Agilent ChemStation for UV-visible Spectroscopy: Dissolution Testing Software

Specifications

General Description

The dissolution testing software for Agilent ChemStation adds single and multibath dissolution testing capabilities to the general purpose software. All spectral processing features of the general purpose software and data analysis features for single and multicomponent analysis of the advanced software are available within the dissolution testing software. It controls only the Agilent 8453 spectrophotometer.

Scalable Sampling Systems

The *dissolution testing mode* is a dedicated mode for single bath dissolution testing.

- Supports offline dissolution testing, with manual sampling, sipper or autosampler operation.
- Supports online dissolution testing with the multicell transport based or valve-based sampling systems.
- The online sampling systems have a direct sampling link to the bath and sampling is done automatically at the times specified in dissolution time table.
- Can be combined for fully automated online dissolution testing with the Zymark Multidose workstation.

The *multibath dissolution testing mode* is a dedicated mode for online dissolution testing on up to four baths in parallel. This mode is compatible only with the valve-based multibath sampling system in combination with the multicell transport.

Both single and multibath valve based sampling dissolution testing have virtually identical functionality.

Data Acquisition and Analysis

- The open architecture of the third-party interface allows integration of baths through dynamic data exchange (DDE). The major bath manufacturers provide the necessary drivers to allow control of the baths through Agilent ChemStation. Data acquired from the bath are also included in the common result file and final report.
- User-defined sequences of prerun and postrun actions can be executed before and after the dissolution test. These actions can be set as optional and a descriptive message for operator guidance can be given.
- Time points for sampling and dissolution-specific actions can be defined in the dissolution timetable.
- Spectral acquisition, for example, for identification of samples or diagnostic of ambiguous values.
- Compensation for volume changes caused, for example by pH changes, evaporation or flow through and Biodiss apparatuses.
- Results can be calculated as %dissolved, weight dissolved or weight dissolved/weight of tablet. Correction for individual tablet weights or by a factor are possible.
- Flexible reporting allows users to define reports based on predefined styles, or design their own customized reports.
- Up to four individual result files can be combined to one result reports for 6 (stage 1), 12 (stage 2) or 24 (stage 3) samples. The statistical evaluation includes a check against the acceptance table criteria for immediate release, extended release or delayed release as defined in USP.

Good Laboratory Practice

The Agilent ChemStation has many features to support GLP, for example, the operator/manager level, and the Verification & Diagnostics mode. In addition to the GLP features of the general purpose software, the dissolution testing mode has the following features to support GLP equirements:

- logbook for actions, errors and messages that occur during a dissolution run
- single binary result file including raw data, bath parameters and results, method parameters and logbook
- software validation kit
- flow test for a selected channel, and cross-contamination test for the sampling systems

21 CFR Part 11

The optional Security Pack software can be added for full support of compliance with 21 CFR Part 11.

- Provides access control, including user setup and password adminstration based on Windows NT or Windows 2000 without using a relational database.
- Locks sessions during automated data acquisition.
- Prevents loss of raw and meta data and their unauthorized modification.
- Stores deleted spectra together with results for review during an audit, or even for restoring.
- Adds versioning at the ChemStation level to store reprocessed versions.
- Supports the detailed requirements for electronic records and passwords as specified by 21 CFR Part 11.

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