Kinesis
Scientific Experts

INFORMATION AND GUIDES

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About QLA – Quality Lab Accessories

Headquartered in Telford, PA, Quality Lab Accessories LLC (QLA) carries a full line of consumables and accessories for various brands and models of dissolution testing machines and are fabricated specifically for the dissolution industry.

The experienced and professional staff bring decades of combined experience and industry expertise to the customers all over the world. They are producers and suppliers of the highest quality products to the entire Pharmaceutical industry, ensuring all products are USP and machine manufacturer compliant.

They pride themselves on offering quality products and customer service second to none in the industry. They offer a product line consisting of items specifically designed to fit various brands of dissolution testing machines as one size does not fit all in this industry.

QLA's success since the beginning has been based entirely on their emphasis on customer service – The engineering team is at customer's service to custom design and fabricate accessory solutions for unique problems.

Old Logo:

New Logo:

Pure Quality Logo for filters

About Dissolution Testing

What is Tablet Dissolution?

The administration of drugs via oral dosage forms is one of the most common and effective means of delivering treatments to patients. When a dosage form is swallowed, the rate at which it releases the active ingredient is critical to ensure that the drug is delivered properly. The rate at which the drug is released is called the dissolution rate.

In fact, all drug forms have a dissolution rate. Creams, skin patches and implants and others, all release their drugs so they can be taken up by the body.

One of the problems facing pharmaceutical manufacturers is to how optimise the amount of drug available to the body, i.e. its **bioavailability**. Inadequacies in bioavailability can mean that the treatment is ineffective and at worst potentially dangerous (toxic overdose). All kinds of factors affect this from the formulation of the dosage form, size, shape, excipients, bindings and other physical characteristics, to the pH, temperature and so on.

The actual drug release in the human body can be measured *in-vivo* by measuring the plasma or urine concentrations in the patient. However, there are certain obvious impracticalities involved in employing such techniques on a routine basis. These difficulties have led to the introduction of official *in-vitro* tests which are now rigorously and comprehensively defined in the respective Pharmacopoeia and recent harmonisation between the various Pharmacopoeia (notably the USP, BP, EP and JP) has lead to global standardisation in the measurement of drug release rates.

Tablet Dissolution Testing

When it comes to measuring the release rates of drugs in a manufacturing environment then the technique of Tablet Dissolution testing is employed.

Tablet Dissolution is a standardised method for measuring the rate of drug release from a dosage form and the key word here is “standardisation" because for any results to be meaningful, it is essential that all the apparatus used for the testing, produces the same sets of results given all other parameters are equal.

There are many discussions about how good dissolution testing may or may not be compared with the actual in-vivo effects, but without a standardised test it is impossible to gain comparative data

The principle function of the dissolution test may be summarised as follows:

- Optimisation of therapeutic effectiveness during product development and stability assessment.
- Routine assessment of production quality to ensure uniformity between production lots.
- Assessment of ‘bioequivalence’, that is to say, production of the same biological availability from discrete batches of products from one or different manufacturers.
- Prediction of *in-vivo* availability, i.e. bioavailability (where applicable).

Dissolution testing was initially developed for oral dosage forms, but the role of the test has now been extended to drug release studies on various other forms such as topical and transdermal systems and suppositories.

Why Test?

From a manufacturing objective, the aim is to:

"Manufacture a dosage form in such a way that the active ingredient is released from the dosage form in a predictable way and within a reasonable time in order for it to be absorbed by the body". Drugs also need to be released in the right area of the body - in the intestine instead of the stomach for example. Most routine dissolution testing is used to confirm the statement above.

When a dosage form is manufactured, there are a number of parameters which need to be checked:

- That the active ingredient is released in the predicted way
- That the manufactured batch is the same as previous batches and falls within the required levels.
- That the product can be stored for the specified shelf life without deterioration
- To ensure that the dosage form does not break up in transit
- To confirm that the drug is stable over time.

The Dissolution Test is a very useful tool and the only *standardised* way to generate scientific data that enables comparison.
In addition, standardised testing promotes globalisation and harmonisation and also acts as a referee to identify mis-branded or substandard products

Application of dissolution data

Testing the dosage form from production to the end of its shelf life produces data that

- Confirms immediate quality control
- Ensures that the drug is still pharmaceutically active throughout its shelf life
- Includes stability testing within well-defined and strict criteria for each drug
- Validates the manufacturing process and confirms therapeutic equivalence

What is tested

Dissolution testing is appropriate to a wide range of products:

- ‘Traditional’ pharmaceuticals
- Dietary supplements
- Veterinary drugs
- Other ‘remedies’

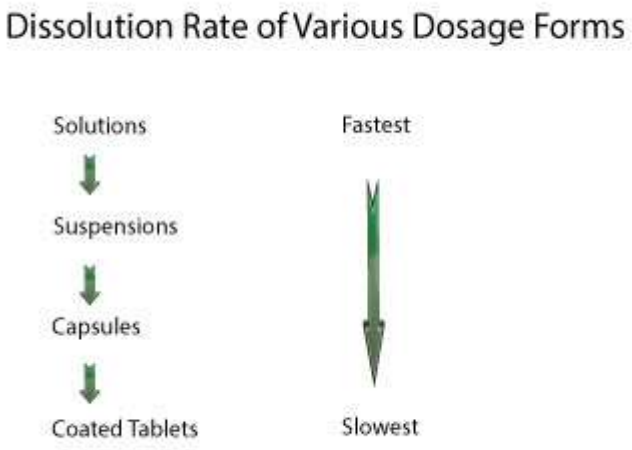
Theoretical Concepts of Dissolution

The basic definition of dissolution rate for a solid dosage form is as follows:

'The amount of active ingredient in a solid dosage form dissolved in unit time under standardised conditions of liquid-solid interface, temperature and media composition.'

Dissolution Rates of Dosage Forms

There are many kinds of dosage forms of course and all of them have a dissolution rate. The dissolution time can range from seconds to hours or even days for implants



Of course there are other dosage forms such as patches, implants, creams etc. but the principles remain the same.

Sink Conditions

If you put a spoon of sugar into a beaker of water it will dissolve readily. A second spoon will also dissolve. But keep adding spoonfuls and it becomes slower for the sugar to dissolve until at some point it becomes impossible for any more to dissolve as the solution becomes saturated.

Relating this to the dissolution of drugs, it is essential that as a drug dissolves, the presence of the already dissolved drug in solution should not affect the ability of more drug to be dissolved in any way. i.e. the concentration of drug in solution should not be anywhere other than the bottom of the saturation curve for that drug. Concentration should never be close to the saturation point.

If the concentration level were to rise too high, the dissolution rate of additional drug would be slowed and the data would cease to be reproducible.

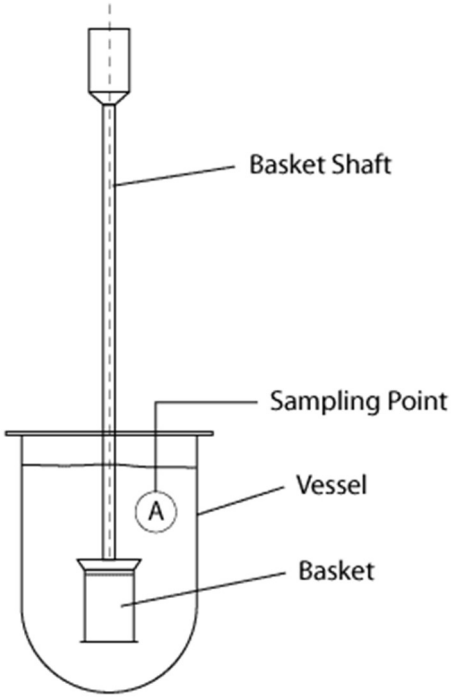
In order to ensure that sufficient media is present in relation to the drug to be dissolved, typically 5 to 10 times greater volume of media is used in respect to that saturation point at which dissolution would slow. This is known as Sink Conditions – sufficient media to ensure un-impaired dissolution.

This is typically why dissolution is performed in larger volumes such as 900ml or 1litre. 500ml tests may be used where sink conditions permit and the measurable level of the drug is lower. In recent years, the introduction of microcapsules and very low dosage levels have led to mini vessel tests in volumes as low as 100mls or 200mls, but in all these cases, sink conditions are maintained. Conversely, if 1000mls is not enough volume, then larger 2000ml vessels can be used.

Next Steps

Having examined some of the basic theory behind dissolution, it is now possible to look at some of the practical issues and the effects that they can have on the dissolution profile. For the purposes of this tutorial we will concentrate on the two most common apparatus1 and apparatus 2, the rotating basket and paddle.

Apparatus 1 - The Rotating Basket



Adopted in 1970 the rotating basket method of dissolution testing was the first official method.
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. The temperature of the media inside the vessel is kept constant by a water bath or heating jacket. The solution in the vessel is stirred smoothly by the rotating stirring element.

The shafts and baskets must rotate freely and within specified limits, and importantly, they must be accurately cantered in the vessel and be free from wobble.

The standard basket consists of a stainless steel 40 mesh construction, but there are many variations depending on the monograph and application. For example, suppository baskets are manufactured from PTFE with vertical slits to facilitate dissolution.

40 Mesh basket *Suppository Basket*

Mesh size refers to the number of openings per linear inch and the diameter of the wire used to create the mesh is specified.
If the basket is reactive with the dosage form then it can be coated with PTFE or an inert substance such as gold or titanium. The basket can be connected to the rotating shaft by use of clips or a push-on O-ring. It is also important to note that different dissolution tester manufacturers will manufacture their baskets and hubs to slightly different specifications but all within the USP guidelines. Even though they look similar, baskets are not interchangeable between different tester manufacturers. QLA tightly controls the manufacture of these items to ensure that they are compatible with the stated bath.

Dissolution Baskets

Dissolution baskets are a precise and fragile piece of precision instrumentation and are easily damaged. The standard mesh size is 40 Mesh (40 openings per linear inch of mesh), but many other sizes exist from 10 mesh, right up to 100 or 150 mesh which is incredibly fine and extremely delicate. Mini baskets for small volume applications, and special baskets for specific new drugs are also available.

10 Mesh Basket | 20 Mesh Basket | 40 Mesh Basket | 100 Mesh Basket | 150Mesh Basket | Suppository Basket

There is a big variation in the quality of baskets available on the market but there are a number of issues to look out for that can make the difference between a short lifetime and long lifetime, and also the ability of the basket to pass the calibration procedures, particularly for wobble.

Simple Test - hold a basket rims between the thumb and forefinger on both hands and gently twist back and forth. If there is any movement in the mesh of the basket then there is a real potential that the basket will easily deform, and worse, that it will not pass the basket wobble test.

A good basket should be rigid with no movement. QLA baskets are manufactured from sintered mesh - mesh that has been woven and then subjected to high temperature which actually welds the wires together at each cross-over point. This creates a rigid and non-moving mesh and will extend the life of the baskets considerably. Because the baskets are rigid, they will pass the wobble test far more easily. Good baskets are reproducible baskets and reproducibility is the goal of any dissolution testing.

Serialisation

Baskets should be individually serialised and certified. Certification should always show the actual serial number and not a generic certificate. This means that the baskets are individually tested and QC tested to ensure that they not only meet the USP specifications but that each individual basket is correctly manufactured.
Serial numbers can be entered into the validation documents and also ensure that the same baskets can be used in the same vessel position every time.

Handling

Correct handling of baskets is important and avoids both physical damage and contamination.
Baskets should only be handled by the rims and never piked up by the mesh. Touching the mesh can not only deform it, but also risks depositing oils and contamination from the hands. A dented basket will also disrupt the media flow around the basket leading to erroneous results and is definitely not permissible. QLA's Basket insertion and removal tool provides a firm grip without damaging the baskets.

Cleaning

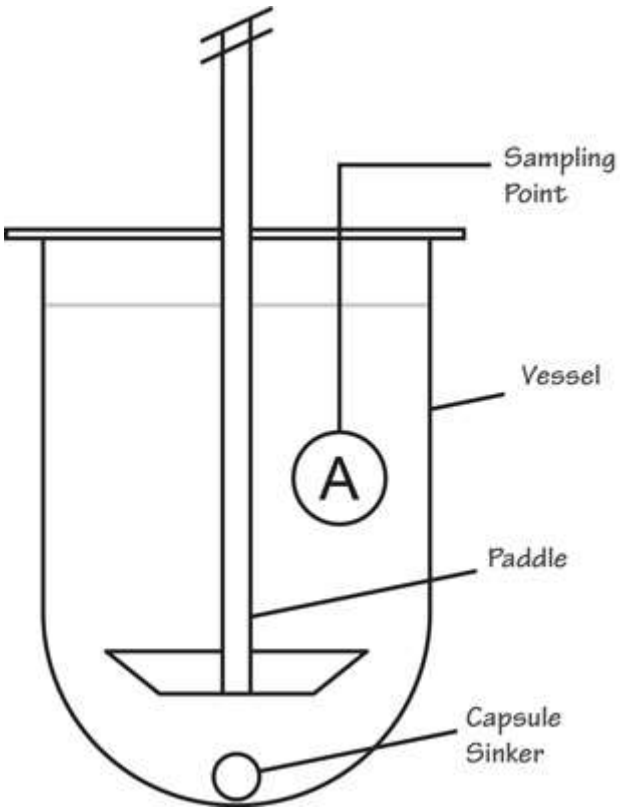
It is essential that baskets are kept clean. They should be rinsed after use and if necessary a short time in an ultrasonic bath can be used to dislodge particles which are blocking mesh holes. Blocked mesh decreases media flow and can lead to lower results. Baskets should then be dried prior to storage or re-use. Never introduce a dosage form into a wet basket.

Storage

Baskets should also be stored properly and not allowed to simply roll around a drawer where they can easily be damaged and become misshapen.
The use of a simple basket storage rack, which is both inexpensive and easy to use, is the best way to ensure that baskets maintain their integrity during storage.

Apparatus 2 - The Paddle Test

The Rotating Paddle, although Method 2, is actually the most widely used method in dissolution testing.



The specifications for Apparatus 2 are identical with those for Apparatus 1 except that the paddle is substituted for the rotating basket.

The dimensions of the paddle are closely controlled. Any variations can easily have a detrimental effect on reproducibility from vessel to vessel. For this reason, paddles should be treated as a precision piece of equipment, stored correctly, and inspected regularly for scratches, dents or other imperfections.

The dissolution test relies on uniform flow patterns and any imperfections can lead to turbulent flow. For that same reason, wobble and other deviations must be tightly controlled with specifications similar to the basket test.

Serialisation

As with the basket test, the paddles should be individually serialised, preferably with laser etching. If detachable paddles and baskets are used - spin on/spin off paddles, then serialisation should be on the shaft as well as the paddle section.

Allowable Variations

Polyfluorocarbon Coating

PTFE or other suitable coatings are permitted by the USP, and have been widely used. The purpose of the coating is to reduce the interaction between steel and the dosage form. As steel quality improves, the need for coating reduces, but care should be exercised to use paddles of suitable steel quality.

Polyfluorocarbon coating is a high temperature process and is difficult to gain a consistent thickness over the paddle. Poor coating and handling leads to flaking of the coating. This exposes the steel but can also disrupt the flow with the rough surface.
Re-coating is an expensive option and easily avoided by storing the paddles in a suitable rack. Many users simply keep paddles and baskets in a lab drawer - a sure recipe for a short life span.

Another alternative is to use a paddle manufactured from solid PTFE or similar material. These paddles have the same dimensions as the steel paddles specified by the USP, but because they are solid, the coating cannot peel off.

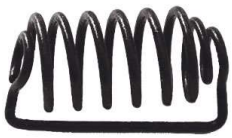
In all other respects the test is the same as with baskets, with the same sampling position requirements. The only other variation that the paddle test might employ, is the use of capsule sinkers.

Capsule Sinkers

Dissolution reproducibility will be severely restricted if the dosage form is not in the same position in the vessel for each test. Floating dosage forms can present a real problem and may be weighted with a sinker which should be heavy enough to cause it to sink to the bottom of the vessel.

A sinker is commonly formed from a wire helix. The USP 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 sinker device is shown in* Figure 2a*. Other validated sinker devices may be used."* The sinker referenced in 'figure 2a' is commonly referred to as the Japanese Sinker (shown below).

In reality, hand forming sinkers from a few turns of wire will not make a reproducible sinker. Commercially produced sinkers are manufactured using a computerised winding machine to ensure uniformity for the wire spirals and will give better results. Even then the wire thickness needs to be uniform to avoid errors. There are many designs of sinker available today:

					
Japanese Sinker (Figure 2a Ref USP Above)	Spiral or Coil Sinker	3 Prong Sinker	'Sotax Style' Spiral Sinker	Basket Sinker	Breath Film Sinker

Consistent sinkers are extremely important. Even a small variation in wire diameter can result in test failure. The two sinkers shown below resulted in a test failure from the sinker on the right because of poor manufacturing and thicker wire.

Good Sinker

Poor Sinker

Sinkers are precision parts and manufacturing processes and QC systems should conform to ISO 9001:2008 requirements. ISO requires all measuring tools to be calibrated using NIST Traceable standards and guarantees consistency.

Problems Associated with Sinkers

Sinkers are usually manufactured from stainless steel. In some cases however, this can react with the dosage form, in which case a PTFE coated sinker can be used. Coated sinkers are most common in the spiral form.

Incorrect sinker selection can result in the wire occluding the surface of the dosage form thus restricting the free flow of media over the surface and reducing the dissolution rate (such as in the example above) Gummy excipients can also clog the wire and affect the flow of media.

Selecting a Sinker

Selecting the correct sinker for your application can require some trial and error. However there are some guidelines to follow to help with this process. Some important factors need to be taken into consideration.

-Sinker Size

Size and dimension is important. The sinker should have minimal surface contact with the tablet as this can affect the dissolution rate. Some dosage forms swell and it is important that the sinker takes account of this if required. It should be easy to put the dosage form in the sinker without scratching the surface.

-Sinker Material

The majority of sinkers are made from 316 stainless steel and are resistant to water or standard dissolution media. PTFE Coated Sinkers can be used with magnetic retrieval systems, or where there may be a reaction or adsorption between steel and the tablet. These tend to have a shorter lifetime as once the surface is scratched the iron inside will quickly corrode. Plastic coated “3 prong” sinkers can also be used although this style will have direct contact with the tablet which is not necessarily desirable.

-Sinker Weight

In general the sinker should be heavy enough to sink the dosage form to the bottom of the vessel. Heavier than that would suggest more wire than in necessary with the associated possible flow effects. For spiral sinkers this means the fewest number of spirals required to sink the dosage form but enough the prevent it coming out of the wire when wet.

Capsules tend to be very buoyant because of their air content, but once the outer surface has dissolved, the microspheres inside can then move freely.

-Special Sinkers

Special sinkers are also available for immediate release dosage forms and films. For 'coin' shaped dosage forms a circular 'basket sinker' may be used. Similar sinkers can be used for some microsphere or powder applications. Custom sinkers are available for special dosage forms.

Capsule Sinker Selection Guide

Sinker Type	Part Number	Image	Style	Material	Coating	Inside Diameter		Inside Length		Wire Diameter		Max Capsule Size	No. of Coils	Weight (g)
						in	mm	in	mm	in	mm			
Basket	CERTBSK-JP		Basket, JP	316 S.S.	-	0.470	11.9	0.935	23.7	0.039	0.99	000	8	4.00
	BSK008-01		Basket, 8 Mesh	316 S.S.	-	0.620	15.7	1.060	26.9	0.028	0.71	000	9	5.40
	BSK008-JP		Basket, 8 Mesh	316 S.S.	-	0.410	10.4	0.790	20.1	0.028	0.71	1	8	3.85
	SNK008-VK		Basket, 8 Mesh	316 S.S.	-	0.788	20.0	0.461	11.7	0.028	0.71	2	-	17.61
	SNK010-VK		Basket, 10 Mesh	316 S.S.	-	0.788	20.0	0.461	11.7	0.025	0.64	2	-	19.00
	SNK040-VK		Basket, 40 Mesh	316 S.S.	-	0.788	20.0	0.461	11.7	0.010	0.25	2	-	20.00
Pronged	CAPWHT-VK		3 Prong	Nylon / P.P.	-	0.200	5.1	1.000	25.4	-	-	2	-	0.90
	MAGWHT-VK		3 Prong	Nylon / P.P.	-	0.200	5.1	1.000	25.4	-	-	2	-	1.20
	CAPWHT-SV		3 Prong	316 S.S.	-	0.275 - 0.210	7.0 - 5.3	1.040	26.4	-	-	1 (min=3)	-	1.25
O-Ring	CAPWHT-S99		O-Ring	316 S.S.	-	0.466	11.8	1.015	25.8	-	-	1	-	1.14
Spiral	CAPWHT-TR		Butterfly	316 S.S.	-	0.224	5.7	0.386	9.8	0.026	0.66	-	-	0.55

	CAPWHT-PC		Strip Film	316 S.S.	-	0.436	11.0	0.436	11.1	0.035	0.89	-	-	1.20
	CAPWST-15		Helix	316 S.S.	-	0.197	5.0	0.610	15.5	0.016	0.41	5	6	0.60
	CAPWHT-04		Helix	Music Wire	PTFE	0.385	9.8	0.840	21.3	0.043	1.09	0	5	1.70
	CAPWHT-4S		Helix	316 S.S.	-	0.385	9.8	0.840	21.3	0.047	1.19	0	5	1.95
	CAPWHT-LG		Helix	Music Wire	PTFE	0.410	10.4	1.100	27.9	0.043	1.09	000	6.5	2.00
	CAPWHT-XL		Helix	Music Wire	PTFE	0.465	11.8	1.150	29.2	0.043	1.09	000	5.5	2.15
	CAPWST-18		Helix	316 S.S.	-	0.236	6.0	0.709	18.0	0.016	0.41	3	8.7	0.75
	CAPWST-19		Helix	316 S.S.	-	0.276	7.0	0.760	19.3	0.016	0.41	2	8	1.00
	CAPWHT-2S		Helix	316 S.S.	-	0.370	9.4	0.840	21.3	0.043	1.09	0	8.5	2.85
	CAPWHT-02		Helix	Music Wire	PTFE	0.370	9.4	0.840	21.3	0.050	1.27	0	8.5	2.05
	CAPWHT-XS		Helix	316 S.S.	-	0.580	14.7	0.885	22.5	0.047	1.19	Special*	8.5	3.60
	CAPWST-23		Helix	316 S.S.	-	0.315	8.0	0.905	23.0	0.016	1.41	0	9	0.95
	CAPWST-31		Helix	316 S.S.	-	0.433	11.0	1.220	31.0	0.031	0.79	000	11.9	3.25
Wire	WIRESK-VK		Sinker Wire 50'	316 S.S.	-	-	-	-	-	0.032	0.81	-	-	-

* The maximum capsule size of CAPWHT-XS is described as "special" because this sinker is often used in veterinary applications where the capsule diameter can be very large - this sinker has an inside diameter of 0.580" (14.7mm) to accommodate such capsules.

Capsule Size Guide

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Capsule Size Guide

Capsule Size Guide

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

Browse our range of capsule sinkers

Filters for Dissolution

QLA is the leading supplier of filters for dissolution testing world-wide.

Manufactured from PURE QUALITY Pure Quality material, QLA filters are fabricated in special moulds in clean-room conditions to ensure the best manufacturing practices. Samples from each batch are then tested for dimensional accuracy and then further tested for heavy metal content, inorganic interference and other possible contaminants.
Genuine QLA filters are guaranteed suitable for dissolution testing and CERTIFIED to be compliant with USP standards.
Only with QLA Pure Quality can you be certain that every batch of every filter will be consistent and the same as every other batch.

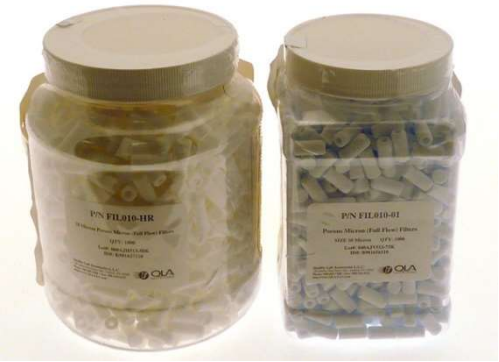
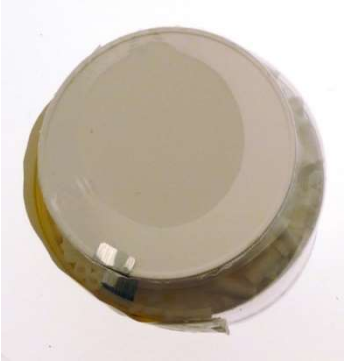
How do I know that my filters are Genuine QLA Pure Quality?

Simply look at the packaging:

1. Genuine QLA Filters have a QLA ISO9000 Holographic Label across the lid and jar (1000 packs). It should be un-broken when you receive the jar.

or

2. Genuine QLA filters are packed in round or square jars and shrink -sealed for security:


3. Genuine QLA filters have the certificate of conformance on the jar and the Pure Quality Label as well.

If your filter packaging does not have these features then the product is not a genuine QLA product and we cannot guarantee the performance. All QLA product is fully guaranteed to be 100% quality and fit for purpose - no argument

Look out for the logos:

PURE QUALITY **from** QLA

4. All QLA filters are supplied with a Lot number and ID number to create a traceable path to the manufacturing process

COC and COA Certificates

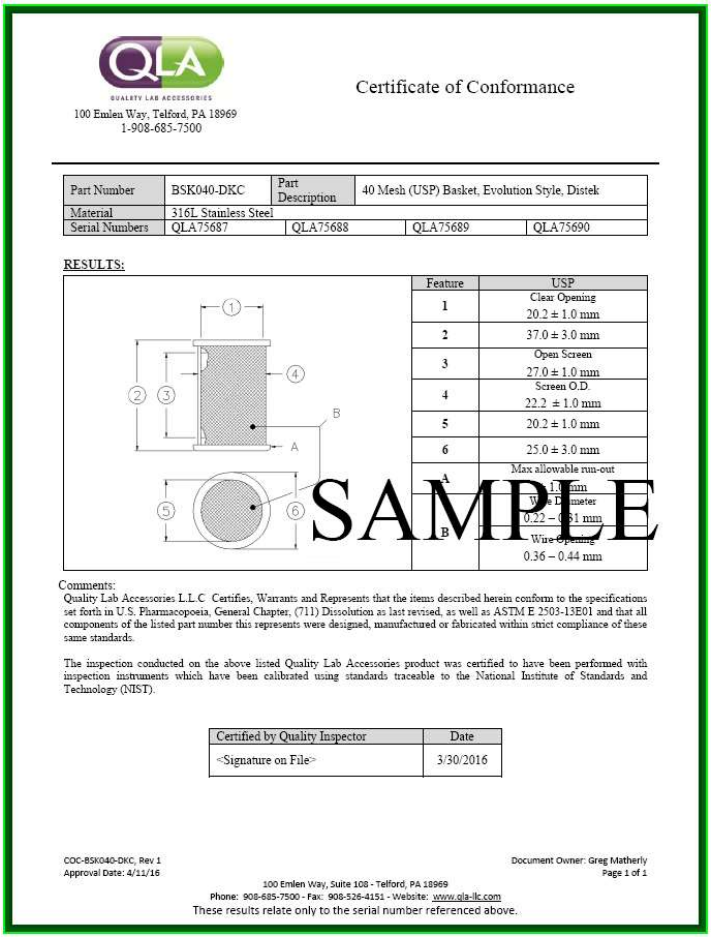
COC - Certificate of Conformance.

For dissolution testing, the guidelines are specified by the USP, EP and/or JP. This means that all dissolution testers and their accessories must meet the specifications defined in the monograph. These specifications are generally physical and can be measured with the appropriate tools. Thus all baskets, paddles, basket shafts, vessels and any other part of the system should be both defined and measurable within the tolerances specified.

All dissolution accessories should conform to these specifications, and the certification that they do so is known as the COC or Certificate of Conformance. The COC generally defines the tolerances that the accessories are manufactured to and these should fall within those defined by the USP

All QLA dissolution accessories are supplied with a COC.

Example COC for a dissolution basket



100 Emlen Way, Telford, PA 18969
1-908-685-7500

Certificate of Conformance

Part Number	BSK040-DKC	Part Description	40 Mesh (USP) Basket, Evolution Style, Distek	
Material	316L Stainless Steel			
Serial Numbers	QLA75687	QLA75688	QLA75689	QLA75690

RESULTS:

Feature	USP
1	Clear Opening 20.2 ± 1.0 mm
2	37.0 ± 3.0 mm
3	Open Screen 27.0 ± 1.0 mm
4	Screen O.D. 22.2 ± 1.0 mm
5	20.2 ± 1.0 mm
6	25.0 ± 3.0 mm
A	Max allowable run-out 1.0 mm
B	Wire Diameter 0.22 – 0.31 mm
	Wire Opening 0.36 – 0.44 mm

SAMPLE

Comments:
Quality Lab Accessories L.L.C Certifies, Warrants and Represents that the items described herein conform to the specifications set forth in U.S. Pharmacopoeia, General Chapter, (711) Dissolution as last revised, as well as ASTM E 2503-13E01 and that all components of the listed part number this represents were designed, manufactured or fabricated within strict compliance of these same standards.

The inspection conducted on the above listed Quality Lab Accessories product was certified to have been performed with inspection instruments which have been calibrated using standards traceable to the National Institute of Standards and Technology (NIST).

Certified by Quality Inspector	Date
<Signature on File>	3/30/2016

COC-BSK040-DKC, Rev 1
Approval Date: 4/11/16

Document Owner: Greg Matherly
Page 1 of 1

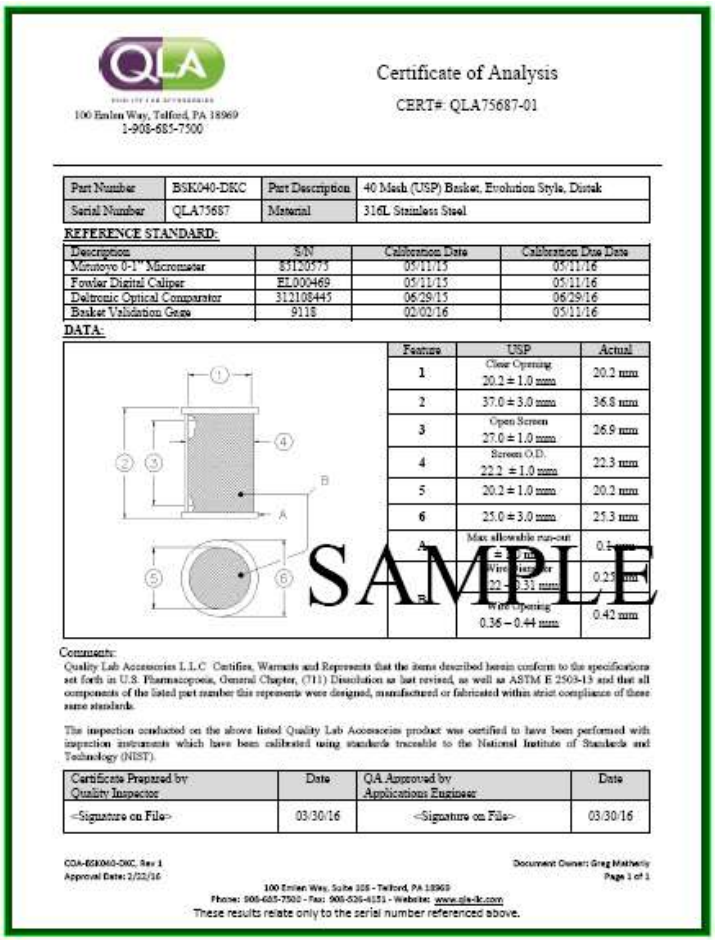
100 Emlen Way, Suite 108 - Telford, PA 18969
Phone: 908-685-7500 - Fax: 908-526-4151 - Website: www.qla-llc.com
These results relate only to the serial number referenced above.

COA - Certificate of Analysis

A COA is far more stringent than a COC and records the actual physical measurements of each individual accessory or part. This means that each part is separately measured and recorded by the manufacturer. The COA exceeds the COC in that it is possible to know the exact measurements and therefore record those for individual test positions.

Because producing a COA is quite time consuming and involved, there is generally an additional charge for those.

Example of a COA for a dissolution basket



100 Emlen Way, Telford, PA 18969
1-908-685-7500

Certificate of Analysis

CERT#: QLA75687-01

Part Number	BSK040-DKC	Part Description	40 Mesh (USP) Basket, Evolution Style, Distek
Serial Number	QLA75687	Material	316L Stainless Steel

REFERENCE STANDARD:

Description	S/N	Calibration Date	Calibration Due Date
Mitutoyo 0-1" Micrometer	83120573	05/11/15	05/11/16
Fowler Digital Caliper	EL000469	05/11/15	05/11/16
Deltronic Optical Comparator	312108445	06/29/15	06/29/16
Basket Validation Gage	9118	02/02/16	05/11/16

DATA:

Feature	USP	Actual
1	Clear Opening 20.2 ± 1.0 mm	20.2 mm
2	37.0 ± 3.0 mm	36.8 mm
3	Open Screen 27.0 ± 1.0 mm	26.9 mm
4	Screen O.D. 22.2 ± 1.0 mm	22.3 mm
5	20.2 ± 1.0 mm	20.2 mm
6	25.0 ± 3.0 mm	25.3 mm
A	Max allowable run-out	0.1 mm
B	Wire Diameter 0.22 – 0.31 mm	0.23 mm
	Wire Opening 0.36 – 0.44 mm	0.42 mm

SAMPLE

Comments:
Quality Lab Accessories LLC Certifies, Warrants and Represents that the items described herein conform to the specifications set forth in U.S. Pharmacopoeia, General Chapter, (711) Dissolution as last revised, as well as ASTM E 2503-13 and that all components of the listed part number this represents were designed, manufactured or fabricated within strict compliance of these same standards.

The inspection conducted on the above listed Quality Lab Accessories product was certified to have been performed with inspection instruments which have been calibrated using standards traceable to the National Institute of Standards and Technology (NIST).

Certificate Prepared by Quality Inspector	Date	QA Approved by Applications Engineer	Date
<Signature on File>	03/30/16	<Signature on File>	03/30/16

COA-BSK040-DKC, Rev 1
Approval Date: 2/22/16

Document Owner: Greg Matherly
Page 1 of 1

100 Emlen Way, Suite 105 - Telford, PA 18969
Phone: 908-685-7500 - Fax: 908-526-6151 - Website: www.qla-llc.com
These results relate only to the serial number referenced above.

How are Accessories Measured?

In addition to using certified and traceable measurement tools, more sophisticated equipment is employed to ensure that all parts meet very tight manufacturing tolerances. Products such as optical comparators are used to compare manufactured parts with perfect originals, and normal tolerances are far tighter than defined in the USP to ensure part to part consistency. This is important to ensure reproducible results between each test position.