $\mu\text{m}$ (Ph. Eur. 2.9.19)	Evaluation of the particle count for suspensions with a low content of particles - or if the total number of particles is of interest, e.g. injectables. Evaluation of particulate contamination.
<b>Raman microscopy (non-GMP)</b>	Renishaw InVia	Raman spectral resolution 0.3-1 $\text{cm}^{-1}$ . Particle size determination down to 1 $\mu\text{m}$ .	Spatial distribution of API in the excipient's matrix. Identification of different species via unique Raman spectra. Reverse engineering, compatibility, and stability studies.
<b>Scanning Electron Microscopy (SEM) (non-GMP)</b>	Zeiss Sigma 500	Size range is 0.1 $\mu\text{m}$ to a few mm (Ph. Eur. 2.9.52)	Provides complementary information for particle size distribution. Evaluation of product surface properties.
<b>Specific surface area by gas adsorption (BET)</b>	Micromeritics Gemini VII	Specific surface area ( $\text{m}^2/\text{g}$ ), volume and size and distribution of nanopores (Ph. Eur. 2.9.26 II)	Provides insight into surface properties, porosity, and surface changes due to crystallization of amorphous solid particles.
<b>Thermo-gravimetric Analysis (TGA)</b>	Mettler Toledo TGA 2	Weight loss upon heating. Measuring range 25°C to 1100°C. (Ph. Eur. 2.2.34)	Determination of residual water, solvent content, oxidative stability, decomposition, dehydration/desolvation kinetics and stoichiometry of hydrate/solvate.
<b>Ultraviolet-visible spectroscopy (UV-Vis) (non-GMP)</b>	Vankel VK7000 /Versa Fiber optics	UV spectrum of compound in solution, from 200 nm to 800 nm. (Ph. Eur. 2.2.25)	Concentration measurements.
<b>X-ray Powder Diffraction (XRPD)</b>	PANalytical X'Pert3 Powder XRD	X-ray diffraction pattern at angles between 3-150 $^{\circ}2\theta$ (Ph. Eur. 2.9.33)	Identification and quantification of crystalline and non-crystalline (i.e. amorphous) polymorphs. Determination of crystallinity percentage & impurity detection.
	Empyrean XRD with climate chamber, micro-CT & Bragg-Brentano optical module	X-ray diffraction analysis at modified humidity and temperature  3D imaging of sample, displaying internal sample structure	<i>In situ</i> observation of temperature- and humidity induced polymorphic transition.
		Transmission/reflection 2D-XRD	Monitoring of coating thickness, voids, binding surfaces and internal structures.

TECHNICAL SHEET



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IN-HOUSE EQUIPMENT

ANALYTICAL TECHNIQUE	INSTRUMENT	SPECIFICATION	APPLICATION
<b>Air Jet Sieve</b>	Hosokawa Alpine e200 LS	Range: 20 µm to 4 mm (Ph. Eur. 2.9.38)	Particle size distribution of dry, powdery materials.
<b>Air permeability</b>	Blaine Air Permeameter	Specific surface area on micronized products (Ph. Eur. 2.9.14)	Evaluation of surface area accessible to water at time zero.
<b>Ball mill</b>	Retsch MM400	Particle size reduction	Provides insight for better and consistent control of particle size reduction and consequent sample preparation.
<b>Bulk and tapped density</b>	Pharmatest PT-TD	Ability to settle, Hausnerindex, Cohesiveness (Ph. Eur. 2.2.42)	Evaluation of behaviour during manufacturing, e.g. compressibility and powder flowability.
<b>Differential Scanning Calorimetry (DSC)</b>	TA DSC 2500 Mettler Toledo DSC823e	Detection of energetic changes during heating and cooling. Measuring range -65°C to 725°C. Measuring range: -85°C to 700°C (Ph. Eur. 2.2.34)	Measures thermal transitions in a broad range of materials including polymers, pharmaceuticals, organic and inorganic materials. Modulated DSC can also be used to resolve complex thermal events.
<b>Dissolution and IDR tester (non-GMP)</b>	Vankel	Dissolution rate in selected media at temperatures 25°C to 50°C.	Evaluation of different crystal forms and particle characteristic, with regard to dissolution behavior. Useful in process control and in evaluation of bioavailability.
<b>Dynamic light scattering (DLS)</b>	Malvern Zetasizer Ultra & Malvern Zetasizer ULTRA/PRO incl. zetapotential	Particles with a diameter in the range 0.3 nm to 10 µm	Apparent sizes – including determination of agglomeration in solutions of proteins/ biomolecules.
<b>Dynamic Vapor Sorption (DVS)</b>	SMS Advantage 1 Dynamic Vapor Sorption (DVS) TA Discovery SA	Sorption isotherm at relative humidity from 0-98%. Temperature range 25°C to 85°C, with imaging option. (Ph. Eur. 2.9.39)	Evaluation of hygroscopicity, amorphous content determination and defining specifications for sample storage. This can be performed with water and organic solvents. Crystalline phase changes and hydrate formation.
<b>Flowability with angle of repose</b>	Copley scientific flowability tester - BEP	Flow rate (Ph. Eur. 2.9.16)	Evaluation and insight into powder flow behavior for manufacturing and optimization of manufacturing processes.
<b>Fourier Transform Infrared Spectroscopy (FTIR)</b>	Shimadzu IRTracer-100 FTIR with SPECAC Golden Gate ATR unit	Infrared spectra at wavenumbers between 7800 and 350 cm <sup>-1</sup> (Ph. Eur. 2.2.24)	Identification of API and impurities, percent crystallinity, polymorphic forms and salt formation.
<b>Helium pycnometry (non-GMP)</b>	Accupyc 1330 from Micromeritics	Density, g/cm <sup>3</sup>	Evaluation of behaviour during manufacturing, quality control and examining the final state of a product.
<b>Hot Stage Microscopy</b>	Línkam FTIR600	Microscope images upon heating. Temperature range 25°C to 375°C and humidity control. (5-90%RH).	Visualization of solid-state changes as a function of time or temperature. Useful for polymorph screening.

