

Ultra High Performance Liquid Chromatograph for Online Dissolution Testing

Nexera FV



Taking Online Dissolution Testing into the New Era of Ultra High Performance Chromatography

Nexera FV

Dissolution tests are widely used in the pharmaceutical development and quality control process and for bioequivalence tests of generic drugs.

The Nexera FV provides substantial labor savings by automating processes ranging from the dispensing of dissolution media to data acquisition and data analysis.

In addition, the system is based on the Nexera X2, renowned for its speed, sensitivity, and stability, allowing users to quickly obtain reliable dissolution test results. The Nexera FV can also be used as a standard UHPLC system, ensuring high laboratory throughput.





● Provides Labor Savings and Faster Speeds in Dissolution Testing

- High-efficiency UHPLC delivers short analysis times
- Unattended operation for overnight testing
- Automated report creation enables quickly reviewing test results

● Enables Testing of Quickly Dissolving Samples

- Handles sampling intervals as short as five minutes
- UHPLC analysis ensures quick generation of results

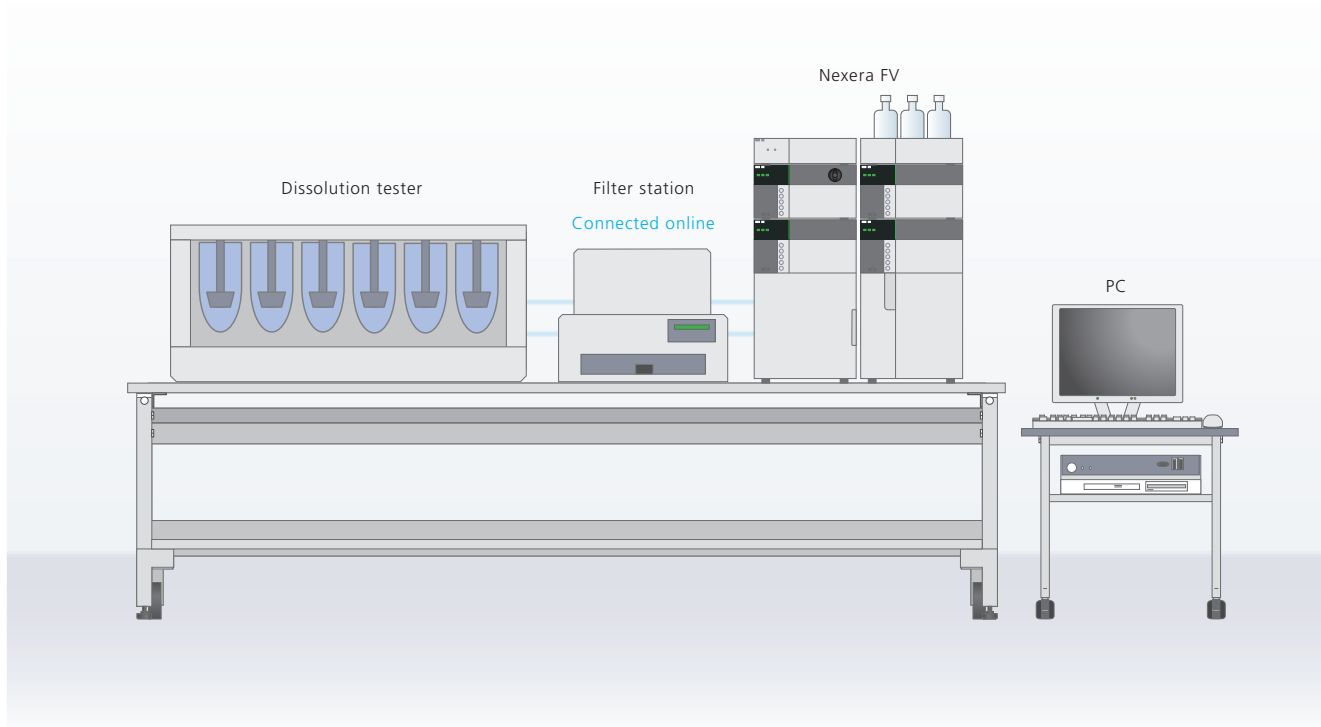
● Substantial Improvements in Work Scheduling

- Dedicated software drastically reduces the burden of preparing exam schedules
- Multi-data report function simplifies the creation of reports



System Configuration for Online Dissolution Testing

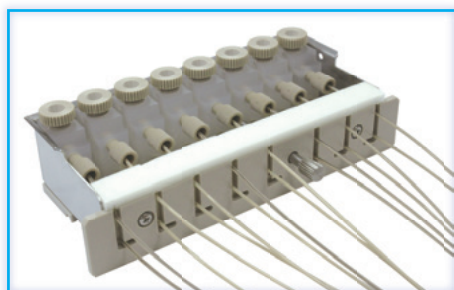
With the Nexera FV, the dissolution tester and the autosampler are connected online, so everything is automated from sampling to dilution to data acquisition and analysis. As a result, there is less test-related work for the operator, and a subsequent increase in processing throughput. In addition, there is no manual dispensing of samples, ensuring reliable results.



① Flow Vials Provide Automated Dissolution Testing

A dissolution medium from the dissolution tester flows directly into flow vials loaded into the autosampler. A bubble suppression design has been adopted for these flow vials, enabling high-accuracy sampling of dissolution media.

Depending on the dissolution tester used, 8 or 12 flow vials can be loaded. Further, since the flow vials are purposefully designed not to control the temperature, salt precipitation from the dissolution medium is suppressed.

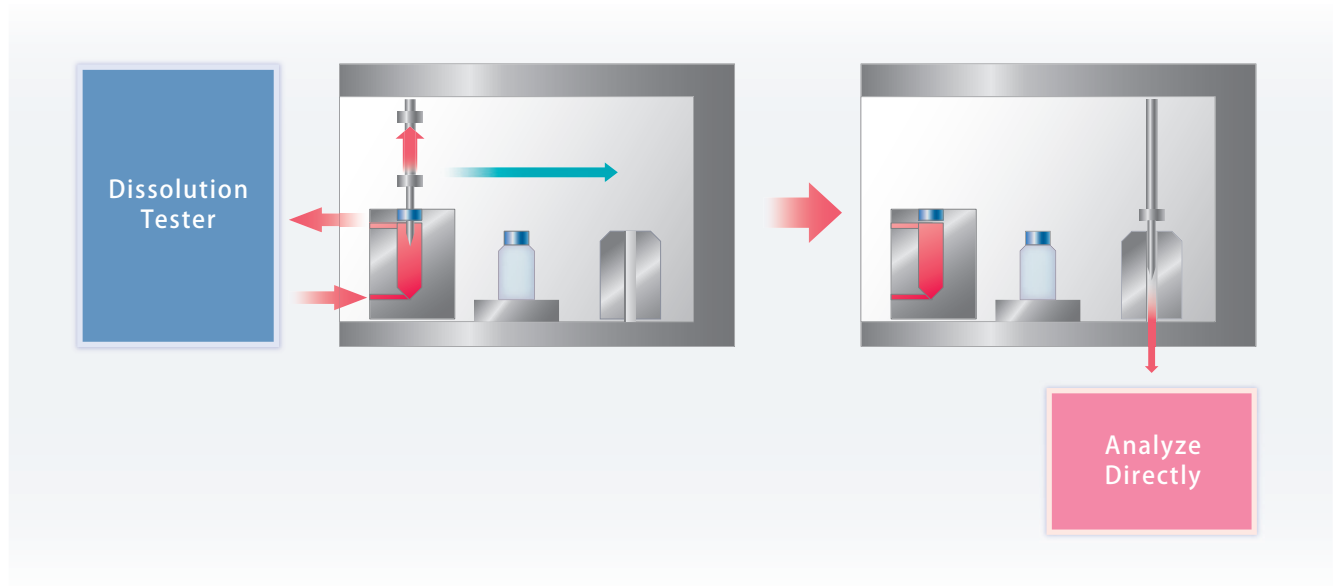


Two Analysis Modes Promote Faster Dissolution Testing

🕒 Direct Injection Analysis Mode: Exclusively with the Nexera System

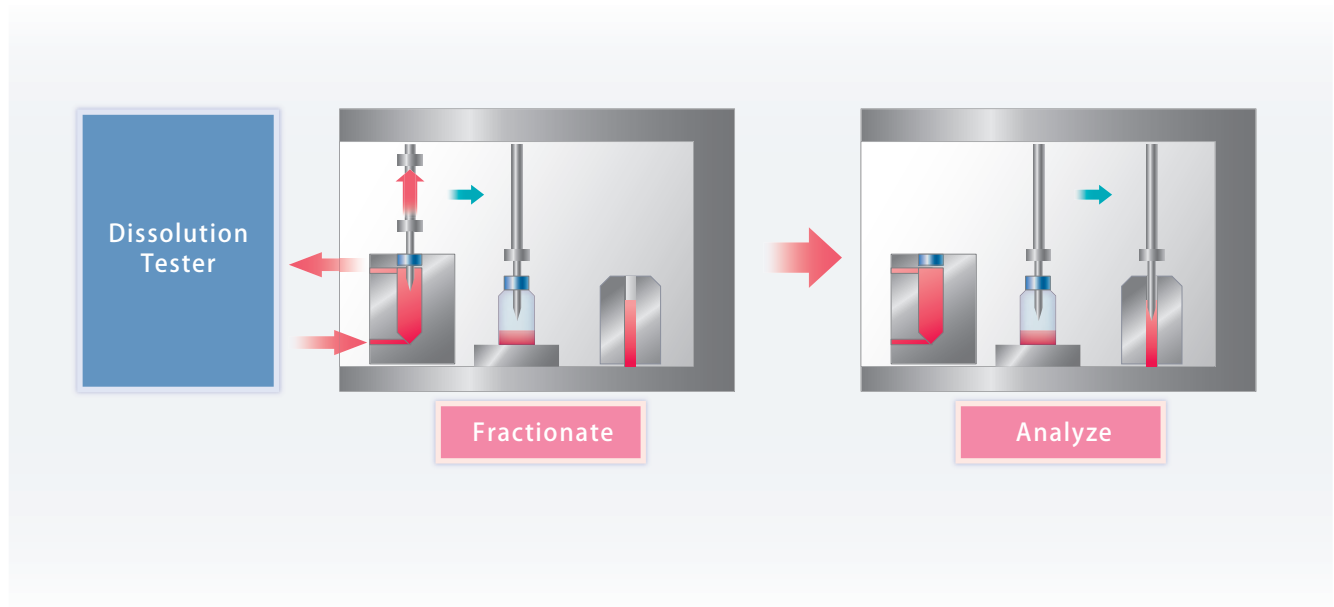
In this mode, the dissolution medium delivered from the dissolution tester is directly loaded and analyzed. This is effective if the analysis of the number of vessels finishes before the next sampling interval.

This analysis mode can be selected precisely because the Nexera FV is compatible with UHPLC analysis.



🕒 Fraction Analysis Mode: For Confirmation of Dissolution Profiles at Short Sampling Intervals

This analysis mode is used for tests in which the sampling interval is short. This is suitable when checking the dissolution profile of instantly soluble samples. The Nexera autosampler's high-speed performance makes this system compatible with sampling intervals as short as five minutes. In addition, up to 768 samples can be fractionated, making this mode effective when the dissolution quantity is large and dilution will be required.



Reliable Performance Expands the Range of Choices

Compatible with High-Concentration Samples Requiring Dilution

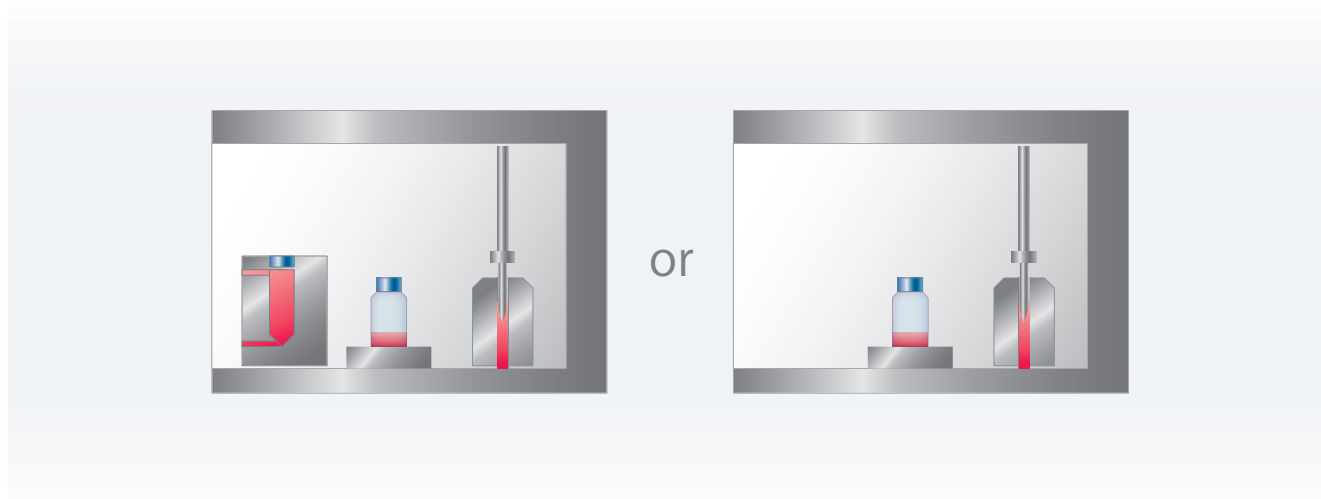
High dissolution quantity samples often require dilution. Samples can be diluted by using the fraction analysis mode. High injection accuracy is provided even at trace quantities, enabling reliable dilution even without manual handling.

The data shows a comparison between a standard liquid (aqueous caffeine solution), with the dilution ratios manually adjusted by an experienced engineer, and a standard liquid automatically diluted by the Nexera FV. This data shows that the system can perform dilution reliably.

Dilution Ratio (Times)	Dilution Accuracy (%)
2	100
5	100
10	101
20	101
50	101
100	102

One System Plays Two Roles, Significantly Improving the Throughput of the Testing Lab

The Nexera FV is a multipurpose system for on-line dissolution testing and high-efficiency UHPLC analysis, such as compound screening, and everyday method development applications. This significantly increases the system operation rate in the laboratory.



Long-Lasting Consumables Provide for High Cost-Effectiveness

A special septum is used for the flow vial that receives the dissolution medium. It boasts a better degree of adherence after needle penetration in comparison to a regular septum, and can be used for 100 continuous injections without leaking. This greatly reduces maintenance, enabling continuous testing.

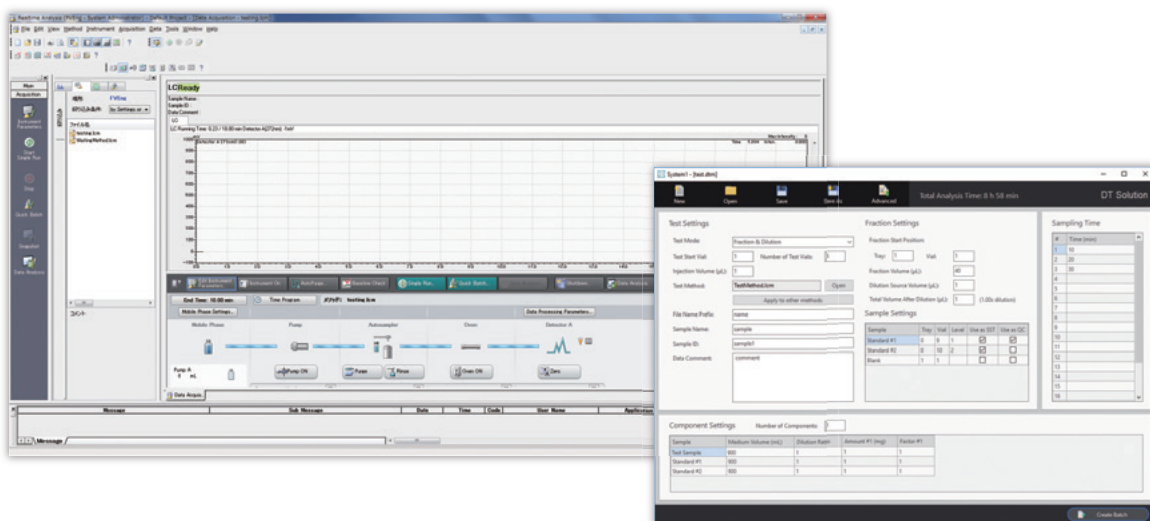


Special Software Enables More Efficient Testing Preparation

DT-Solution Software Supports the Creation and Implementation of Test Schedules

With dissolution tests, one of the most labor-intensive processes is establishing a batch schedule for the test. The custom DT-Solution software eases the burden. With this software, the user can configure all the required information in a single window. Then, click a single

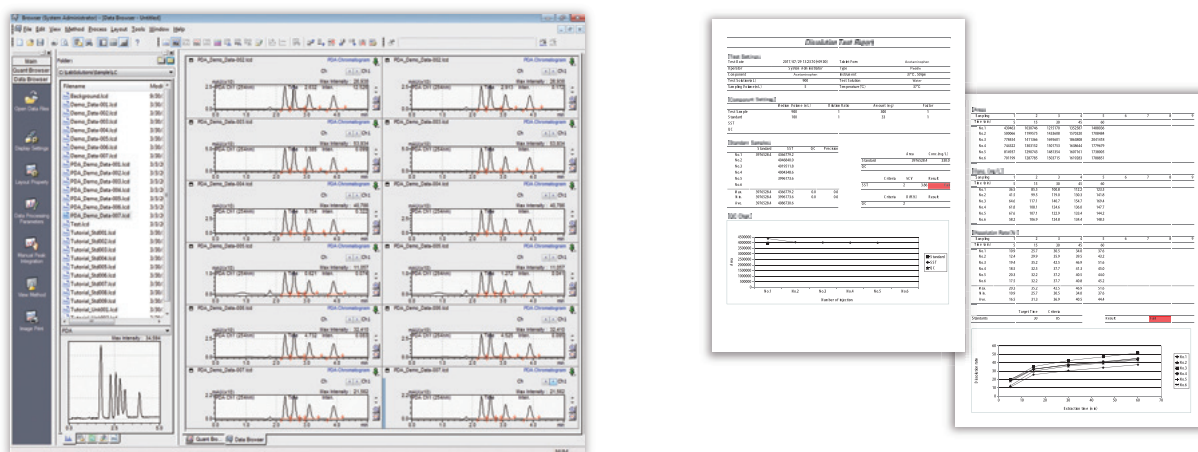
button to automatically generate a batch schedule in LabSolutions software so that testing can start. In dissolution tests performed with the Nexera FV, preparation time is minimal.



Rapid Confirmation of Test Results and Automatic Generation of Reports

The browser function built into LabSolutions is convenient for assessing changes in the chromatogram over time. Multiple data sets can be displayed simultaneously in a single window, so the data can be compared at a glance. In addition, the creation of reports can be

completely automated with the multi-data report function. When the test finishes, a result table, pivot graphs, and test pass/fail judgments for each component are created automatically, so the test results can be rapidly confirmed.





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