

Mechanical Qualification of USP Apparatus 1 and 2

Provided to Help You Get the Most from Your Agilent Dissolution Products!

In most countries, regulatory agencies will accept periodic qualification of USP Dissolution Apparatus 1 (Rotating Basket) and 2 (Paddle) performed using one of two procedures. These options are:

- **USP Performance Verification Test (PVT)**
 - Also referred to as Performance Qualification or “PQ”
 - Requires verification of physical parameters according to tolerances specified in USP General Chapter <711> Dissolution
 - Requires chemical testing using the current lot of Prednisone tablets
- **Enhanced Mechanical Calibration**
 - Also referred to as Mechanical Qualification or “MQ”
 - Requires verification of physical parameters according to tolerances specified in ASTM E2503 or FDA DPA-LOP.002.
 - Requires adherence to additional guidelines described in ASTM/FDA procedures including COCs for accessories and SOPs governing daily use and maintenance

It is necessary for the laboratory to decide which procedure meets their internal requirements best. This is sometimes determined by the local regulatory agency, although both procedures are readily accepted worldwide. Agilent can provide either of these services for our own dissolution instruments as well as most non-Agilent models. The physical parameters measured by the 280-DS Mechanical Qualification System (MQS) are verified as part of both procedures.



Technical details

These procedures are typically performed at 6-month intervals as prescribed by regulatory authorities. Each procedure refers to the qualification performed on USP Apparatus 1 (Rotating Basket) and USP Apparatus 2 (Paddle) type instruments. These modes account for approximately 75-80% of all dissolution methods. For Agilent's Dissolution Product Line, this includes the 708-DS model.

Agilent Ordering Information

The 280-DS MQS is used by Agilent Service Engineers or licensed Agilent Service Providers for PQ or MQ services. It is also available for purchase by laboratories performing their own qualifications as well as routine monitoring of dissolution instrumentation.

280-DS Mechanical Qualification System

Description	Part No.
280-DS Mechanical Qualification System, with 280-DS Workstation Software	G7980AA
Cable kit for Agilent/Varian/VanKel Dissolution Apparatus connection	G7980AA #100
Spacer kit for 280-DS VM (for use with shorter vessels)	G7980AA #105
HP ProBook laptop for use with 280-DS	G7980AA #650
Add Familiarization Service	G7980AA #44L
Add Installation Service	G7980AA #44K

Helpful Links

- [280-DS MQS Brochure](#)
- [280-DS MQS Specification Sheet](#)
- [280-DS MQS Video](#)
- [280-DS MQS Cost Savings Calculator](#)

White Papers / Technical Overviews

- [Proper Implementation of Enhanced Mechanical Calibration of Dissolution Apparatus 1 and 2](#)
- [Redefining Dissolution Qualification](#) – an in-depth examination of the USP PVT and the ramifications of moving to a fully mechanical qualification
- [Agilent 280-DS Mechanical Qualification System for Dissolution Apparatus 1 & 2 - a user-friendly system with software built for 21 CFR part 11 compliance](#)

Additional Information

- [Practical Solutions – the MQ Edition](#)
- [Mechanical Qualification Guide \(POSTER\)](#)
- [Enhanced Mechanical Calibration of Dissolution Test Equipment \(Dissolution Technologies\)](#)

Agilent Sites and Services for Your Dissolution Workflow



Agilent Dissolution Systems Digital Source Book
www.nxtbook.com/nxtbooks/agilent/dissolution_sourcebook/index.php

Dissolution Exchange
www.dissolution.chem.agilent.com

Dissolution 1-on-1 Training
www.dissolution.chem.agilent.com/learn-dissolution-1-on-1

Dissolution Hotline (Email Address)
dissolution.hotline@agilent.com

Dissolution Discussion Group (DDG)
www.dissolution.com