DISSOLUTION ACCESSORIES



SAMPLING CANNULAE



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Dissolution Sampling

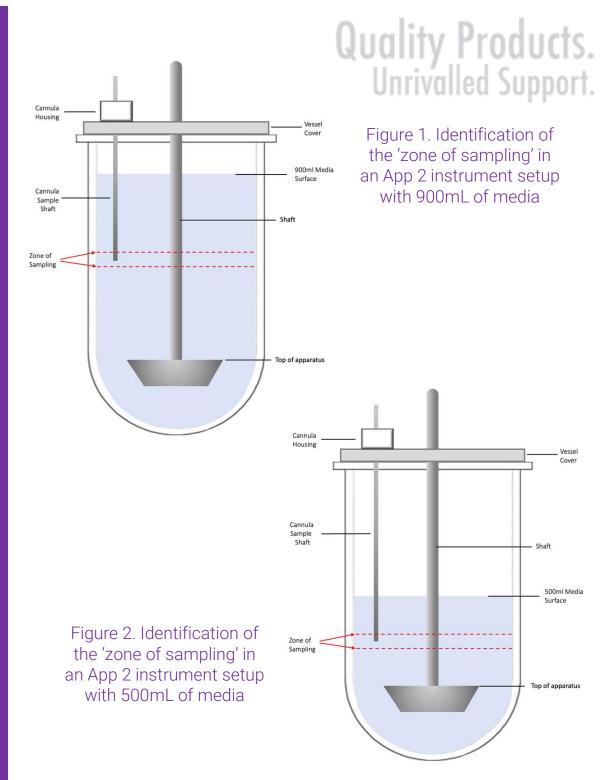
Sampling is one of the most critical aspects of the dissolution test, and also an aspect that is often overlooked.

Robust, well documented and well executed dissolution sampling practices will help to produce reliable, reproducible dissolution results.

Sample timing, and the position in the vessel from which the sample is to be withdrawn (also known as the 'zone of sampling' are defined in USP Chapter <711>:

'Within the time interval specified, or at each of the times stated, withdraw a specimen from a zone midway between the surface of the Dissolution Medium and the top of the rotating basket or blade, not less than 1 cm from the vessel wall.'

'Specimens are to be withdrawn only at the stated times within a tolerance of ±2%.'



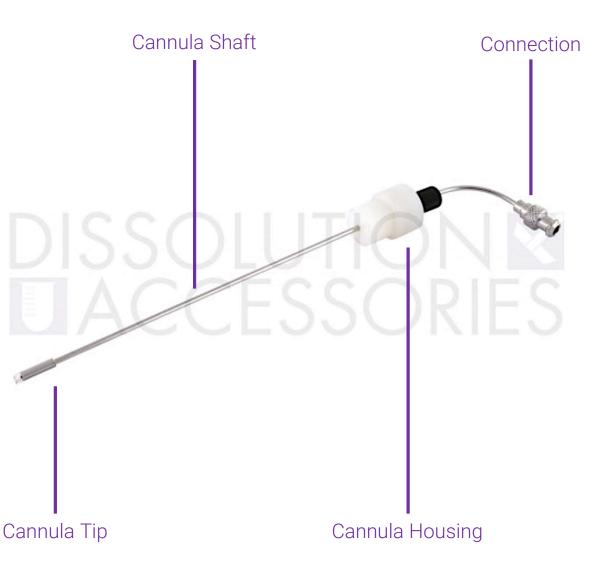


Dissolution Sampling

As sampling procedures need to be reliable and repeatable to conform with the guidance set in USP Chapter <711>, and to give robust dissolution results, many variables must be considered when selecting an appropriate sampling cannula:

- Dissolution Test Volume
 - Affects the length of cannula required
- Dissolution Apparatus Type
 - Affects the length of cannula required
- Dissolution Tester Type
 - Affects the length of cannula required
 - Affects the type of cannula housing required
- Sampling Filter Type
 - Affects the diameter of the cannula shaft
 - Affects the type of cannula housing required
- Material
 - Affects the type of cannula shaft required
 - Affects the type of cannula housing required
- Connection
 - Affects the cannula housing type required







Sampling Cannula Length

The required length of the cannula will be determined by the following factors:

• Dissolution test volume

As the apparatus depth is fixed, the volume of media in the vessel will alter the height of the midway zone. Larger volumes therefore result in shorter probe lengths.

• Dissolution test apparatus type

Apparatus depth is fixed, but the apparatus itself varies in length, altering the height if the midway zone.

• Vessel size

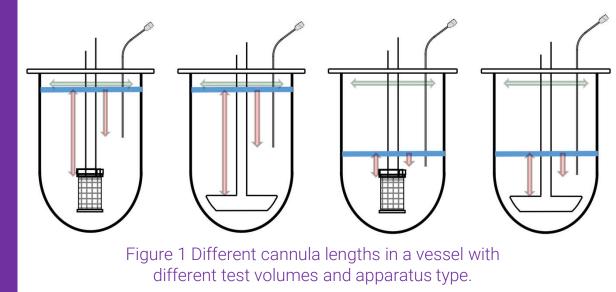
Using alternate vessels such as small volume and 2000ml, will alter the height of the midway zone.

• Dissolution tester type (Open or Closed)

This will affect cannula length as in Open systems, the cannula will fit into ports in the vessel cover, which is placed directly on the vessel. In Closed systems, the cannula must pass through the entire drive head, greatly increasing the cannula length required.



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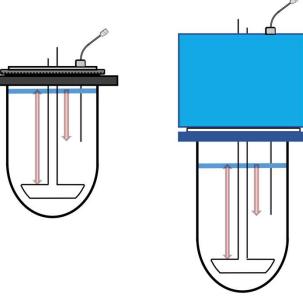


Figure 2 Different cannula lengths in different tester types, open (L) and closed (R).

Cannula Sampling Shaft Diameter

The two most common diameters of cannula sampling shaft are 1/8" OD (1/16" ID) and 1/16" OD (1/32" ID).

The cannula sampling shaft diameter will be determined by the following factors:

Required filter type

If a cannula filter tip is required, these are most commonly available for 1/8"OD sampling shafts. Whilst some filter tips are available for 1/16"OD sampling shafts, the range is limited.

If an in-line disc filter is required, this probe housing is usually available only with a 1/6"OD sampling shaft. If syringe filters are required, filtration typically occurs after separately to sample withdrawal, so the sampling shaft OD is irrelevant.

Impact on fluid dynamics

Cannulas with thinner sampling shafts create less disturbance to natural fluid dynamics of the vessel. If this is an area of concern, 1/16" OD cannula should be used.

Requirement for a smaller dead volume

If smaller dead volumes are required, sampling shafts with smaller ID's should be used.



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Figure 1. 1/8" OD cannula (without housing). Can be used with filter tips or filtration via syringe filter. 900mL.



Figure 2. 1/16" OD cannula with two-piece housing to accommodate an in-line filter disc. 900mL



Figure 3. 1/16" OD cannula shaft with 1/8" tip for use with filter tips. Unique to Dissolution Accessories 900mL

Cannula Materials

Most sampling cannulae consist of a 316 Stainless Steel shaft, and plastic housing or stopper.

If your sample cannot be exposed to any plastic containing materials, then you can purchase a Stainless Steel cannula that can be combined with a plastic stopper that slides over the outside of the shaft, preventing your sample from plastic exposure.

If your sample cannot be exposed to any metals, then you can purchase sampling cannulae with PEEK sampling shafts instead of Stainless Steel. These can be combined with a polypropylene in-line probe housing, or as a direct cannula that can be combined with a plastic stopper that slides over the outside of the shaft, preventing your sample from exposure to the polypropylene as well.

PEEK sampling cannula are available with both 1/8" and 1/16" outer diameters, and with suitable housings to permit use with cannula tip, in-line disc and syringe filtration.



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Figure 1. 316 SS cannula



Figure 2. 316 SS cannula with slide-over plastic housing



Figure 3. Direct PEEK cannula



Figure 4. PEEK cannula with plastic housing

Cannula Housing

The cannula housing (also known as the stopper) is essential for securely locating the sampling cannula in the dissolution vessel.

Various different stopper shapes and sizes are required and available for different models of dissolution tester, different vessel cover types, and different sampling shaft diameters.

Cannula housings are also available as a single, solid piece, or as a two-piece with a chamber than can accommodate an in-line disc filter, as well as a cannula tip style filter.

Adjustable cannula housings are also available, and permit the housing to be moved up and down the sampling shaft to alter the length of the portion of the sampling shaft that sits within the vessel. This allows one set of probes to be used for multiple media volumes, though accurate adjustment is required every time and must be verified.



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Figure 1. Examples of different cannula housing types. Clockwise from top left: Adjustable housing suitable for Distek covers. Adjustable housing suitable for Vankel / Varian covers. Adjustable housing suitable for Sotax systems. Upper portion of a two-piece housing with the filter disc chamber visible, suitable for Distek sampling cannulas. Complete in-line housing assembly suitable for use with filter discs. Adjustable housing suitable for use with Hanson Vision series covers.

Connectors and Adapters

The complete sampling cannula needs to connect to either a syringe for manual sampling, or to an auto sampler line for automated sampling.

Most cannulas connect via a luer / luer lock system, or via ¼-28 UNF thread, though there are some exceptions for certain auto samplers and sampling manifolds.

A range of connectors and adapters are available to permit the connection of any probe to any syringe, auto-sampler or sampling manifold. Different connectors and adapters can be combined to achieve this.



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Figure 1. Examples of different cannula connectors. Clockwise from top left: Threaded union for two ¼-28 UNF threads. ¼-28 UNF threaded nut to pass over an auto sampler line. 1/24-28 UNF thread to female luer adapter. ¼-28 UNF thread to male luer lock adapter. Male luer lock adapter to barbed fitting. Push fit luer elbow.

Sampling Cannula Advice

Use a different sampling cannula for each dissolution position.

Remove all filters at the end of each dissolution test.

Clean and dry the sampling cannulae at the end of each run.

Store them safely to ensure they do not become bent or damaged.

Check them regularly for blockages damage. Replace and clear as required.

Ensure you have the correct length, material and probe type for the dissolution test conditions being used.

Ensure that the sampling cannula fit snugly into their respective receptables in your dissolution tester or vessel covers.



<u>Do Not</u>

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 \mathbf{X} Use aggressive cleaning reagents, acids or solvents on sampling cannulae.

 \mathbf{X} Leave filters on or in the sampling cannulae after use.

 $\pmb{\times}$ Use sharp implements to remove filters from within the probe housing.

 $\pmb{\times}$ Leave them in cleaning solution or store them in water.

 \mathbf{X} Wash them in a laboratory dishwasher.

 \mathbf{X} Use the same sampling cannula to sample multiple positions without cleaning it between samples.

 \mathbf{X} Bend or adapt the sampling cannula to make it fit a particular dissolution configuration.

 $\pmb{\times}$ Use PTFE tape or adhesive to connect probes and adapters together.

Dissolution Accessories are available in the UK exclusively from Omicron

You can view the entire Dissolution Accessories range, online at

https://www.dissolutionaccessories.com/en/

If you would like a catalogue sent out, or for any quotations, enquiries or product information, please contact us via one of the following:

Web: https://www.omicron-uk.com/contact (Live Chat Available)

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