

# DISSOLUTION ACCESSORIES



## BASKETS

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## Dissolution Baskets

Dissolution basket apparatus should be used for dissolution testing of tablets, capsules, beads and granules.

Basket apparatus is particularly useful for:

- Dosages that float
- Dosages that are prone to coning
- Dissolutions where a media change is required

Non-compendial basket apparatus is also available for dissolution testing of large dosage forms and suppositories.

All basket apparatus, except for the Palmeri basket, are manufactured from Stainless Steel. All baskets are serialized and supplied with a certificate.

Gold and PTFE coated baskets are also available for most basket types, as well as a range of mesh sizes.

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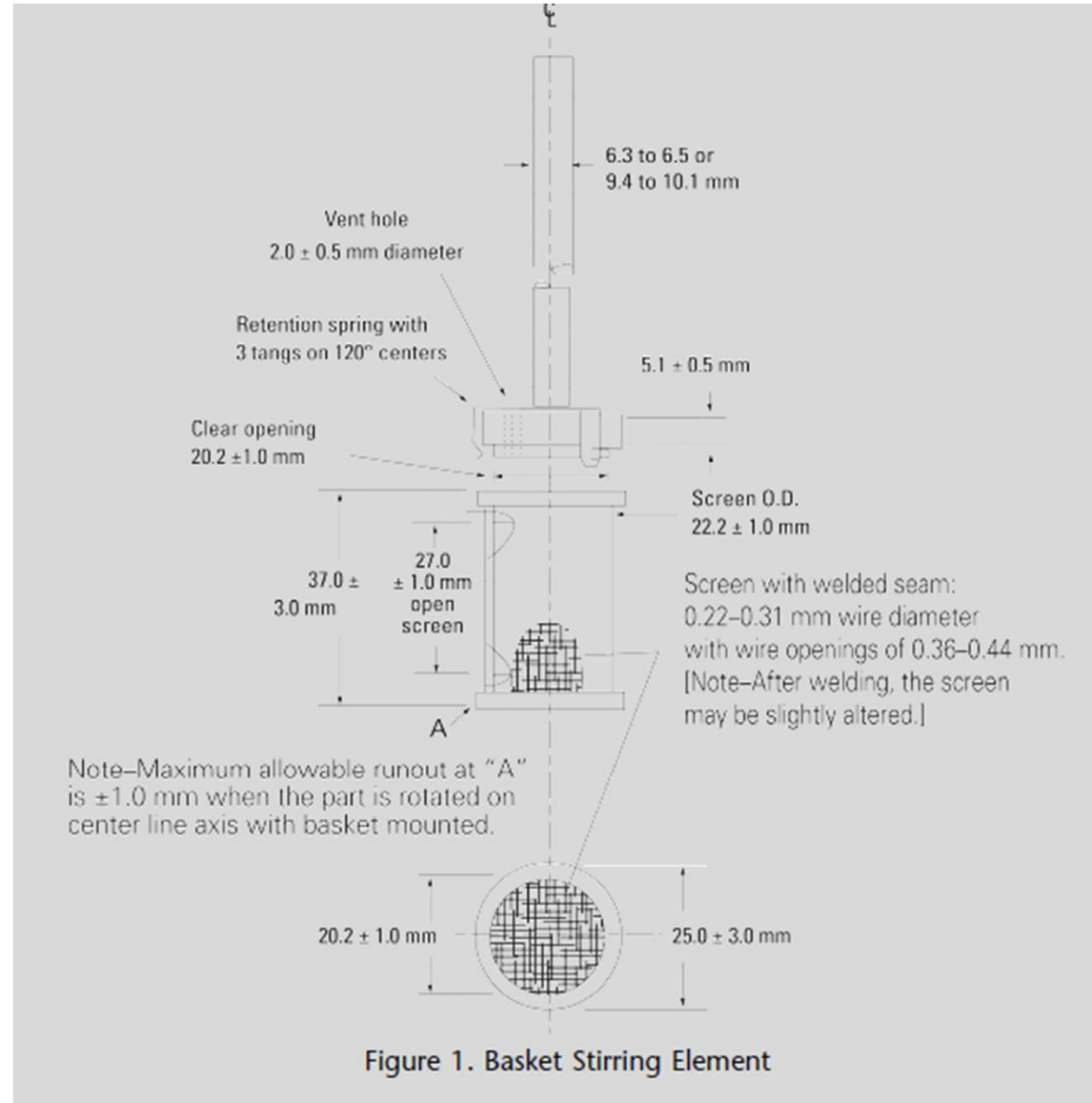
## USP Apparatus 1

USP Apparatus I are the most common basket apparatus; this basket has a clearly defined specification to ensure consistency and compliance.

USP Chapter <711> specifies that Apparatus I should be made of Stainless Steel type 316, or other inert material. A gold coating of about  $2.5\mu\text{m}$  thick or PTFE coating is also permitted. The basket should have 40 mesh (wire openings of  $0.36 - 0.44\text{mm}$ ) and comply with the dimensions in the diagram included in USP Chapter <711>.

The dissolution tester should be set up so the distance between the inside bottom of the basket and the bottom of the holder is maintained at  $25 \pm 2\text{ mm}$  during the test. The dosage is placed in a dry basket at the beginning of each test.

Spring clips or O-rings are used to retain the basket on the holder for the duration of the test. These should be regularly checked for integrity to ensure a secure fit for the duration of the test.



## Basket Hubs/Adaptors

Aside from the basket itself, the other key component of USP Apparatus I is the attachment site on the dissolution shaft, often referred to as the basket hub or adaptor. Depending on the dissolution bath manufacturer, these can either be a separate part that screws on to the base of the shaft or can be fused to the shaft itself.

There are 2 styles of basket attachment:

- Retention springs – 3 springs spaced 120° apart
- Push-on o-ring

Retention springs can also be added to push-on o-ring adaptors for additional security.

Basket adaptors are also made from Stainless Steel. If coated baskets are to be used, the adaptors should also have the same coating.

The basket adaptor should have a vent hole to prevent air bubbles inside the basket. This should measure 2mm diameter (+/- 0.5mm) to comply with USP Chapter <711>.

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# Non-Compndial Basket Apparatus

## Palmeri Baskets

The Palmeri basket is designed for testing oil-based suppositories, the base of these formulations is known to block the mesh of a standard 40 mesh basket apparatus, giving unreproducible results. The basket is designed to fit a standard USP Apparatus I adaptor and has the same dimensions as USP Apparatus I, however instead it is made of an inert plastic with 12 linear slots. This provides approximately 50% porosity which is close to that of a 10 mesh basket.

## Long Baskets

These 40 mesh baskets are the same diameter as a standard basket but are an extended length (65mm). They are designed to hold large dosage forms that will not fit in a standard USP I basket.

## Miniature Baskets

A scaled-down basket apparatus designed to fit a small volume kit with 100ml or 200ml vessels for small volume dissolution testing.

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## Mesh Sizes

For some formulations it may be necessary to use a non-standard mesh size. Although only 40 mesh is specified as USP compliant, using a different mesh size is justifiable in some cases.

- The mesh number refers to the number of openings per linear inch, therefore the finer the mesh the higher the number.
- Baskets are available in mesh sizes from 10 mesh up to 400 mesh.
- Fine mesh is supported by a 20 mesh outer layer for added structure and protection.
- Baskets of  $\leq 40$  mesh size can be supplied with gold or PTFE coating. Finer mesh sizes cannot be coated as the coating will block the mesh openings.

A wider mesh size should be considering if the formulation clogs the basket holes during the dissolution, impacting the release rate.

A finer mesh size should be considered if particles freely fall through the basket during the disintegration stage. Again, skewing the results for the release profile.



10 Mesh



20 Mesh



40 Mesh



80 Mesh



100 Mesh



140 Mesh



150 Mesh



200 Mesh



400 Mesh

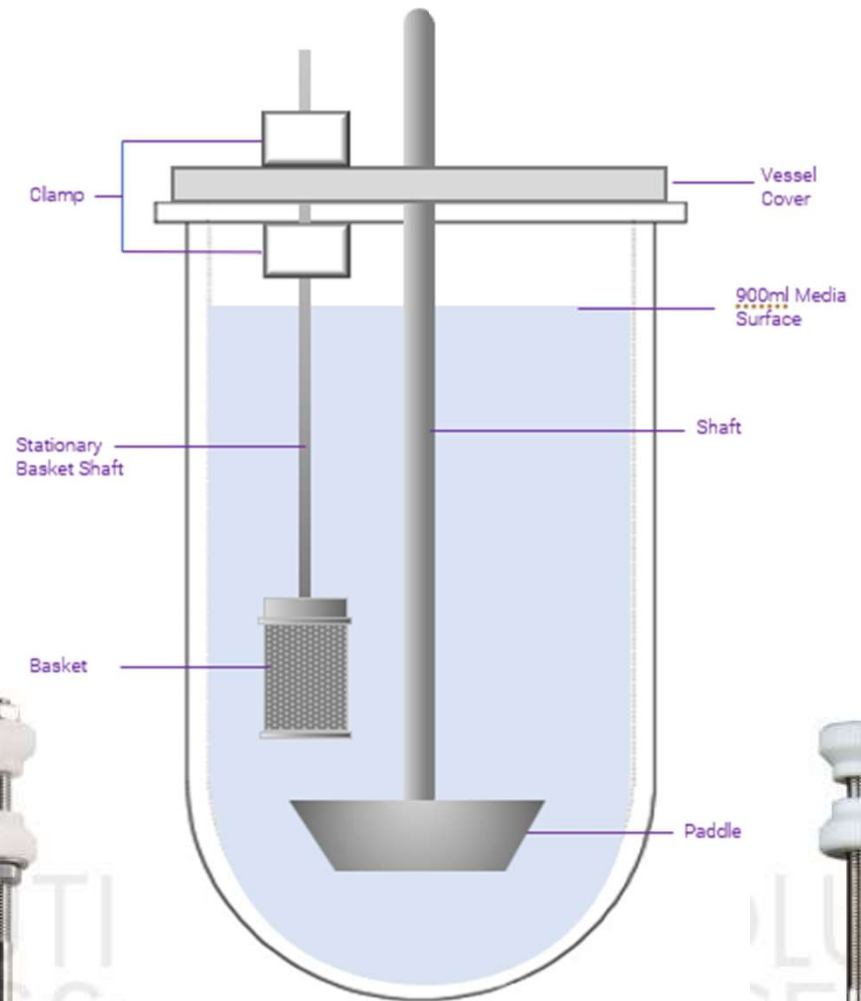
## Stationary Baskets

The Stationary Basket is a possible solution for formulations which may be prone to the usual traits requiring basket apparatus; coning, floating, sticking or swelling, but where the increased hydrodynamics of a paddle is also beneficial.

Sinkers may also be used to solve similar issues but sometimes the movement of the sinker in the vessel can contribute to variability in the results.

Stationary basket apparatus is a fixed shaft that is held in position next to rotating paddle (USP Apparatus II). Any basket with USP dimensions with any mesh size or coating is compatible with the stationary basket shaft.

A defined example is the USP Monograph for Felodipine Extended Release Tablets. This has a specific design of Stationary Basket featuring a fixed shaft with a square basket which is fused diagonally to the shaft and has a cover placed inside the horizontal diagonal of the basket.



Felodipine Stationary Basket



Stationary Basket Shaft

## Basket Accessories

### **Go-NoGo Gauge**

Each Basket should be checked for damage and USP compliance before each dissolution test. The Go-NoGo gauge is a simple device which checks the basket height, I.D. and O.D. of the top and bottom rings. It also allows for an easy check of the cylindrical symmetry of the basket, ensures that there are no dents in the baskets and gently reshapes minor defects.

### **Basket Attachment Tool**

This tool makes it easy to firmly grip baskets without causing any damage while attaching and removing baskets from the shaft.

### **Basket Storage**

Stackable storage trays are available to keep baskets safe from damage when not in use. These are compatible with all USP baskets, XL and Palmeri baskets.

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## Basket Cleaning

Baskets should be thoroughly cleaned after each dissolution test and fully dry before the next use.

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

1. Carefully remove the basket from the basket adaptor, handling it by the upper and lower ring.
2. Check the inside of the basket and record any observations of any remaining dosage.
3. Check the basket adaptors for residue, including the vent hole, rinse with deionised water and dry.
4. Place baskets in a beaker of warm water to remove any remaining solids, dispose of rinse liquid safely and responsibly.
5. Rinse baskets under the tap and then with deionised water.
6. Rinse with alcohol and leave to dry on a drying rack or in an oven.

For sticky formulations it may be necessary to place the baskets in a beaker of water and place in an ultrasonic bath before continuing with Steps 5-6.

## Do Not

✘ Twist, squeeze or squash the baskets when removing from the shaft as this will misshape the basket and damage the mesh.

✘ Use sharp tools such as metal tweezers or spatulas to remove residue from the basket, this could damage the mesh.

✘ Leave residue to dry inside the basket before cleaning.

✘ Use baskets that are not fully dry.

✘ Forget about the basket adaptors on the shaft! Usually these will only need rinse but certain formulations such as capsules or coated products can leave sticky residue which will require more intensive cleaning.

✘ Wash them in a laboratory dishwasher unless it is absolutely necessary, and then only once a thorough evaluation has been performed.

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## Basket Checks

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

- The basket is clean, dry and free of residue.
- The basket mesh is not damaged.
- The basket sides are straight and at a right-angle to the base and top rings.
- If the basket has a coating, check to ensure it is in good condition.
- The vent hole on the basket adaptor is not blocked.
- The o-ring and/or clips on the basket adaptor are not damaged.
- The basket is the correct type to fit the adaptor installed on the shaft.
- The serial number is correct for the corresponding position on the tester.
- Before attaching the basket, dry the adaptor.
- Ensure the adaptor is fitted securely before starting the test.
- Observe any air bubbles that may be present inside the basket after lowering into the media and record the observation.

## Basket Tips

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- When handling baskets, always hold them by the upper or lower rings, not the mesh sides.
- Store baskets in the original OEM packaging or on a basket rack to prevent damage when not in use.
- Only remove and clean one set of baskets at a time to keep the correct set with the correct dissolution tester.
- Keep a visible chart of which apparatus (serial number) belongs with which position. Provide labelled, designated positions for each basket in the storage packaging to make setting up a dissolution more efficient.
- When installing basket adaptors to shafts, either remove the vessel or ensure it is covered. This will prevent the vessel from being broken in the event the apparatus is dropped.
- If you have different sets of apparatus 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)

Email: [sales@omicron-uk.com](mailto:sales@omicron-uk.com)

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