

Dissolution Testing



Dissolution testing is a method to determine the drug release over time of a formulation product in an in vitro environment. The USP requirements include both automated and manual techniques with corresponding instrumentation configurations. The illustration below represents a basic configuration showing (1) a pump arrangement for programmed emptying, washing and refilling dissolution vessels and (2) a pump for sample delivery and dispensing.

Fractions are taken via a sampling probe at timed intervals and delivered to fraction vials or on line flow cells before being analyzed by a spectrophotometer or HPLC. Either a peristaltic or piston pump is used typically to dispense sample material to its respective vial.

Selection of the type of pump to be used depends on the method of filling the vessels and collection of samples. For automated operation, vessels can be filled, emptied and washed using a peristaltic or gear pump as shown in the illustration. Consideration must be made for volume accuracy and precision along with proper tubing material selection.

For sample collection, an alternate approach is to over-fill the collection vials and then aspirate the excess fluid until the desired volume is achieved. In this case a peristaltic pump may be used to provide simultaneous sample delivery to the vials. While syringe pumps have been tried for this application, they require filling time and the interruption of flow during the fill cycle.

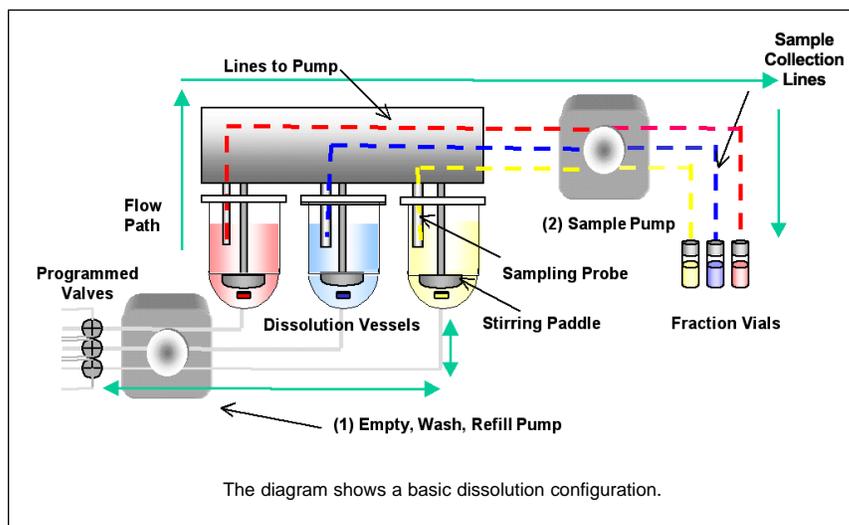
Advantages of a Micropump Positive Displacement Pump

- Continuous pulse-free flow
- Precise delivery of sample volumes
- Small package size
- Low vibration
- Multi-channel programmable capability

Common Pumping Requirements

When selecting a pump consider the following factors:

- Number of vessels (and vessel volume) to be analyzed
- USP method to be used
- On-line or off-line analysis
- Level of automation and control
- Method of filling, emptying and washing of dissolution vessels



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System Configuration Variations

Another configuration would require the use of switching valves. In this case media from the vessels continually circulates through the respective switching valve prior to returning to the vessel. At preset time intervals, the valves open, diverting a measured volume of sample to the sample collection line and to the respective vial. For optimum accuracy, a multi-channel peristaltic or piston pump would be recommended for this method. The following illustration shows a flow path for the switching valve method.

For continuous sampling through flow-through cells, either a piston or peristaltic pump may be employed. This method requires a cell changing mechanism to move each cell into the light path where the absorbance of each sample is analyzed. These measurements are done over predetermined intervals. It is important, therefore, that the flow be virtually pulse-free and constant. The accuracy of the analysis will, indeed, depend on the accuracy and precision of the flow rate.

Pumping Technology

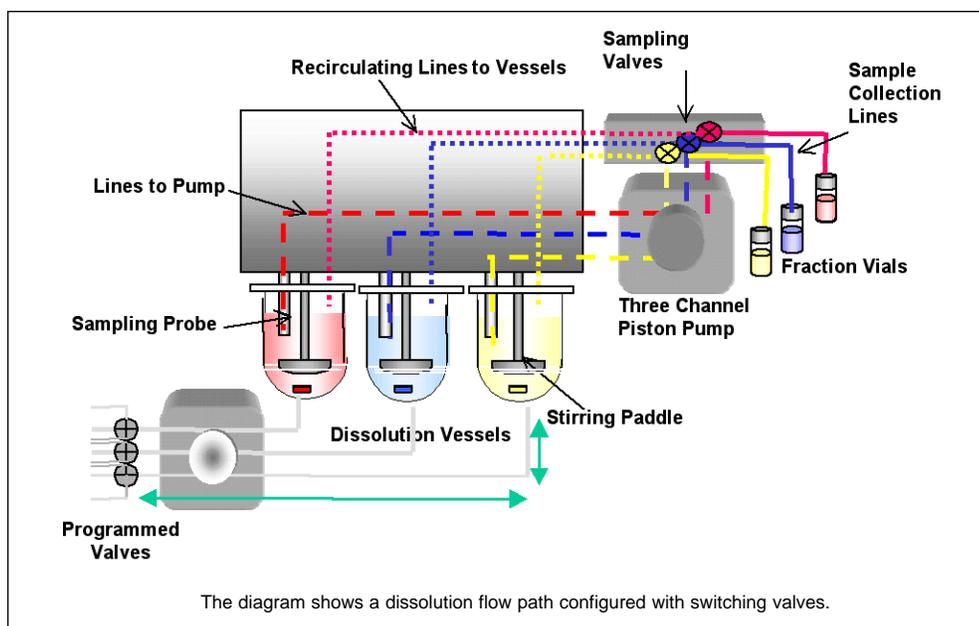
Manufacturers of dissolution apparatus will find an array of pump choices from Micropump.

An external gear or peristaltic pump are options for (1) Empty, Wash, Refill Pump:

- Series GA (180)
- Series GJ (120)
- Peristaltic pump model dependent on pumping requirements

A piston, peristaltic or micro annular gear pump are options for (2) Sample Pump:

- Series Delta multiple piston pump
- Peristaltic pump model dependent on exact pumping requirements
- Micro annular gear pump model dependent on exact pumping requirements



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