

DISSOLUTION ACCESSORIES



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Dissolution Sinkers

Sinkers are used to adjust the buoyancy of a dosage form that would otherwise float. They can also be used to stop dosages sticking to the bottom of the vessel.

USP Chapter <711> states:

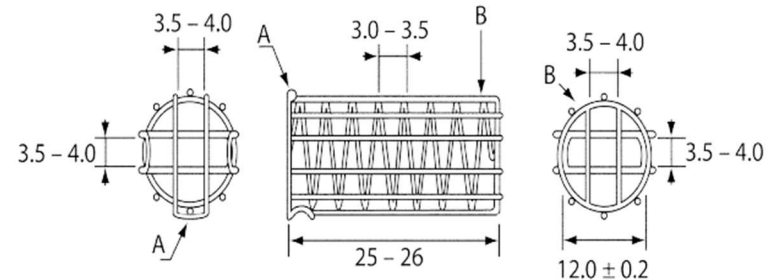
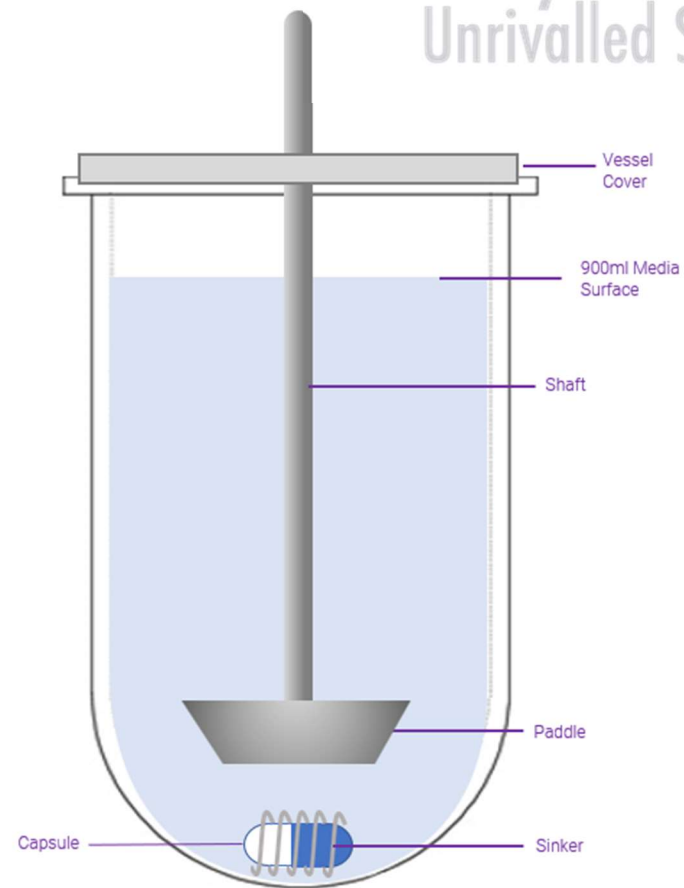
"A small, loose piece of non-reactive material, such as not more than a few turns of wire helix, may be attached to dosage units that would otherwise float. An alternative device is shown in Figure 2a. Other validated sinker devices may be used."

However, although possible, it is not always practical to make sinkers by hand as it can be difficult to maintain reproducibility. If the sinkers are not the same for each vessel this will impact the reproducibility of the dissolution results too.

Fortunately, there are also a wide range of commercially available options that will fit with the guidelines outlined in the USP chapter as well as non-compendial options too.



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A: Acid-resistant wire clasp

B: Acid-resistant wire support

Figure 2a. Alternative sinker. All dimensions are expressed in mm.

Types of Sinkers

Spiral

Available in different sizes and coils for different dosage sizes. The sinker can be made heavier by adding more turns to the helix. PTFE coated options are also available. This simple design of sinker fits the USP description of *"a small, loose piece of non-reactive material, such as not more than a few turns of wire helix."*

Cage and Basket

Available in a variety of sizes and mesh grades, this type of sinker does not grip the dosage but it is fully enclosed on all sides. The Japanese Pharmacopeia Basket sinker also complies with the specification of the Alternative Sinkers detailed in USP Chapter <711>.

Pronged

A 3-pronged longitudinal sinker available in stainless steel or plastic. These grip the dosage on the long edge rather than top and bottom, the sides are open so the dosage is easily released as it disintegrates. However, this type of sinker may provide insufficient sinking weight for low-fill capsules and lighter dosages.



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Types of Sinker

O-Ring

O-ring sinkers feature an expandable rubber ring which allows the capsule swell, while the stainless steel support provides weight for sinking with minimal contact with the dosage.



Time release

Intended for extended-release dosages, this type of sinker is designed to have minimal contact or coverage of the dosage. This is so it can be held in place at the bottom of the vessel but the extended-release mechanism will not be compromised.



Metformin

A rectangular basket-style sinker type for Metformin Extended-Release tablets complying with specific dimensions outlined in the USP monograph.



Pouch

Stainless steel mesh pouches allow more space for large dosages or dosages that swell while still keeping them at the bottom of the vessel. The finer mesh pouches can be used to contain powders or granules. Available in 20, 40, 60 and 100 mesh.



Selecting a Sinkers

The following points should be taken into consideration when selecting a sinker:

Surface contact: should be minimal between the dosage and the sinker

Weight: heavy enough to sink to the bottom of the vessel at the beginning of the test and does not move around the bottom of the vessel during the dissolution

Size: the sinker should be appropriate for the dosage form. Not too tight so that it restricts disintegration of the dosage. Not too loose so the dosage will escape or change orientation within the sinker

Coating: a sinker with PTFE coating maybe required for sticky dosages or those that may react with stainless steel.

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Additional considerations:

- If using capsules, they should be able to open freely within the sinker
- No part of the dosage should become trapped underneath or inside the sinker
- The shape should be defined in the procedure and be reproducible
- If sinkers are handmade, the material and construction procedure should be documented.
- It should be possible to reproduce dissolution results using the same sinkers specification under the same conditions.

Sinker Sizes

Selecting the correct size of sinker is important to ensure the dosage is held securely at the beginning of the test. However, it should not be too tight that disintegration is impeded, or the coating/capsule is damaged by the sinker.

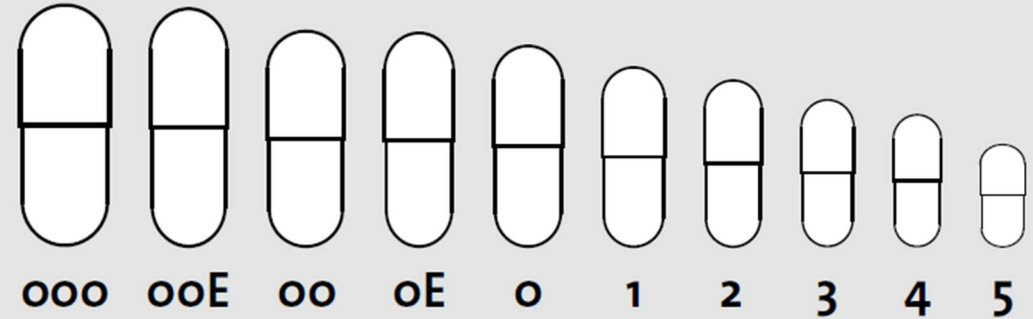
The sizes of sinker that are commercially available are designed around standard capsule sizes.

A comprehensive chart detailing the individual dimensions of all sinkers available in the Dissolution Accessories range is available in the Dissolution Accessories catalogue to make the selection process easier.

Contact Omicron using the details on the next page to receive your free copy of the Dissolution Accessories catalogue.

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Capsule Sizes



CAPSULES				
Capsule Size	Length		Diameter	
	(inches)	(mm)	(inches)	(mm)
000	1.029	26.1	0.390	9.91
00E	1.012	25.7	0.336	8.53
00	0.917	23.3	0.336	8.53
0E	0.909	23.1	0.301	7.65
0	0.854	21.7	0.301	7.65
1	0.765	19.4	0.272	6.91
2	0.709	18.0	0.250	6.35
3	0.626	15.9	0.229	5.83
4	0.563	14.3	0.209	5.32
5	0.437	11.1	0.193	4.91

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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