

Solutions for the
pharmaceutical industry

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Don't worry,
be compliant

Anton Paar's portfolio for the pharmaceutical industry covers a wide range of your measurement needs and allows you to be fully compliant at the same time. Samples such as gels, creams, infusions, APIs, blood samples, essential oils, proteins, and polymers can be investigated by measuring various parameters such as density, viscosity, refractive index, optical rotation, particle size, turbidity, and many more.

Anton Paar's instruments can be easily combined to create multiparameter measurement systems. Our solutions support you in the laboratory as well as inline and at-line, meeting your requirements from R&D to quality control.



Anton Paar's Pharma Qualification Packages

Anton Paar's instruments comply with the methods stated in US Pharmacopeia (USP), European Pharmacopoeia (Ph.Eur.), and other Pharmacopoeias to ensure easy method validation.

Anton Paar offers two Pharma Qualification Packages for different levels of regulations: PQP and PQP-S(mart). They both cover Anton Paar's 6Q model which includes:



ISO 9001:2015

The backbone of Anton Paar's qualification documentation



Requalification

An instrument qualification is not a one-time event. Depending on the reason for the requalification (e.g. yearly requalification, change of location, software update, etc.) and on your needs a customized document is created based on the initial instrument qualification (PQP/PQP-S).

PQP-S(mart)

Ideal if you have to follow GAMP 5 and GMP but do not have to be compliant with 21 CFR Part 11, also including: Risk Analysis, Standard Operating Procedure (SOP) as a word file.

PQP

Covers the complete instrument-specific pharma qualification procedure according to the USP <1058> 4Q model, also including: Risk Analysis, Deviation List, Traceability Matrix, reports for every qualification step, 21 CFR Part 11 Check List to fulfill all requirements of FDA 21 CFR Part 11. Standard Operating Procedure (SOP) as a word file that can be used as the basis for your internal instrument SOP.

Instrument Qualification

- PQP
- PQP-S
- Requalifications
- According to USP <1058> and EU GMP Annex 15
- SOP as a word file

Compliant and reliable instruments

- Pharma-compliant software features such as user management, audit trail, and electronic signature
- Complete compliance and traceability, reducing the work required to integrate the new device into your system

Installation support and user training

- The instrument is qualified and ready for use within 1 to 3 days
- Personalized qualification documents
- Installation, qualification, and user training performed by representatives trained and certified by Anton Paar

Modularity

- Individual multiparameter measuring systems or a preconfigured Modulyzer system
- Combinations of density meters, refractometers, rolling-ball viscometers, and automation units in one lab workstation
- Expansion of the system at a later date, if needed

Complete control in the pharmaceutical industry



RESEARCH

- Density
- Optical & specific rotation
- Turbidity
- Reference temperature measurement & calibration
- Microwave synthesis
- Digestion & extraction
- Automated pipetting, sampling, dosing, and weighing
- Nanostructure analysis
- Surface analysis on solid samples
- Inline refractive index
- Particle analysis
- Refractive index & concentration
- Viscosity
- Flow properties & rheological investigations
- Surface area & pore size

PRODUCTION

- Density
- Optical & specific rotation
- Viscosity
- Refractive index & concentration
- Inline density measurement
- Inline refractive index
- Consistency
- Particle analysis



1 CHECKING the incoming materials

- Density
- Digestion for determination of elemental impurities
- Optical & specific rotation
- Viscosity
- Refractive index & concentration
- Consistency
- Particle analysis
- Flow properties & rheological investigations
- Surface area & pore size

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FILLING

- Density
- Concentration & optical rotation
- Viscosity
- Refractive index & concentration
- Inline density measurement
- Inline refractive index
- Consistency
- Particle analysis
- Flow properties & rheological investigations

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Final QUALITY CONTROL

- Density
- Digestion for determination of elemental impurities
- Optical & specific rotation
- Viscosity
- Refractive index & concentration
- Inline density measurement
- Inline refractive index
- Consistency
- Particle analysis
- Flow properties & rheological investigations
- Refractive index
- Extraction
- Reference temperature measurement & calibration
- Surface area & pore size

Product portfolio

DENSITY MEASUREMENT OF LIQUIDS

DMA M

- The **DMA M** density meters provide up to six-digit accuracy for density and determine numerous concentration values at the same time.
- Easy combination with measurement of sound velocity, viscosity, refractive index, and optical rotation
- Automation for user-independent filling
- The software is in compliance with 21 CFR Part 11.
- Available documentation: PQP/PQP-S

USP <841> | Ph.Eur. 2.2.5 | JP 17 2.56

DMA 35 portable density meter

- The portable density and concentration meter quickly measures incoming raw materials and intermediate products.
- 2 mL of sample is filled using the built-in pump and measured directly on-site.
- Available documentation: PQP-S

DMA 501

- The rugged and compact 3-digit density meter easily fits into tight spaces in storage facilities or the production area and is ideal for quick quality checks on incoming liquids and intermediate products.
- Available documentation: PQP-S

DMA 1001

- The compact stand-alone lab instrument is the most straightforward way to comply with your industry standards. It measures accurate to 4 digits and is ideally suitable if density is measured at a fixed temperature.
- Available documentation: PQP/PQP-S
- The software is in compliance with 21 CFR Part 11.

USP <841> | Ph. Eur. 2.2.5 | JP 17 2.56



DENSITY MEASUREMENT OF SOLIDS

UltraPyc series

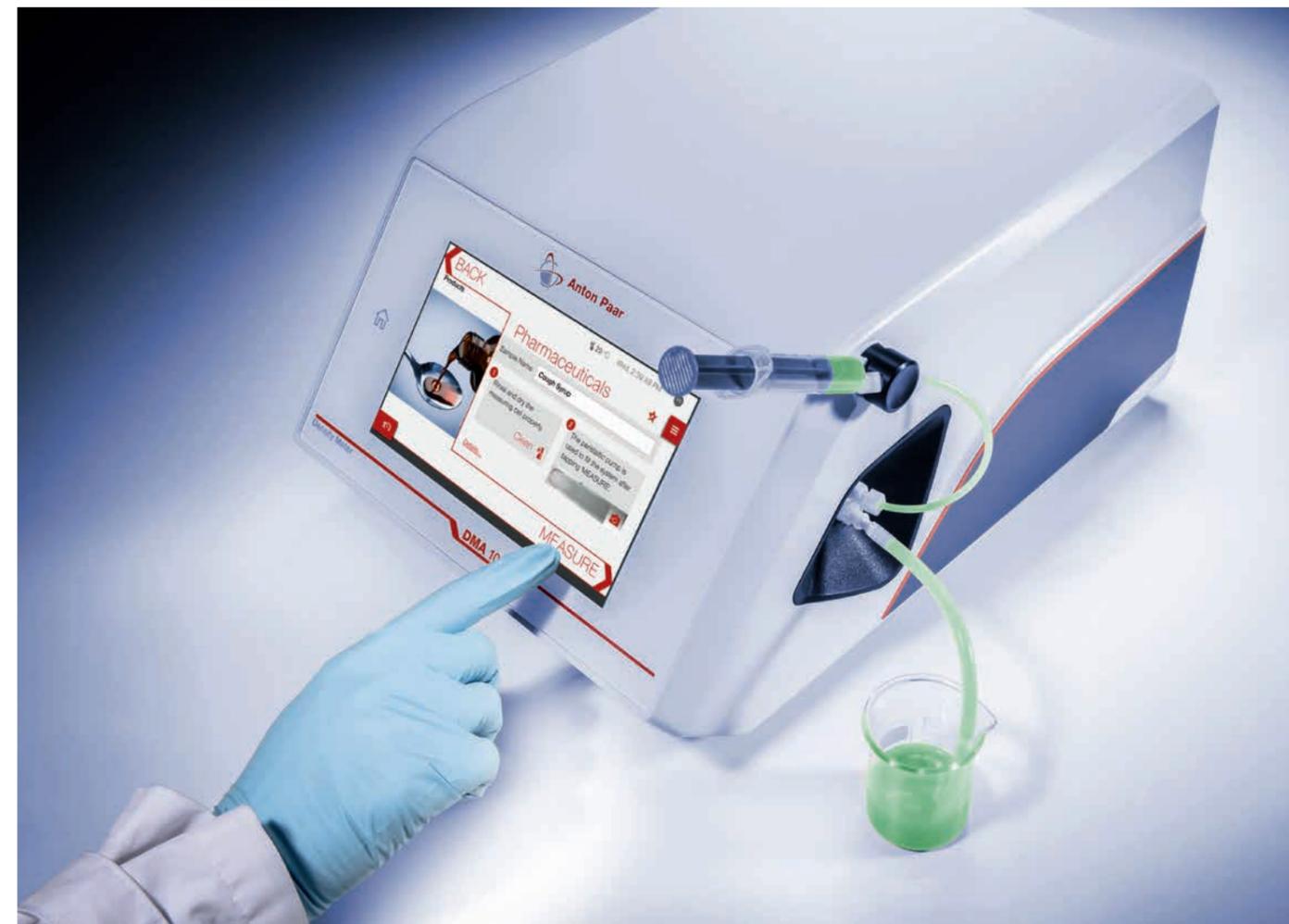
- The **gas pycnometers** measure the true skeletal density of powders, granules, and tablets.
- Electronic balance interface
- Sample chamber can be thermostatted
- Available documentation: IQ/OQ

USP <699> | Eur.Ph. 2.9.23

Autotap

- **Autotap** is a density analyzer that measures packed powder density.
- Provides data for compressibility and flowability calculations (Carr, Hausner)
- Available with 1 or 2 measuring positions
- Available documentation: IQ/OQ

USP <616> | Eur.Ph. 2.9.34



Product portfolio

FLOW PROPERTIES & RHEOLOGICAL INVESTIGATIONS

MCR rheometer series

- The **MCR rheometer** series allows investigations of the viscoelastic properties of raw materials, formulations, and final products from QC to R&D.
- **Toolmaster™** – the automatic tool recognition and configuration feature – ensures easy handling and error-proofing.
- **The RheoCompass™** software provides reports and documentation in compliance with 21 CFR Part 11.
- Available documentation: PQP/PQP-S

USP <912> | Ph.Eur. 2.2.8, 2.2.10



DIGESTION & EXTRACTION

Multiwave 7000 | Multiwave PRO

- The **Multiwave 7000** microwave digestion system with the novel pressurized digestion cavity (PDC) delivers the solutions you need; digestion of all samples with up to 300 °C and 199 bar in one run – no sample clustering needed.
- Compliant with 21 CFR Part 11
- Available documentation: PQP
- **Multiwave PRO** is a modular platform system with maximum flexibility in your choice of configurations. This versatile concept allows unique applications and methods including microwave acid digestion, acid leaching, solvent extraction, and synthesis.
- Compliant with 21 CFR Part 11
- Available documentation: PQP

USP <232>, <233> | Ph.Eur. 5.20, 2.4.8



CONSISTENCY

PNR 12 penetrometer

- The **PNR 12** penetrometer determines the consistency and plasticity of pasty, creamy, semi-solid, and highly viscous samples.
- Test kits according to European and US Pharmacopeia are available.
- Program navigation is performed by a self-explanatory jog wheel.
- Available documentation: PQP-S

Ph.Eur. 2.9.9 & according to USP consistency measurement by penetration



MICROWAVE SYNTHESIS

Monowave 400/450

- The **Monowave 400/450** microwave reactor allows sequential reactions at up to 300 °C and 30 bar.

Masterwave BTR

- The **Masterwave BTR** benchtop reactor features a 1 L reaction vessel for efficient batch-type processing on the kilolab scale.

Multiwave PRO

- The **Multiwave PRO** microwave reactor performs parallel synthesis at up to 300 °C and 80 bar.
- Available documentation: PQP



Product portfolio

VISCOSITY MEASUREMENT

SVM viscometers

- The **SVM series** measures viscosity and density from one syringe.
- **FillingCheck™** detects filling errors.
- **SVM viscometers** can be combined with Anton Paar refractometers.
- Automation for user-independent filling
- Available documentation: PQP/PQP-S

USP <912>* | Ph.Eur. 2.2.8, 2.2.10*

Lovis 2000 M/ME

- The **Lovis 2000 M/ME** microviscometer provides high-precision viscosity measurements on low-viscosity substances.
- Automation for user-independent filling

USP <913> | Ph.Eur. 2.2.8, 2.2.49

* for Newtonian liquids only



ViscoQC 100 rotational viscometer

- Determines single-point dynamic viscosity of liquids: From infusions to ointments
- Non-storage mode
- Traceability of results by automatic spindle and guard detection as well as digital leveling function
- Available documentation: PQP-S

USP <912> | Ph. Eur. 2.2.8, 2.2.10

RheolabQC rotational rheometer

- Rotational rheological tests: From liquid-like emulsions to semi-solid lotions
- Toolmaster™ for automatic bob detection
- Bar code option for sample identification
- The RheoCompass™ software provides reports and documentation in compliance with 21 CFR Part 11.
- Available documentation: PQP

USP <912> | Ph. Eur. 2.2.8, 2.2.10

ViscoQC 300 rotational viscometer

- Determines multi-point dynamic viscosity of liquids: From infusions to ointments
- Upgrade with V-Comply software to fulfill regulations of 21 CFR Part 11
- Traceability of results by automatic spindle and guard detection as well as digital leveling function
- Bar code option for sample identification
- LIMS functionality for data processing
- Available documentation: PQP

USP <912> | Ph. Eur. 2.2.8, 2.2.10



CONCENTRATION & REFRACTIVE INDEX WITH TEMPERATURE CALIBRATION

Abbemat refractometers

- The **Abbemat refractometers** provide quick and reliable refractive index and concentration measurements.
- Measurements in a wide range from 1.26 nD to 1.72 nD
- **Abbemat T-Check** calibrates and adjusts the internal temperature sensor to ensure precision.
- Automation for user-independent filling
- Available documentation: PQP/PQP-S

USP <831> | Ph.Eur. 2.2.6



Product portfolio

OPTICAL & SPECIFIC ROTATION

MCP polarimeters

- The **MCP polarimeters** measure the optical rotation of chiral substances.
- **FillingCheck™** automatically detects filling errors.
- A multiple wavelength option for up to 8 different wavelengths is available.
- Available documentation: PQP/PQP-S

USP <781> | Ph.Eur. 2.2.7



INLINE DENSITY & REFRACTIVE INDEX MEASUREMENT

L-Dens 7000 series

- The **L-Dens 7000** series of density sensors provides continuous density measurement and calculation of concentrations.

USP <841> | Ph.Eur. 2.2.5.

L-Rix 5000/5100/5200

- The **L-Rix 5000/5100/5200** inline refractometer delivers refractive index and concentration results.

USP <912>* | Ph.Eur. 2.2.8, 2.2.10*

* These sensors are easily connected to common evaluation units and PLCs.



PARTICLE ANALYSIS

Litesizer

- **Litesizer** measures the particle size, zeta potential, and molecular mass of liquid dispersions using light scattering technologies and determines the transmittance and refractive index.
- The ingeniously simple Kalliope™ software for Litesizer (and PSA) provides customizable reports as well a one-page workflow function, user management, and audit trails.
- Compliant with 21 CFR Part 11
- Available documentation: PQP

USP <729>

PSA

- **PSA** measures the particle size of dry powders and liquid dispersions from the upper nanometer to the millimeter range by laser diffraction.
- PSA particle size analyzers are calibrated according to the ISO 13320 and USP <429> standards.
- Compliant with 21 CFR Part 11
- Available documentation: PQP

USP <429>, <729>



TURBIDITY MEASUREMENT

HazeQC ME | HazeQC ME Heavy Duty

- The **HazeQC ME** and **HazeQC ME Heavy Duty** turbidity modules measure the turbidity of liquids using a ratio method based on the evaluation of scattered light at 0°, 25°, and 90°. This analysis method considers particles of any size and is not influenced by the sample's color.
- **HazeQC ME Heavy Duty** withstands aggressive cleaning liquids and samples thanks to the Kalrez® sealings used.

USP <855> | Ph.Eur. 2.2.1.



Product portfolio

SURFACE AREA & PORE SIZE ANALYSIS

autosorb iQ-MP series

- **High-vacuum volumetric surface area analyzers** that measure samples with a very low surface area (analysis gas: krypton)
- Available with 1, 2, or 3 analysis stations
- Built-in sample preparation (vacuum degassing) stations
- 21 CFR Part 11 compatible software features
- Available documentation: IQ/OQ

USP <846> | Ph.Eur. 2.9.26

NOVAtouch LX series

- **Vacuum volumetric surface area analyzers** that measure BET surface area and mesopore size distribution (analysis gas: nitrogen)
- Available with 2 or 4 analysis stations
- Built-in sample preparation (flow or vacuum degassing) stations
- 21 CFR Part 11 compatible software features
- Available documentation: IQ/OQ

QUADRASORB evo

- High-performance **surface area and pore size analyzer**
- Four independent analysis stations for work flow flexibility
- Available with high vacuum capability for low surface area (analysis gas: krypton)
- 21 CFR Part 11 compatible software features
- Available documentation: IQ/OQ

PoreMaster Series

- **Mercury intrusion porosimeters** measure meso- and macropore size distributions in granules and tablets
- Advanced safety features
- Available documentation: IQ/OQ

USP <267>



REFERENCE TEMPERATURE MEASUREMENT & CALIBRATION

MKT 10 | MKT 50

- The **MKT 50** Millikelvin thermometer provides traceable comparison calibration (PRT) and fixed-point calibration (SPRT). It provides a resolution of 0.1 mK and 40 $\mu\Omega$ and complies with DIN EN 60751 and ITS-90.
- **MKT 10** is ideal for at-line measurements and quick measurements on-site as it measures with an accuracy of 10 mK.



NANOSTRUCTURE ANALYSIS

SAXSpout 2.0 | SAXSpace

- **SAXSpout 2.0** and **SAXSpace** are small- and wide-angle X-ray scattering systems for structure investigations on nanometer-sized structures such as biomolecules in solution under biological conditions.
- Resolving nanostructures up to 150 nm in diameter
- Simultaneous and continuous small- and wide-angle measurements up to 60 ° 2 θ



SURFACE CHARGE ANALYSIS ON SOLID SAMPLES

SurPASS 3

- **SurPASS 3** analyzes the zeta potential of solid surfaces and gives insights into the charge and adsorption characteristics at solid/liquid interfaces.
- An integrated titration unit provides fully automated pH titration.
- **SurPASS 3** features calibration-free electronics as well as maintenance-free electrodes.



AUTOMATED PIPETTING, SAMPLING, DOSING & WEIGHING

Modular Sample Processor

- The **Modular Sample Processor** carries out automatic dosing, blending, subsampling, and transferring of liquids prior to analysis.
- Available as stand-alone benchtop unit or can optionally be integrated into complete automated workflows
- With individual adaptations the Modular Sample Processor perfectly carries out any desired liquid handling operation.



Anton Paar Certified Service

Engineers with the right skills & qualifications

Your Anton Paar service engineer is trained and authorized by Anton Paar to perform all maintenance work and additionally receives training on GMP and other relevant regulations needed to install your instrument, including the Pharma Qualification Packages.

Keep your results on-spec and compliant

Regular checks, calibrations, and adjustments, e.g. performed during an annual maintenance, ensure that your instrument continues to deliver measuring results which meet the specifications and standards. Based on our Pharma Qualification Packages individual requalifications can be issued to ensure the compliance of your instrument over its whole life cycle.

Certified test equipment

Anton Paar service engineers only use certified test equipment to check and adjust your instrument, so you can be sure of the highest level of accuracy.

Complete documentation

Benefit from the Pharma Qualification Packages with Anton Paar's certified installation and requalification services. After a maintenance performed by an Anton Paar certified service engineer you receive a separate service and maintenance record, which is a highly useful document for your audits. Rest assured that your instrument has been checked according to the highest standards.

Your maintenance budgets are now easy to plan

Purchasing an Anton Paar Certified Service program means you can plan and approve one single expense, giving you peace of mind regardless of what happens that year.

Electrical safety check for complete certainty

Your Anton Paar service engineer carries out a safety check to ensure that the electrical safety devices in the instrument are in full working order.



