



Anton Paar

Driving XRD in Regulated Environments

XRDynamic 500



**Supporting
FDA Title
21 CFR Part 11**



The XRDynamic 500 automated multipurpose powder X-ray diffractometer drives unbeatable XRD data quality with maximum efficiency. Enjoy the benefits of a versatile platform covering a wide variety of applications while ensuring compliance with FDA Title 21 CFR Part 11 and ALCOA+ guidelines.

FIND OUT MORE



[www.anton-paar.com/
apb-driving-xrd](http://www.anton-paar.com/apb-driving-xrd)

XRDynamic 500, the XRDdrive control software, and the XRDview data visualization package seamlessly combine straightforward instrument handling and intuitive workflows with as much or as little detail as you want, thanks to intelligent system automation.

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

Research

XRDynamic 500 is the solution if you are looking for a flexible, straightforward-to-use instrument that delivers outstanding results. Whether it's for capillary measurements or zero background sample holders, measurements are possible with even the smallest sample quantities of your precious APIs. In addition, with 60 years of experience in the field, no other instrument on the market has been designed for non-ambient X-ray diffraction experiments from the ground up. XRDynamic 500 offers the most complete integration of non-ambient XRD attachments to facilitate stability studies under varying temperature and humidity. You can easily investigate the behavior of your sample between 5 % and 95 % relative humidity or under temperature ranges of -190 °C to +2,300 °C.

Quality control

Are you looking to test your samples according to USP chapter <941> or Eu 2.9.33? With XRDynamic 500, you can enjoy the highest sensitivity due to the unique evacuated beam path combined with best-in-class measurement resolution. It's >20 % better in a standard Bragg-Brentano configuration than conventional instruments, due to the larger goniometer radius and advanced detector with small channel size. This makes identification of even the smallest quantities of impurities or other phases in a sample possible. Dedicated monochromator optics eliminate unwanted components of the emission spectrum, resulting in improved sensitivity and shorter measurement times to significantly increase your sample throughput.

Minimizing all potential human error is ensured via complete component recognition and full automation of sample and optics alignments, together with intuitive software flows. Traceability is ensured via software packages fulfilling the requirements of 21 CFR Part 11.

Qualification documents

More than the sum of their pages, Anton Paar qualification documents are written according to regulatory standards and help avoid non-compliance and other related risks. The documents, together with installation support, reduce the work required by your in-house personnel to get your new instrument ready for routine operation by up to 70 %, saving you time and money.

Our PQD complies with USP 1058, GAMP 5, GMP, EU GMP Annex 15 and 21 CFR Part 11(1), comprising the following content and chapters:

- FDA 4Q model (Design Qualification, Installation Qualification, Operational Qualification, Performance Qualification)
- Risk assessment
- 21 CFR Part 11 checklist
- Final qualification summary
- Traceability matrix
- Final report for audit readiness
- Instrument SOP
Availability as a Word file that can be used as the basis of your internal instrument SOPs

Installation support

- The instrument is ready for use after five days
- Personalized qualification documents
- Installation, qualification, and user training performed by representatives trained and certified by Anton Paar

Requalification

An instrument qualification isn't a one-time event. Depending on your needs and 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.

Safety and security with uninterrupted instrument uptime

XRDynamic 500 conforms to the most stringent safety standards, so you only need to focus on your measurement and nothing else. We are confident in the high quality of our instruments, providing you with a full three-year warranty, for all of our instruments as standard.

