

Solutions for the
Pharmaceutical Industry

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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.

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

AP Connect Pharma, the software for your paperless lab: It connects your instruments, communicates measurement information, and ensures compliance.

DON'T WORRY, BE COMPLIANT

FIND OUT MORE



www.anton-paar.com/pharma



Anton Paar's Pharma Qualification Packages

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

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



- QUALIFICATION INSTRUCTION (QI)**
- DESIGN QUALIFICATION (DQ)**
- INSTALLATION QUALIFICATION (IQ)**
- OPERATIONAL QUALIFICATION (OQ)**
- PERFORMANCE QUALIFICATION (PQ)**
- FINAL QUALIFICATION (FQ)**

ISO 9001:2015

The backbone of Anton Paar's qualification documentation



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 checklist to fulfill all requirements of FDA 21 CFR Part 11, and standard operating procedure (SOP) as a Word file that can be used as the basis for your internal instrument SOP.

PQP-S(MART)

Your ideal tool if you have to follow GAMP 5 and GMP but don't have to be compliant with 21 CFR Part 11, also including: risk analysis and standard operating procedure (SOP) as a Word file.

REQUALIFICATION

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

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 workload required to integrate the new device into your system

INSTALLATION SUPPORT

- The instrument is qualified and ready for use after one to three 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
- Chemical composition

PRODUCTION

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



CHECKING 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
- Chemical composition

FILLING

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

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 4101/4501/5001

- The **DMA 4101/4501/5001** density meter series provides up to 6-digit accuracy for density and determines numerous concentration values simultaneously
- Automation for user-independent filling with Xsample sample changers
- Can be combined with pH and turbidity measuring modules for multiparameter analysis
- Supported by AP Connect
- Software compliance with 21 CFR Part 11
- Available documentation: PQP/PQP-S

USP <841> | Ph.Eur. 2.2.5 | JP 17 2.56 | ChP 2020 (Vol IV) 0601

DMA 501

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

ChP 2020 (Vol IV) 0601

DMA 1001

- The compact stand-alone lab instrument is the most straightforward way to comply with your industry standards, it measures with 4-digit accuracy and is perfectly suited to measuring density at a fixed temperature
- Software compliance with 21 CFR Part 11
- Available documentation: PQP/PQP-S

USP <841> | Ph. Eur. 2.2.5 | JP 17 2.56 | ChP 2020 (Vol IV) 0601

DMA 35

- The portable density and concentration meter measures incoming raw materials and intermediate products in a few seconds
- 2 mL sample volume, filling with the built-in pump, measurement on-site
- Available documentation: PQP-S

LAB EXECUTION SOFTWARE

AP Connect Pharma

- Software for data storage from all connected instruments in a central database, offering features for handling data automatically or upon request
- Connection of up to 30 out of 50+ instruments with one license key
- Data can be checked anytime across the entire company network (multi-user architecture)
- Data integrity and full compliance with regulatory requirements
- Compliant with 21 CFR Part 11
- Pharma-essential functions:
 - Configurable approval process of all your data with electronic signature
 - User management: Active Directory support to manage AP Connect users
 - Role management: configuration of specific roles with dedicated permissions
 - Audit trail for full traceability: complete audit trail of all connected instruments and the software itself; full review function from any place in the company network
- Available documentation: PQP

DENSITY MEASUREMENT OF SOLIDS

Ultrapyc series

- Precise and simple-to-use gas pycnometers measure the true and skeletal density of powders and tablets
- TruPyc technology ensures accurate measurements for various sample amounts
- PowderProtect mode eliminates the risk of instrument contamination
- Ultrapyc 5000 instruments feature built-in temperature control
- Available documentation: PQP-S

USP <699> | Ph.Eur. 2.9.23

Autotap

- Density analyzer that measures packed powder density
- Provides data for compressibility and flowability calculations (Carr, Hausner)
- Available with one or two measuring stations
- Available documentation: IQ/OQ

USP <616> | Ph.Eur. 2.9.34



Product Portfolio

FLOW PROPERTIES & RHEOLOGICAL INVESTIGATIONS

MCR 72 and MCR 92 – MCR Evolution rheometer series

- The two best choices for quick and easy rheological measurements in QC
- For checking the rheological properties of materials such as liquids and gels to ensure consistently high quality of raw materials and end products
- **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
- **Powder cells** for the complete characterization of powder behavior: flowability, compressibility, permeability, fluidization properties, and many other parameters
- Available documentation: PQP/PQP-S

USP <912> , <1174>, <1911>, <1912> | 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>, <1911>, <1912> | Ph. Eur. 2.2.8, 2.2.10

PARTICLE ANALYSIS

Litesizer

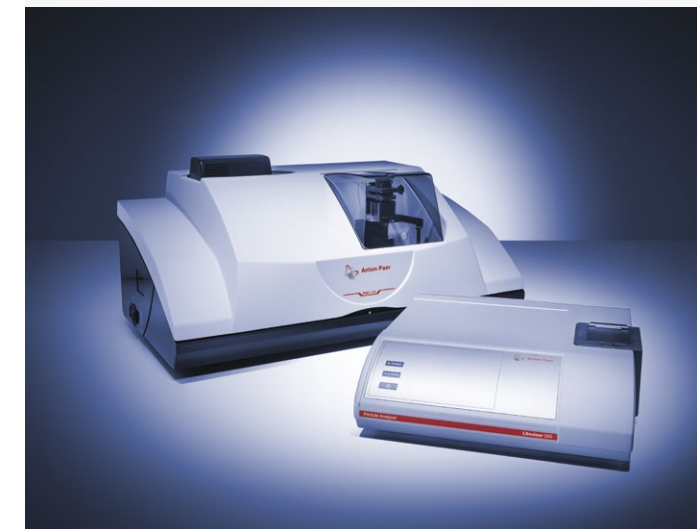
- For measurements of the particle size, zeta potential, and molecular mass of liquid dispersions using light-scattering technologies and the determination of the transmittance and refractive index
- The ingeniously simple Kalliope software for Litesizer and PSA provides customizable reports as well as a one-page workflow function, customizable user management, and audit trails
- Software compliance with 21 CFR Part 11
- Available documentation: PQP

USP <729>, <1430>

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
- Software compliance with 21 CFR Part 11
- Available documentation: PQP

USP <429>, <729>, <1430>



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 with Xsample sample changers
- Supported by AP Connect
- Software compliance with 21 CFR Part 11
- Available documentation: PQP/PQP-S

USP* <912>, <1911>, <1912> | Ph. Eur. 2.2.8, 2.2.10*

* for Newtonian liquids only

Lovis 2000 M/ME

- This microviscometer provides high-precision viscosity measurements on low-viscosity substances
- Automation for user-independent filling with Xsample sample changers
- Software compliance with 21 CFR Part 11

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

ViscoQC 100 rotational viscometer

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

USP <912>, <1911>, <1912> | 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 via automatic spindle, guard detection, and digital leveling function
- Bar code option for sample identification
- LIMS functionality for data processing
- Supported by AP Connect
- Available documentation: PQP

USP <912>, <1911>, <1912> | Ph. Eur. 2.2.8, 2.2.10

DIGESTION & EXTRACTION

Multiwave 7000

- The **Multiwave 7000** microwave digestion system with the pressurized digestion cavity (PDC) delivers the solutions you need; digestion of all samples at up to 300 °C and 199 bar in one run – no sample clustering needed
- Software compliance with 21 CFR Part 11
- Available documentation: PQP

Multiwave 5000

- **Multiwave 5000** is a modular platform system, offering maximum flexibility for your configurations; this versatile concept allows unique applications and methods, including microwave acid digestion, acid leaching, solvent extraction, and synthesis
- GS and ETL certification
- Software compliance with 21 CFR Part 11
- Available documentation: PQP

Multiwave GO Plus

- **Multiwave GO Plus** is the smallest and most economic rotor-based microwave digestion system on the market for digesting up to 12 different samples in a single run
- Available documentation: PQP-S

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

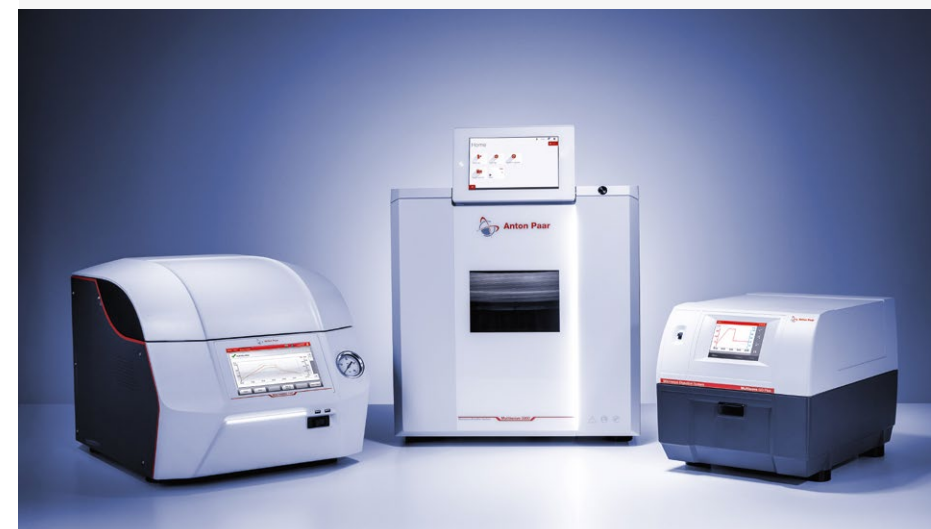
MICROWAVE SYNTHESIS

Monowave 400/450

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

Multiwave 5000

- The **Multiwave 5000** microwave reactor performs parallel synthesis at up to 300 °C and 80 bar of up to 96 samples
- GS and ETL certification
- Software compliance with 21 CFR Part 11
- Available documentation: PQP



Product Portfolio

CONCENTRATION & REFRACTIVE INDEX WITH TEMPERATURE CALIBRATION

Abbemat refractometers

- These instruments provide quick and reliable refractive index and concentration measurements
- Measurements in a wide range from 1.26 nD to 1.72 nD
- Supported by AP Connect
- **Abbemat T-Check** calibrates and adjusts the internal temperature sensor to ensure precision
- Automation for user-independent filling with Xsample sample changers
- Software solutions for data integrity: embedded or fully desktop-controlled operations mode possible
- Software compliance with 21 CFR Part 11
- Available documentation: PQP/PQP-S

USP <831> | Ph.Eur. 2.2.6



OPTICAL & SPECIFIC ROTATION

MCP polarimeters

- These instruments measure the optical rotation of chiral substances
- **FillingCheck™** automatically detects filling errors
- A multiple-wavelength option for up to eight different wavelengths is available
- Supported by AP Connect
- Software solutions for data integrity: embedded or fully desktop-controlled operations mode possible
- Software compliance with 21 CFR Part 11
- Available documentation: PQP/PQP-S

USP <781> | Ph.Eur. 2.2.7



IDENTITY TESTING WITH RAMAN SPECTROSCOPY

Cora 5001 for Pharma

- Cora 5001 Raman spectrometer, when combined with Anton Paar's Spectroscopy Suite software, is a solution tailored to incoming goods inspections and R&D in the regulated environment
- All workflows, like running samples, setting up methods, and generating reference libraries, are specifically designed to adhere to stringent compliance regulations
- Lifetime data integrity
- 100 % traceable audit trail with search function
- Transparent and secure electronic signing
- Compliant with 21 CFR Part 11
- Available documentation: PQP

USP <858>, <1858> | Ph.Eur. 2.2.48



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

USP <915> | Ph.Eur. 2.9.9



INLINE DENSITY & REFRACTIVE INDEX MEASUREMENT

L-Dens 7000 series

- This series of density sensors provides continuous density measurement and calculation of concentrations

USP <841> | Ph.Eur. 2.2.5.

L-Rix 5000/5100/5200

- These inline refractometers deliver refractive index and concentration results

USP <831>* | Ph.Eur. 2.2.6*

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

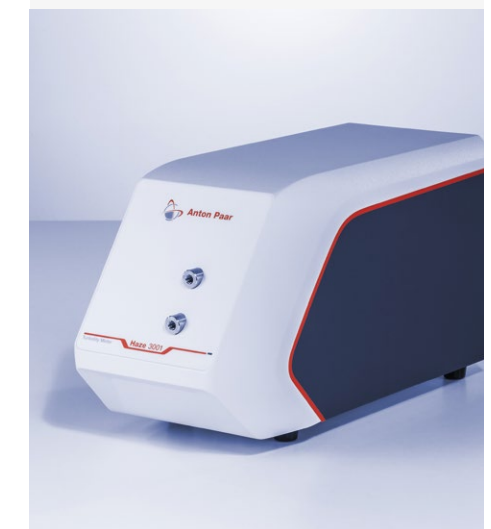


TURBIDITY MEASUREMENT

Haze 3001/ Haze 3001 Heavy Duty

- These 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
- **Haze 3001 Heavy Duty** withstands aggressive cleaning liquids and samples thanks to the Kalrez® sealings used
- Supported by AP Connect

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 one, two, or three analysis stations
- Built-in sample preparation (vacuum degassing) stations
- Includes 21 CFR Part 11-compatible software features
- Available documentation: IQ/OQ

Nova series

- **Vacuum volumetric gas adsorption analyzer** that measures surface area, pore volume and mesopore size
- Fully integrated design with four sample preparation ports and up to four analysis stations
- Analyze with velocity: four samples for 5-point BET surface area within 20 minutes
- Available documentation: IQ/OQ

QUADRASORB evo

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

USP <846> | Ph.Eur. 2.9.26

PoreMaster series

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

USP <267>



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 | 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

SAXSpoint 5.0 | SAXSpace

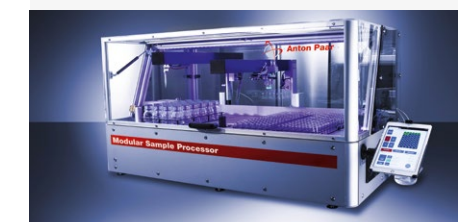
- Small- and wide-angle X-ray scattering systems for structure investigations on nanometer-sized structures, such as biomolecules in solution under biological conditions
- Resolving nanostructures up to 300 nm in diameter
- Simultaneous and continuous small- and wide-angle measurements up to 74 ° 2 θ



AUTOMATED PIPETTING, SAMPLING, DOSING, & WEIGHING

Modular Sample Processor

- Carries out automatic dosing, blending, subsampling, and transferring of liquids prior to analysis
- Available as a stand-alone benchtop unit or optional integration into completely automated workflows
- After individual adaptations, the Modular Sample Processor perfectly carries out any desired liquid handling operation





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 annual maintenance, ensure that your instrument continues to deliver measuring results that 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

Our service engineers only use certified test equipment to check and adjust your instrument, so rest assured you will reach the highest level of accuracy.

COMPLETE DOCUMENTATION

Benefit from the Pharma Qualification Packages with our certified installation and requalification services. After maintenance performed by one of our certified service engineers, you receive a separate service and maintenance record, which is a highly useful document for your audits. Know that your instrument is checked according to the highest standards.

YOUR MAINTENANCE BUDGETS ARE NOW EASY TO PLAN

Investing in an Anton Paar Certified Service program means you can plan and approve a single expense on service per year, ensuring no unpredictable costs and giving you peace of mind.

ELECTRICAL SAFETY CHECK

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.

