

# DISSOLUTION ✓ ACCESSORIES



## VESSELS

## Dissolution Vessels

Dissolution vessels are considered one of the most critical components of the dissolution tester, and must be considered as a precision part.

Numerous studies have shown the significant impact that vessels have on both the dissolution rate and final dissolution result

All vessels should be both serialized and certified, either by the manufacturer or by an internal procedure, and maintained in their designated position, and orientation, in the dissolution tester.

In addition to the 'standard' 1 Litre vessel specified in the USP Chapter <711> for use with USP dissolution apparatus 1, 2, 5 and 6, a wide variety of different sizes, coatings and configurations are also commonly used by solid dose scientists.



## 1 Litre Vessels

The 1000mL vessel is the standard vessel used for dissolution.

Its' dimensions are specified in the USP:

Vessel Height: 160mm - 210mm.

Inside Diameter: 98mm -106mm

Smooth, Hemispherical Bottom

1000mL vessels are usually of clear glass, but may be made from an alternative inert, transparent material, as specified in USP Chapter <711>.

The top flange of the vessel can vary as different dissolution tester manufacturers and models have different mechanisms to secure the vessels to the vessel plate.

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Smooth, hemispherical bottom



Vessels with alternative flange types

## Alternative Coatings and Materials

Vessels are usually constructed from glass, but can also be made from clear plastic. Although cheaper to purchase, plastic vessels are not as robust, and have a much lower thermal transmission rate between the water bath or heater jacket and dissolution media.

Instead, glass vessels can be coated to provide additional protection or to combat specific challenges encountered with a specific dosage form. The most common coatings are:

- Amber – used for photosensitive compounds as it reduces the amount of light penetrating the vessel. It should be used with a darkened vessel cover
- PTFE – used to prevent the dosage form sticking to the vessels for formulations where this is a known issue

Most vessels are available with amber or PTFE coatings

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## Vessel Sizes and Volumes

Vessels are available in a range of different sizes and volumes, depending on your methodology.

As well as the 1000mL vessel, they are also available in the following sizes:

- 100mL for Small Volume Apparatus
- 150mL for Small Volume Apparatus
- 200mL for Small Volume Apparatus
- 250mL for Chinese Small Volume Apparatus
- 500mL for standard sized apparatus
- 2000mL for standard sized apparatus
- 4000ml for standard sized apparatus

Dissolutions requiring 500mL of media are more commonly performed in 1000mL vessels.

1000mL, 2000mL and 4000ml are the only vessel volumes with specific definition Chapter <711>.

All other vessel sizes are considered non-compendial but small volume vessels (particularly 100mL and 200mL) are increasingly used, and relatively standardised.

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100mL and 200mL Vessels



500mL Vessel



1000mL Vessel



2000mL Vessel



4000mL Vessel

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## Alternative Vessel Shapes

USP Chapter <711> defines the dissolution vessel as having a smooth, hemispherical bottom, but this is not suitable for all applications.

For methods in which the dosage unit cones when disintegrates, a Peak or Apex vessel can be used. This vessel type has a small concave peak in the bottom to prevent cone formation. This vessel type often requires justification for use, but is becoming increasingly accepted in the industry.

For other applications such as paddle-over-disc intrinsic dissolution, and the dissolution of topical ointments and gels delivered using an immersion cell, enhancer cell of cup, semi-flat or flat-bottomed vessels are sometimes used to assist with dosage introduction and positioning reproducibility.

These vessels are also available with amber and PFTE coatings.





# High Precision Vessels

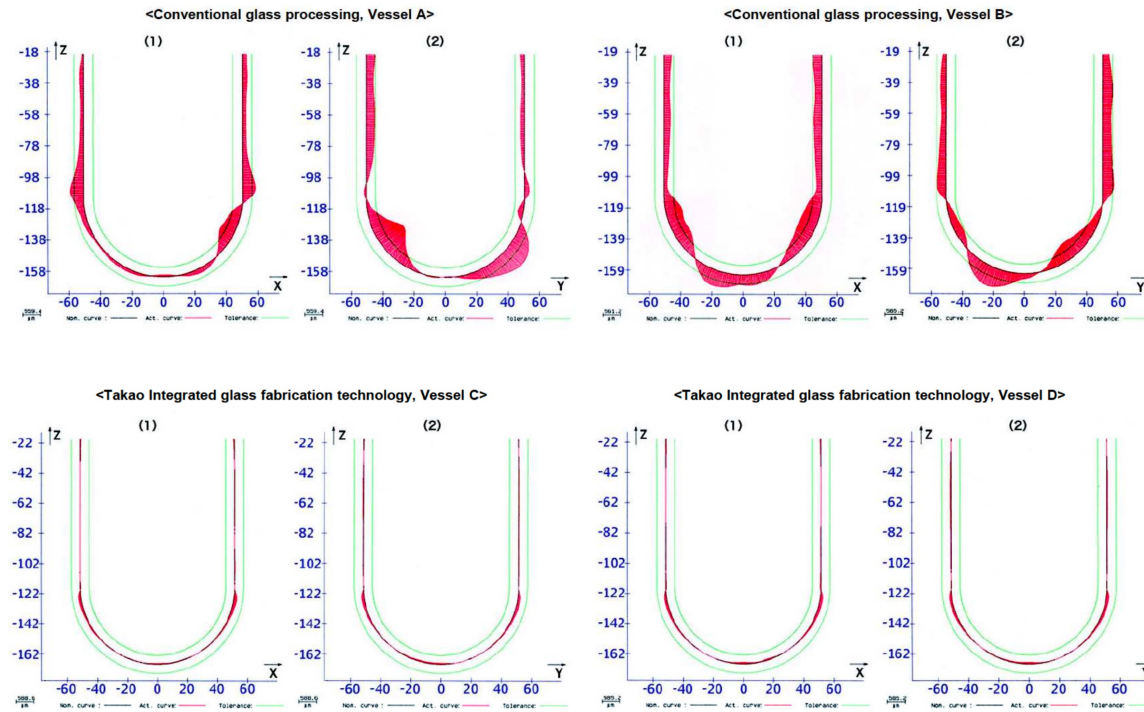
All Dissolution Accessories vessels are compliant with the relevant regulatory and pharmacopeial requirements (where they apply), and supplied with a certificate of compliance.

However, the tolerated variance in standard vessels, although compliant, can still significantly contribute to variations in the dissolution release rate and result.

For more sensitive methods, High Precision vessels are available. These are the highest specification vessels, with precise sphericity, circularity, concentricity of inner surface, vertical centre and uniform geometry. This in turn reduces variations in dissolution results, increasing reproducibility and increasing the discrimination between dosage units during dissolution.

As a result, it can also help optimise conditions to pass the USP PVT (Performance Verification Test) at Stage 1.

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Comparison of deviation from the ideal interior form of the vessel between the two kinds of glass vessels manufactured by conventional glass processing and an integrated fabrication technology. The centre line between the two green lines indicates the ideal interior form of the vessel. The red zone indicates the actual deviation of the interior form of the vessel from its ideal interior form. The green lines indicate the ideal interior form  $\pm 0.3\text{mm}$ . Each right figure (2) indicates the result of the determination at an angle of  $90^\circ$  from the left figure (1). Each determination was carried out by utilizing a three-dimensional coordinate measuring machine (Brown & Sharpe, PMM-C700P).

## Vessel Cleaning

Vessels should be thoroughly cleaned after each dissolution test.

As a basic guide, they should be cleaned as follows:

1. Carefully remove the vessel from the dissolution tester.
2. Dispose of the vessel contents safely and responsibly.
3. Clean first using soap and warm water.
4. Then rinse in high purity or deionised water.
5. Finally, rinse with alcohol before drying.
6. Place the clean, dry vessel back into the dissolution tester in the correct position and orientation.

Soft, non-abrasive cleaning tools such as sponges, soft brushes and non-scratch scourers can be used.

Additional caution must be employed when cleaning vessels with coatings such as PTFE and Amber, as the coatings are less resilient to scratching.

## Do Not

- ✗ Use aggressive cleaning reagents, acids or solvents on vessels, particularly if they have coatings.
- ✗ Use abrasive cleaning tools such as hard scouring pads, wire wool and stiff brushes as this will result in the vessels becoming scratched and etched.
- ✗ Rinse with water that has not been deionised or purified.
- ✗ Place vessels back into the dissolution tester without drying first. Drying vessels in place can place additional strain on the vessel flange, causing to crack or knock against the vessel support plate and chip.
- ✗ Wash them in a laboratory dishwasher unless it is absolutely necessary, and then only once a thorough evaluation has been performed on the impact on the vessel of doing this.



## Vessel Checks

Prior to the start of each dissolution, the following checks should be made:

- The vessel is clean, and free of residue.
- The vessel body does not have any scratching, etching, pitting or cracks.
- The vessel flange does not have any cracks or chips – these can affect how securely it attaches to the vessel plate and are also a safety risk when handling the vessel.
- If the vessel has a coating, check to ensure it is in good condition, free of nicks, cracks and tears.
- The vessel is the correct size and type.
- The serial number is correct and that it is installed in the correct position in the tester.
- It is in the correct orientation.
- The vessel retention assemblies are in good order, and are securely holding the vessel in place, and firmly to the vessel support plate.

## Vessel Tips

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- ✓ When handling vessels, always hold them with two hands; one supporting the hemispherical bottom and one the flange.
- ✓ During cleaning, take care not to knock the vessel on any hard surface, and place it on a soft surface (towel or cloth) when placing it down during the cleaning process.
- ✓ Complete the cleaning cycle for one vessel before moving to the next.
- ✓ When the dissolution tester is not in use, keep the vessels covered to prevent the ingress of dust and dirt.
- ✓ When changing between apparatus types, either remove the vessel or ensure it is covered. This will prevent the vessel from being broken in the event a part of the apparatus is dropped.
- ✓ If you have different sets of vessels for your dissolution tester, ensure they are all inspected as part of any external PM or OQ procedure each time the system is serviced.

# 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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