

Measuring Technology for
the Pharmaceutical Industry

Solutions for the **Pharmaceutical Industry**

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.

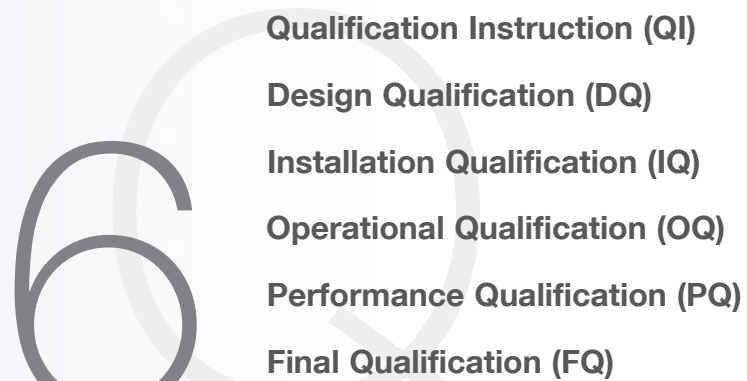
Don't worry,
be compliant



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 9001:2008

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 full all requirements of the 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 work station
- Expansion of the system at a later date, if needed

Complete Control in the Pharmaceutical Industry

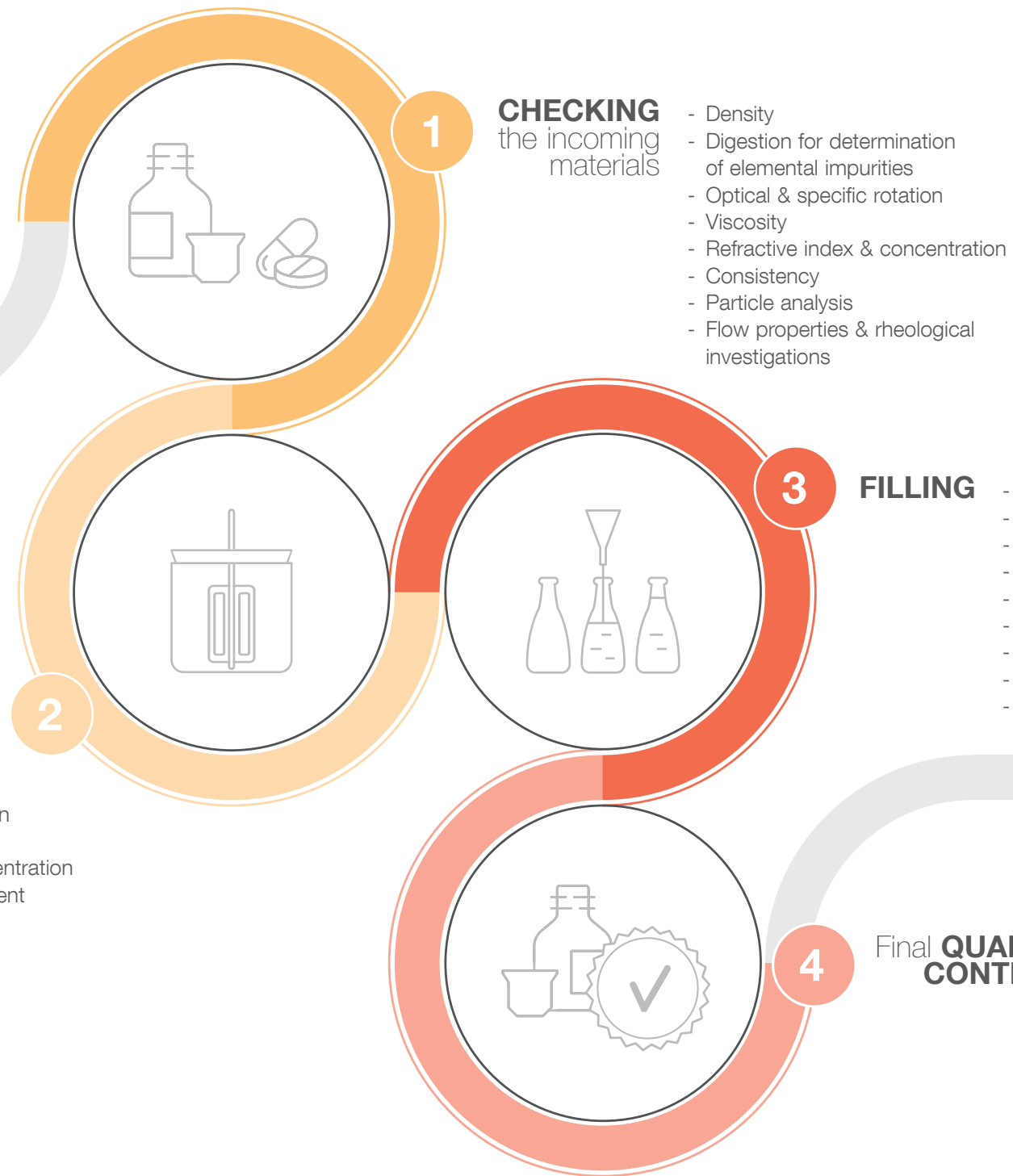


RESEARCH

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

PRODUCTION

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



- 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

Product Portfolio

DENSITY MEASUREMENT

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

DMA™ 35 Portable Density Meter

- The portable density and concentration meter quickly measures incoming raw materials and intermediate products. 2 mL of sample are 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-S

USP <841> | Ph.Eur. 2.2.5



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



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.

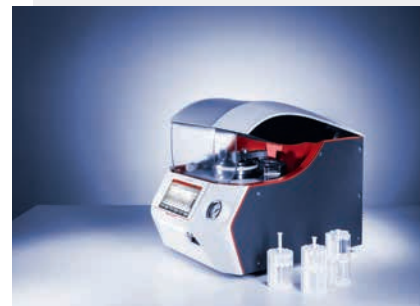


DIGESTION & EXTRACTION

Multiwave 7000 / Multiwave PRO

- **Multiwave 7000** microwave digestion system delivers the solutions you need to obtain reproducible and accurate measuring results for all kinds of pharmaceutical samples.
- **Multiwave PRO** is a platform system designed for microwave acid digestion, synthesis and solvent extraction applications.
- The software are in compliance with 21 CFR Part 11.
- Available documentation: PQP

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



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



VISCOSITY MEASUREMENT

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

SVM™ Stabinger Viscometer™

- 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*

* for Newtonian liquids only



ROTATIONAL VISCOSITY TESTING

RheolabQC

- **RheolabQC** can be used for viscosity testing from single-point checks to rheological investigations (from liquid-like emulsions to semi-solid lotions).
- **Toolmaster™** for automatic measuring system recognition.
- Bar code option for sample identification.
- Available documentation: PQP/PQP-S

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



MICROWAVE SYNTHESIS

Monowave 400/450

- The **Monowave 400/450** microwave reactor allows 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
- USP <232>, <233> | Ph.Eur. 5.20, 2.4.8



PARTICLE ANALYSIS

Litesizer™ and PSA

- **Litesizer™** measures the particle size, zeta potential, and molecular mass of liquid samples by 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 as data security functions, user management, and audit trails. Compliant with 21 CFR Part 11.
- **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.
- Available documentation: PQP

USP <429>, <729>



OPTICAL & SPECIFIC ROTATION

MCP polarimeters

- The **MCP polarimeters** measure the optical rotation of chiral substances.
- **FillingCheck™** automatically detects filling errors.
- 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 510/520

- The **L-Rix 510/520** inline refractometer delivers refractive index and concentration results.

USP <831> | Ph.Eur. 2.2.6.

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



TURBIDITY MEASUREMENT

HazeQC ME

- 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.



NANOSTRUCTURE ANALYSIS

SAXSpace/SAXSpout 2.0

- **SAXSpace** and **SAXSpout 2.0** 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 ° 2θ



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.



REFERENCE TEMPERATURE MEASUREMENT & CALIBRATION

MKT 10 | 50

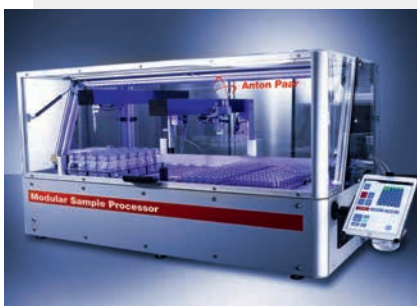
- The **MKT 50** Millikelvin thermometer provides traceable comparison calibration (PRT) and fixed-point calibration (SPRT). It provides a resolution of 0.1 mK and 40 µΩ and complies with DIN EN 60751 and ITS-90. The **MKT 10** is ideal for at-line measurements and quick measurements on site as it measures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



AUTOMATED PIPETTING, SAMPLING, DOSING & WEIGHING

Modular Sample Processor

- The **Modular Sample Processor** automates sample preparation prior to analysis. It separates one sample into many samples or combines samples. The subsampling process is gravimetrically controlled.



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.



