#### THE BASKET METHOD Apparatus 1

Adopted in 1970, the rotating basket method of dissolution testing was the first official method. It essentially consists of an approximately 1 inch (25.4mm) × 1 3/8 inch (34.925mm) stainless steel, 40 mesh wire basket rotated at a constant speed between 25 and 150rpm. This method is now called Apparatus 1 (or Method 1).

The apparatus consists of a metallic drive shaft connected to the cylindrical basket. The basket is positioned inside a vessel made of glass or other inert, transparent material (see page 20). The vessel contents are kept at a constant temperature by being placed inside a water bath or heating jacket. The solution in the vessel is stirred smoothly by the rotating basket.

The USP Method 1 requires a 40 mesh screen unless otherwise specified in the monograph. Other meshes can be used to solve individual problems.

Baskets and basket shafts should be serialized where possible and the serial number noted for each test. All baskets are supplied with a Certificate of Conformance (COC) stating that they are USP compliant, where applicable, and that they meet the machine manufacturer specifications. A Certificate of Analysis (COA) is available at an additional cost.

#### **KEY CONSIDERATIONS**

Mesh Openings — One of the biggest problems associated with the basket method involves the clogging of the mesh openings by particles or excipients or the random release of particles through the mesh to the bottom of the vessel. Baskets with a wide variety of mesh openings are available and if the disaggregated particle size is consistent, a variation of mesh size may solve some difficult dissolution problems.

Sintered Mesh — Every QLA stainless steel basket, that conforms to USP, is manufactured using a sintered mesh. Sintering is a strengthening process that compresses and heats the mesh under high pressures and temperatures. This results in welded joints at all the wire overlaps and adds considerable strength and longevity to the basket.

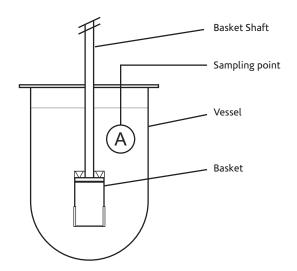
Suppository Baskets — Made from plastic, these baskets have vertical slots instead of mesh to facilitate dissolution. Blocking and/or clogging of the mesh opening is prevented by the use of such a basket, particularly when oil-based suppositories are used.

#### **CARE & MAINTENANCE**

Basket Handling — Since dissolution basket mesh is easily deformed, baskets should only be handled by the upper rim. QLA offers a special tool for installation and removal of baskets from the basket shaft (see page 6).

Basket Cleaning — Care should be exercised to ensure that baskets are clean prior to use. Often the dosage form can clog the mesh which will prevent free media movement into the basket. Careful cleaning is required to ensure there is no contamination between tests.

Basket Storage — Baskets should be stored correctly to extend their life. They can frequently be found rolling around in a lab drawer! Baskets can easily be stored in the supplier's case or using a specially designed basket holder (see page 7).





Note: Other mesh sizes are available on request. For more information, contact your QLA Sales Rep.

> Note: All baskets are laser marked with a unique serial number and come with COC (where applicable).





# BASKETS

#### AGILENT **COMPATIBLE BASKETS** (INCLUDES LEGACY VANKEL)

| Part No.  | Description  | OEM Ref |
|-----------|--|---------|
| BSK010-01 | 10 Mesh Basket, Clip Style, 316 SS, Serialized         | 12-2125 |
| BSK020-01 | 20 Mesh Basket, Clip Style, 316 SS, Serialized         | 12-2120 |
| BSK040-01 | 40 Mesh (USP) Basket, Clip Style, 316 SS, Serialized   | 12-2100 |
| BSK100-01 | 100 Mesh Basket, Clip Style, 316 SS, Serialized        | 12-2154 |
| BSKPTV-40 | 40 Mesh Basket, Clip Style, PTFE Coated over<br>316 SS | 12-2110 |
| BSKSUP-01 | Suppository Basket, Plastic                            | 12-2130 |





BSKPTV-40



BSK040-01

BSK100-01

BSKSUP-01

#### DISTEK COMPATIBLE BASKETS

| Part No.   | Description  | OEM Ref   |
|------------|--|-----------|
| BSK010-DK  | 10 Mesh Basket, Standard Push-On Style,<br>316 SS, Serialized        | 2821-0160 |
| BSK010-DKC | 10 Mesh Basket, Evolution Style, 316 SS, Serialized                  | 2800-0041 |
| BSK020-DK  | 20 Mesh Basket, Standard Push-On Style,<br>316 SS, Serialized        | 2821-0159 |
| BSK020-DKC | 20 Mesh Basket, Evolution Style, 316 SS, Serialized                  | 2800-0042 |
| BSK040-DK  | 40 Mesh (USP) Basket, Standard Push-On Style,<br>316 SS, Serialized  | 2821-0072 |
| BSK040-DKC | 40 Mesh (USP) Basket, Evolution Style,<br>316 SS, Serialized         | 2800-0032 |
| BSK100-DK  | 100 Mesh Basket, Standard Push-On Style,<br>316 SS, Serialized       | 2800-0004 |
| BSK100-DKC | 100 Mesh Basket, Evolution Style,<br>316 SS, Serialized              | 2800-0043 |
| BSKPTD-40  | 40 Mesh Basket, Standard Push-On Style, PTFE<br>Coated over 316 SS   | QLA       |
| BSKSUP-DK  | Suppository Basket, Plastic  | 3250-0445 |
| BSKHUB-DK  | Basket Adapter Hub for Standard Push-On Style,<br>316 SS, Serialized | 2821-1052 |
| BSKHUB-DKC | Basket Adapter Hub for Evolution Style,<br>316 SS, Serialized        | 2821-0459 |
| BSKCLP-DKC | Basket Clip for Evolution Style Hub, 316 SS                          | 3100-0017 |









BSK010-DK

BSK010-DKC

BSK020-DKC







BSK040-DK

BSK040-DKC

BSK100-DKC

BSKSUP-DK





BSKHUB-DK

BSKHUB-DKC

BSKCLP-DKC

#### ERWEKA COMPATIBLE BASKETS

| Part No.  | Description  | OEM Ref     | (THE      | California   | 0         |         |
|-----------|--|-------------|-----------|--|-----------|---------|
| BSK010-EW | 10 Mesh Basket, Clip Style, 316 SS, Serialized       | 90-000-6010 |           | and the second s |           |         |
| BSK020-EW | 20 Mesh Basket, Clip Style, 316 SS, Serialized       | 90-000-6020 |           |  |           |         |
| BSK040-EW | 40 Mesh (USP) Basket, Clip Style, 316 SS, Serialized | 90-000-6040 |           |  |           |         |
| BSKSUP-EW | Suppository Basket, Plastic                          | 70-000-5004 | BSK010-EW | BSK020-EW  | BSK040-EW | BSKSUP- |



#### HANSON COMPATIBLE BASKETS

| Part No.   | Description   | OEM Ref    |
|------------|---|------------|
| BSK010-HR  | 10 Mesh Basket, Clip Style, 316 SS, Serialized                    | 65-220-010 |
| BSK020-HR  | 20 Mesh Basket, Clip Style, 316 SS, Serialized                    | 65-220-020 |
| BSK040-HRP | 40-Mesh (USP) Precision Basket, Clip Style,<br>316 SS, Serialized | 74-105-252 |
| BSK100-HR  | 100 Mesh Basket, Clip Style, 316 SS, Serialized                   | QLA        |
| BSKPTH-40  | 40 Mesh Basket, Clip Style, PTFE Coated over 316 SS               | QLA        |
| BSKSUP-HR  | Suppository Basket, Plastic                                       | 65-700-048 |



BSK100-HR

ARC DECIMA



BSKPTH-40



**PHARMATEST** COMPATIBLE BASKETS

|           |  |          | ARE HERE   |                     |
|-----------|--|----------|------------|---------------------|
| Part No.  | Description  | OEM Ref  |            |                     |
| BSK010-PT | 10 Mesh Basket, Clip Style, 316 SS, Serialized       | 311-2804 | ALCEN CONT |                     |
| BSK020-PT | 20 Mesh Basket, Clip Style, 316 SS, Serialized       | QLA      |            |                     |
| BSK040-PT | 40 Mesh (USP) Basket, Clip Style, 316 SS, Serialized | 311-2803 | BSK010-PT  | BSK040-PT BSKSUP-PT |
| BSKPTP-40 | 40 Mesh Basket, Clip Style, PTFE Coated over 316 SS  | QLA      |            |                     |
| BSKSUP-PT | Suppository Basket, Plastic                          | QLA      | BSK020-F   | PT BSKPTP-40        |
|           |  |          |            |                     |

# SOTAX COMPATIBLE BASKETS

| Part No.  | Description  | OEM Ref |
|-----------|--|---------|
| BSK010-ST | 10 Mesh Basket, Clip Style, 316 SS, Serialized       | QLA     |
| BSK020-ST | 20 Mesh Basket, Clip Style, 316 SS, Serialized       | QLA     |
| BSK040-ST | 40 Mesh (USP) Basket, Clip Style, 316 SS, Serialized | 2830    |
| BSKSUP-ST | Suppository Basket, Plastic                          | QLA     |



# BASKET INSERTION AND REMOVAL TOOL

QLA's Basket Tool provides a firm grip on baskets without damage to the basket during insertion and removal from shafts. The tool grabs the lower rim and protects the delicate wire mesh for an easy fit of basket onto shaft.

Key Benefits:

- Can be used with any standard size dissolution basket
- Decreases contamination from hands
- Basket damage can result in excessive basket wobble and mechanical calibration failure
- Simple but effective design
- Can significantly increase the life of baskets and pay for itself in no time.

| Part No.   | Description   | OEM Ref |
|------------|---|---------|
| BSKTOOL    | Basket Insertion/Removal Tool                       | QLA     |
| BSKTOOL-DK | Basket Insertion/Removal Tool for thick rim baskets | QLA     |







### OVERSIZE 40 MESH 24.5MM ID BASKET AND BASKET SHAFTS

|  | Part No.     | Description  | OEM Re |
|--|--------------|--|--------|
|  | CUSTBSK-40   | 40 Mesh Basket, Clip Style, 24.5mm ID, 316 SS,<br>Serialized                                   | QLA    |
|  | CLIPHUB-DK   | Detachable Basket Hub for 24.5mm Basket, 316 SS,<br>Serialized (Distek compatible)             | QLA    |
|  | CUSTSHT-DK   | 16.5" (420mm) Basket Shaft for 24.5mm Basket,<br>316 SS, Serialized (Distek compatible)        | QLA    |
|  | CUSTSHT-EW20 | 20" (508mm) Basket Shaft for 24.5mm Basket,<br>316 SS, Serialized (Erweka compatible)          | QLA    |
|  | CUSTSHT-HR   | 16" Basket (405mm) shaft for 24.5mm Basket,<br>316 SS, Serialized (Hanson SR8-Plus compatible) | QLA    |
|  | CUSTSHT-HRV  | Basket Shaft for 24.5mm Basket, 316 SS, Serialized<br>(Hanson Vision compatible)               | QLA    |
|  | CUSTSHT-VK15 | 15" (380mm) Basket Shaft for 24.5mm Basket,<br>316 SS, Serialized (VanKel/Varian compatible)   | QLA    |
|  | CUSTSHT-VK13 | 14.5" (370mm) Basket Shaft for 24.5mm Basket,<br>316 SS, Serialized (V-Series compatible)      | QLA    |
|  | CUSTSHT-VK19 | 19" (480mm) Basket Shaft for 24.5mm Basket,<br>316 SS, Serialized                              | QLA    |
|  |              |  |        |

#### 1 Ref



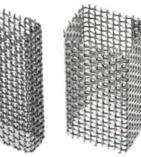
CUSTBSK-40

BASKET SHAFT FOR 24.5MM BASKET

**Note:** Custom length shafts and other mesh sizes are available upon request.

#### METFORMIN SAMPLE HOLDERS

| Part No.<br>VERTHLD-500 | Description<br>Vertical Sample Holder for Metformin 500mg,<br>316 SS | OEM Ref   | OEM Key<br>AGILENT |
|-------------------------|--|-----------|--------------------|
| VERTHLD-750-1K          | Vertical Sample Holder for Metformin 750mg or 1000mg, 316 SS         | 12-2165 🛕 |                    |



VERTHLD-500

VERTHLD-750-1K

#### **BASKET STORAGE**

QLA's Basket Holders provide a convenient way to organize and store baskets when not in use. The chances of accidentally damaging baskets can be significantly reduced with the use of a good quality basket holder.

Key Benefits:

- Compatible with all popular basket types (Agilent, Distek, Erweka, Hanson, Pharmatest, Sotax)
- To ensure your tests meet USP requirements, it is essential that all baskets are not bent or deformed
- O-rings ensure baskets are held firmly to the holder
- Fully stackable to maximize storage space and transport many baskets
- Low cost it pays for itself by preventing damage to just one basket!

| Part No.  | Description               | OEM Ref |
|-----------|---------------------------|---------|
| BSKHLD-6  | 6 Position Basket Holder  | QLA     |
| BSKHLD-12 | 12 Position Basket Holder | QLA     |





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# **FELODIPINE BASKETS**

Can be used on most dissolution testers.

The USP Monograph for Felodipine Extended-Release Tablets specifies the use of a quadrangular stationary basket. The QLA Stationary Basket fully complies with the USP Monograph.

The QLA Felodipine Basket is made from precision welded 316 stainless steel mesh and the basket is securely fixed to the shaft and will not easily bend or break off. The basket also features a small flap to prevent the tablet from escaping during testing. The flap is fabricated so that it will not fall off or be lost during use.

USP 26 requires the use of a basket suspended a precise distance from the paddle shaft, which in turn requires the use of a modified vessel cover.

Key Considerations:

BASKETS

- The Felodipine Basket method offers a potential solution to problems associated with floating, sticking and swelling dosage forms.
- While the use of sinkers may solve similar problems, their final position in the dissolution vessel may vary, thus contributing to variations in test results these variations can be eliminated by using the stationary basket.
- Suitability for certain applications must be verified.

| Part No.   | Description                                    | OEM Ref |
|------------|--|---------|
| STABSK-VK8 | Felodipine Quadrangular Basket, 8 Mesh, 316 SS | QLA     |

# Vessel Felodipine Basket Paddle



## STATIONARY BASKETS

Can be used on most dissolution testers. A modified vessel cover may be needed.

| Part No.  | Description   | OEM Ref |          |
|-----------|---|---------|----------|
| STABSK-10 | Stationary Basket Assembly with Basket Shaft and 10 Mesh Basket, 316 SS | 12-2061 | A        |
| STABSK-20 | Stationary Basket Assembly with Basket Shaft and 20 Mesh Basket, 316 SS | 12-2060 | A        |
| STABSK-40 | Stationary Basket Assembly with Basket Shaft and 40 Mesh Basket, 316 SS | 12-2063 | <b>A</b> |





## QLA is the Only On-site Basket Manufacturer in the Industry

All baskets made in our facility with a focus on precision and quality.



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