

Selecting the Optimal Water Quality for Dissolution Testing

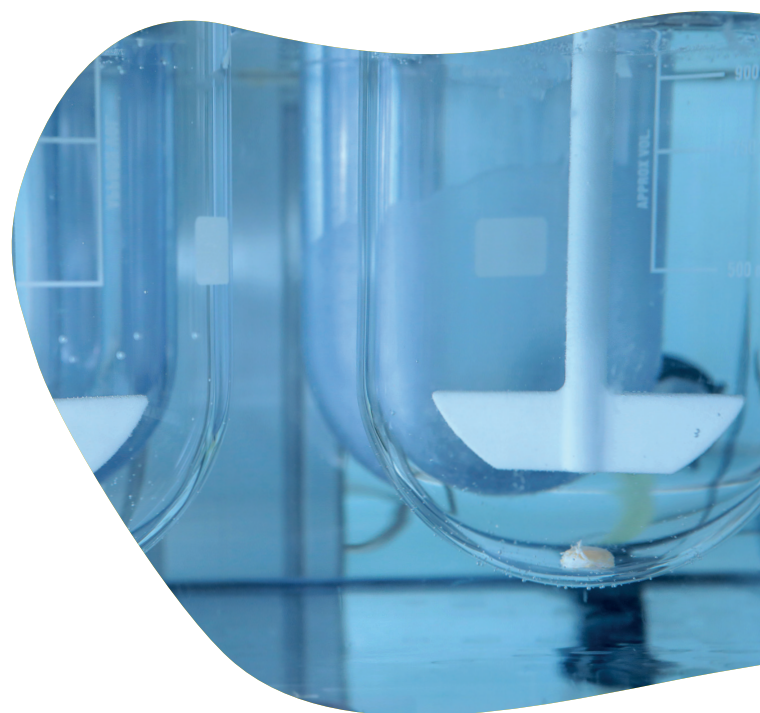
Dissolution testing, described in several Pharmacopeia and in FDA guidelines, is used in many steps of the drug development and manufacturing process, from the development of new formulations to quality control of products. These tests provide key information about the *in vitro* release of a drug's active pharmaceutical ingredient(s) (API) from the dosage form, such as a tablet or a capsule, under physiological conditions.

Purified water is an important ingredient for the preparation of dissolution media or biorelevant solutions, and the correct quality water can help to ensure reliable results. If the correct quality water is not selected, contaminants could impact test results:

- **Ions** may affect the pH or salt concentration of the media, thereby affecting the dissolution process. For this reason, pure water with low conductivity should be used.
- Using water free of **particles** and **bacteria** will ensure they won't interfere with the dissolution process, or deposit in sampling lines (if automation is used), eventually clogging them.
- **Gases** dissolved in the water used to prepare media may interfere with the dissolution process and should be kept to a minimum.
- **Organics** may interact with the API or the excipients and should be low.

Using high-quality purified water to prepare dissolution media is an important factor in obtaining accurate and reproducible results and meeting regulatory guidelines.

The Milli-Q® IX water purification system delivers consistent-quality pure water that answers the specific requirements of dissolution testing. Pure water delivered by this system can not only be used to prepare dissolution media, but also to rinse vessels and in thermostated water baths.



Advance your Purpose

With the Milli-Q® IX 7003/05/10/15

Pure Water System

Increase Lab Productivity

- Easy to use and maintain
- Smart touchscreen interactions
- Ergonomic dispensing options

Assure quality as you dispense

- Constant, reliable pure water quality
- Continuous quality monitoring
- Pure water quality meets Pharmacopeia and ISO® requirements

Simplify traceability

- Automatic e-record archiving
- Paperless data management
- Support audit preparation



Water quality specifications

Pure, Type 2 water specifications¹

Resistivity at 25 °C ²	>5 MΩ·cm; typically 10–15 MΩ·cm
Conductivity at 25 °C	0.2 µS/cm; typically 0.1 µS/cm
TOC	≤30 ppb
Production flow rate	3 L/h (Milli-Q® IX 7003) 5 L/h (Milli-Q® IX 7005) 10 L/h (Milli-Q® IX 7010) 15 L/h (Milli-Q® IX 7015)

From an E-POD® dispenser with final filter, the following water quality specifications are achieved:¹

Particulates ³	No particles with size >0.22 µm
Bacteria ⁴	≤10 cfu/L
Pyrogens (endotoxins) ⁵	<0.001 EU/mL
RNases ⁶	<1 pg/mL
DNases ⁶	<5 pg/mL
Proteases ⁶	<0.15 µg/mL
Flow rate	Up to 2 L/min

1. These values are typical and may vary depending on the nature and concentration of contaminants in the feed water.
2. Resistivity can also be displayed non-temperature-compensated as required by USP.
3. With Millipak® or Millipak® Gold filter.
4. With Millipak® or Millipak® Gold filters or Biopak® polisher when installed and used in a laminar flow hood.
5. With Biopak® polisher when installed and used in a laminar flow hood.
6. With Biopak® polisher.



Design that supports your sustainability initiatives.

For more information, contact your local Milli-Q® expert or visit SigmaAldrich.com/Milli-Q-IX

