



Pharmaceutical
industry

SOLUTIONS FOR
QUALITY CONTROL
LABORATORIES
AND **PRODUCTION**
BATCH RELEASE

Your measurement tasks & results – in full compliance

AS A LAB OPERATOR, YOU NEED TO MEASURE SPECIFIC PARAMETERS FOR EACH PRODUCT SO IT CAN BE SUCCESSFULLY CERTIFIED.

AS A LAB MANAGER, YOU NEED TO MAKE SURE THAT THE RESULTS CAN BE TRUSTED AND THAT PRODUCT QUALITY IS VERIFIED. THERE ARE CLEAR SOPs THAT NEED TO BE FOLLOWED.

AS HEAD OF QUALITY CONTROL, YOU NEED TO BE ABLE TO ACCESS ALL MEASUREMENT DATA FOR A PRODUCTION BATCH FROM START TO FINISH.

YOUR CHALLENGE

Products in the pharmaceutical industry have different measurement requirements comprising specific parameters or a certain number of measurements. Quite often, operators need different instruments to perform these tasks. And the numbers of samples can be overwhelming.

Any activity in the pharmaceutical industry needs to be documented and has to be fully traceable. A four- or six-eye principle for review and approval has to be followed and actions have to be in complete compliance with internal and external regulations.

Data and metadata from different labs and production points can be difficult to access – if they are properly recorded at all. This task becomes harder if more parameters and instruments are involved.

OUR SOLUTION

We offer instruments with highly intuitive user interfaces, guided user workflows, and instrument features which allow for simple handling, as well as automation options for high workloads.

Our measuring technologies and dedicated instrument features enable compliant analytical workflows, such as functions assuring correct sample filling and handling, customizable user management, and a complete audit trail. Additionally, the instruments – stand-alone or in combination with AP Connect Pharma – offer full 21 CFR part 11-compliant electronic signatures and review processes.

AP Connect Pharma collects all data, metadata (e.g. pictures of filled measuring cells or measurement settings), and the audit trail of each connected instrument in a single database. Remote access is possible.

YOUR BENEFIT

Enjoy complete prevention of measurement errors while saving time. There is no need to adapt to different instruments and user interfaces when measuring different physical parameters.

Compliant instruments and functions assist operators and managers to achieve 100 % compliance for analytical procedures, providing credible verification for produced pharmaceuticals.

All relevant information is accessible at one central location. It is easy to organize, search, and customize. Also, reporting for routine review tasks can be automated to significantly save time. Requests for audit data can be fulfilled simply on-the-spot, allowing you to focus on the more important parts of an audit.

Anton Paar's solution portfolio



RESULTS	PARAMETERS MEASURED	MONOGRAPHS	INSTRUMENTS	TYPICAL SAMPLES
Concentration, purity	Density/Specific gravity	USP 841 Pharm.Eu. 2.2.5 JP 2.56 ChP 2020 (Vol IV) 0601	DMA 4101 4501 5001(*) DMA 501 1001 Density meters	Liquid formulations & injectables Medically used buffers and sugar solutions (saline, Ringer's solution, dextrose for injections) Antibiotic solutions
Concentration, purity, substance identification	Specific optical rotation	USP 781 Pharm.Eu. 2.2.7 JP 2.49 ChP 2020 (Vol IV) 0621	MCP 5100 5300 5500(*) MCP 150 Polarimeters	Small molecular APIs in liquid formulation Medically used sugars & syrups
Concentration, purity, substance identification	Refractive index	USP 831 Pharm. Eu. 2.2.6 JP 2.45 ChP 2020 (Vol IV) 0622	AbbeMat 350 550(*) AbbeMat 300 500 Refractometers	General anesthetics Organic liquid chemicals & liquid excipients (glycerol, siloxanes ...) Medically used natural oils
Viscosity, consistency	Dynamic viscosity	USP 912 Pharm.Eu. 2.2.8 ChP 2020 (Vol IV) 0633	ViscoQC 300(*) Rotational viscometer	Gel, cremes, ointments Syrup base & syrups Medically used thickeners (gum arabic, xanthan, alginin, methylcellulose)
Viscosity, (Polymer molar mass)	Dynamic & kinematic viscosity	USP 913 Pharm.Eu. 2.2.49	Lovis 2000 ME (module in master instrument)(*) Rolling-ball viscometer	Collagen, hyaluronic acid, polysaccharides & biopolymers Vaccines & injectables
Consistency, resistance & hardness of semisolids	Penetration	USP 915 Pharm.Eu. 2.2.9 ChP 2020 (Vol IV) 0983	PNR 12 Penetrometer	Suppositories Gel, cremes, ointments Paraffins, waxes, petroleum jelly

ADDED SERVICES

Pharma Qualification Packages & Qualification Services individually available for each instrument, complying to e.g. USP 1058, GAMP 5, GMP, EU GMP Annex 15 and 21 CFR Part 11(1)
3-year instrument warranty

AP CONNECT - YOUR WAY TO A PAPERLESS LAB

Connect and collect, plug and play. All your lab data in a single hub – just a click away. Choose AP Connect – the lab execution software that connects your instruments, communicates measurement information and metadata, ensures compliance, and simplifies reporting.

(*) ... compatible as system solution with AP Connect Pharma
(1) ... exact scope depending on instrument & features

Solutions for **quality control** laboratories and **production** **batch releases**

**DENSITY
REFRACTIVE INDEX
OPTICAL ROTATION
VISCOSITY
CONSISTENCY**

GET THE BEST COMBINATION OF PARAMETERS AND SOFTWARE SOLUTIONS FOR FINAL PRODUCT CONTROL AND PRODUCTION BATCH RELEASE ACTIVITIES

Final quality control is a crucial step before the batch release of a pharmaceutical product. Finished products have to undergo rigorous testing to ensure correct properties and have to fulfill specifications and norms before being authorized for storage, further processing, or sale. Compliance to the target markets' strict regulations as well as to international standards and guidelines is the key factor for safe and effective medication.

ANTON PAAR'S UNIQUE COMBINATION OF MEASURING TECHNOLOGIES, INSTRUMENT FEATURES, SOFTWARE TOOLS, AND QUALIFICATION DOCUMENTS AND SERVICES PROVIDES SUPPORT AS YOU TACKLE DIFFERENT CHALLENGES IN THIS FIELD OF APPLICATION.

FIND OUT MORE



www.anton-paar.com/apc



