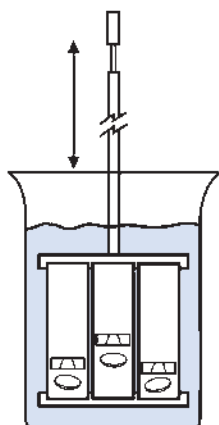


Disintegration

INTRODUCTION ►►►



Copley Philosophy

Robust	✓	Reliable	✓
Easy to use	✓	Compliant	✓

Approximately two thirds of all medicines prescribed today take the form of solid dosage forms and half of these are tablets. These tablets comprise a mixture of active drug and other excipients, usually in powder form, pressed or compacted into a solid.

It has long been recognised that before a tablet/hard gelatin capsule can dissolve and hence allow the active drug to be absorbed into the body, it must first disintegrate into smaller particles.

The current test apparatus described in the Pharmacopoeia* was designed to provide a reproducible and standardised method of ensuring that disintegration had taken place. Each of the tablets to be tested is placed in one of six vertical tubes each measuring approx. 77.5 mm long x 21 mm inside diameter positioned in a circular basket arrangement. The lower end of the tubes is covered by a 2 mm sieve mesh.

A larger basket is available for large tablets, capsules and boluses according to Ph.Eur. Chapter 2.9.1 Test B and for dietary supplements according to USP Chapter <2040>.

The basket assembly is raised and lowered in simulated gastric fluid at body temperature (37 degrees Celsius) through a distance of 55 mm at a constant frequency of 30 cycles per minute. A plastic disc of defined proportions "hammers" the tablet during the operation, thus assisting in the disintegration process.

The tablet is said to pass the test providing that no tablet residue remains on the sieve mesh after the designated time, typically 30 minutes for ordinary tablets and 60 minutes for enteric coated tablets.

All Copley Tablet Disintegration Testers feature:

- Sturdy, robust design, including novel "quick release" basket, one-piece water bath and independent heater/circulator
- Simple, easy-to-use operation ensures that the number of operations required to perform a test are kept to a minimum
- Full supporting documentation (including full IQ/OQ/PQ qualification documentation if required)
- Special accessories available for hard/soft gelatin capsules and large tablets, capsules and boluses

* Ph.Eur. 2.9.1 and USP <701>





Disintegration
Tester DTG 1000



Disintegration
Tester DTG 2000

DISINTEGRATION TESTERS SERIES DTG

The Disintegration Tester Series DTG is the result of over 50 years' experience in the field of pharmaceutical testing.

The Testers have been specifically designed for use in the quality and production control of normal, plain coated and delayed release coated tablets and gelatin capsules in accordance with the specifications as laid down in European, United States and associated Pharmacopoeias.

The series is available with one (DTG 1000), two (DTG 2000), three (DTG 3000) or four (DTG 4000) test stations. Each individual test station is capable of accepting one batch of six tablets or capsules.

Foremost in the design specification were those features that you, the user, identified as being essential to the "ideal" disintegration tester.

PHARMACOPOEIAL COMPLIANCE AND QUALIFICATION

The most critical factors in the design of any disintegration tester are (a) that it complies with the respective Pharmacopoeia, (b) that this compliance can be proved or qualified and (c) that both compliance and qualification are documented.

Copley offers a three tier approach to address these points:

- **Certificate of Compliance to USP/ Ph.Eur.:** Provided free of charge with each unit. This is a written statement that the product, by design, complies with the current pharmacopoeial specifications.
- **Laser Numbering and Certification:** Identification and measurement of critical components to provide documented verification of compliance with current pharmacopoeial specifications. Available as an optional service.
- **IQ/OQ/PQ Qualification Documentation:** Comprehensive documentation to guide the user through the installation, operating and performance checks of the equipment in its operating environment, using specified test protocols. This optional service provides a comprehensive record of the suitability of the equipment to perform its specified task, to be created and archived.

Please see the ordering information for further details on our verification and qualification services.

DESIGN AND CONSTRUCTION

All of the DTG series feature a robust **all metal** construction. The motor drive employed operates at a fixed speed of 30 rpm (+/- 1) and a stroke of 55 mm (+/- 1).

Depending on the model, the DTG has the capacity of testing one, two, three or four different tablet batches of six tablets/capsules simultaneously, under identical test conditions.

The control of all models is provided by a membrane keypad linked to a 4-line, 20 character, back-lit LCD screen, which together with the electronics is mounted in the head of the instrument so as to avoid any accidental spillages in the test area.

Particular attention has been given to the design of the basket rack assembly in respect of its removal and cleaning.

The novel "**quick-release**" basket **design** not only provides a firm and rigid location for the basket during operation, but also allows the basket to be removed from the instrument for rapid cleaning.

Another unique feature of the basket design is the use of **thumb screws** to hold the various components together.



◀ Disintegration Tester DTG 3000



Disintegration Tester DTG 4000 ▶

DISINTEGRATION TESTERS SERIES DTG

This means that if it is necessary to disassemble the basket before cleaning, this can be done very quickly and without the use of any specialised tools.

A common problem associated with fabricated water baths, used for warming the media, is that of leaks.

This problem has now been eliminated through the use of a **one-piece water bath** vacuum formed in rigid PETG. This construction not only eliminates any possibility of leaks, but also makes it far easier to clean because of its rounded corners. The bath is fitted with a sturdy 8 mm clear view lid and secured to the base by four easily removed thumb screws.

The temperature of the warming solution is controlled by means of an **independent digital heater/circulator** to an accuracy of **+/- 0.25 degrees C**. This has two advantages: firstly, it removes the necessity for priming and secondly, it can be removed for cleaning without dismantling the whole disintegration tester. A **low water-level alarm** indicator is built into the unit as standard.

OPERATION

Considerable attention was paid to the design of the DTG series to ensure that the number of actions necessary to perform a test are kept to a minimum.

The membrane keypad allows for the selection of test run times up to **99 hours 59 minutes 59 seconds**. Thereafter, it is only necessary to press the START key to automatically lower the basket rack assemblies into the test media and begin or repeat a test.

During the test, the time elapsed from the start of the test (or if you prefer, time remaining to the end of the test) is displayed on the LCD screen.

At the end of the test, the **basket rack assemblies are automatically removed from the test media** and an audible alarm alerts the user that the run is completed.

Bath and beaker temperatures can be constantly monitored using the **PT100 temperature probe** provided for this purpose. Temperature is critical to the test and is displayed permanently on the LCD screen as soon as the unit is switched on.

Ordinarily, temperature calibration can prove to be a time-consuming and inaccurate process involving the use of iced water. This is not the case with the DTG series. Available as an option, the **electronic temperature calibration kit** comprises two UKAS certified test keys (0 and 37 degrees C), which you simply plug into the PT100 socket to perform the calibration.

Dimensions (mm):
DTG 1000/2000 = 450 x 450 x 720 mm (w x d x h)
DTG 3000/4000 = 700 x 450 x 720 mm (w x d x h)

Cat. No. Description

1201	Disintegration Tester Model DTG 1000 (1 Station)
1202	Disintegration Tester Model DTG 2000 (2 Station)
1203	Disintegration Tester Model DTG 3000 (3 Station)
1204	Disintegration Tester Model DTG 4000 (4 Station)
1205	Extra for Numbering and Certification (per basket)
1206	IQ/OQ/PQ Documentation Pack
1207	Electronic Temperature Calibration Kit
1228	Qualification Tools



"Quick-Release" Basket Assembly ▲

DISINTEGRATION TESTERS SERIES DTG

The Disintegration Tester Series DTG described on the preceding two pages is ideal for quality control and R&D where it is important that the testing is carried out under identical test conditions.

As previously stated, the series offers the user an unparalleled number of standard features including:

- Conforms to all current Ph.Eur. and USP specifications
- Choice of 1, 2, 3 or 4 test baskets
- "Quick-Release" basket design combines stability with easy removal
- Automatically lowers and raises the baskets out of the test media at the start and finish of the test
- Easy to clean vacuum formed water bath eradicates leaks
- Independent digital heater/circulator: no priming and easy to remove
- Low liquid level sensor
- Easy to use membrane control panel

- 99 hour test programme permits delayed release as well as normal testing
- Acoustic signal at the end of the test
- PT100 temperature sensor as standard
- Constant monitoring of time and temperature via LCD screen
- Electronic temperature calibration kit (option)
- Certification and IQ/OQ/PQ documentation packs available (option)

DISINTEGRATION TESTER DTG 2000 IS

There are, however, certain occasions when it is useful to have **independent control over each of the test stations.**

This is particularly helpful in research and development when the user is comparing one formulation directly against another, or one formulation under varying conditions, or in the



▲ Disintegration Tester DTG 2000 IS

case of delayed release or enteric coated tablets where it is necessary to immerse the sample for specified periods of time in different media.

Alternatively, there are times in QC operations when it is more convenient to carry out tests at different times, e.g. when one disintegration tester serves to support two tablet presses.

The **DTG 2000 IS** is a two-station unit which has been specifically designed for these types of tests. It has all of the features of the standard DTG series mentioned above.

However, on this unit, **each basket rack assembly** can be controlled, started and stopped **individually** using separate membrane keypads.



▶ Drain tap used on rear of DTG 3000 and DTG 4000 water bath

Cat. No. Description

1208	Disintegration Tester Model DTG 2000 IS
1205	Extra for Numbering and Certification (per basket)
1206	IQ/OQ/PQ Documentation Pack
1207	Electronic Temperature Calibration Kit
1228	Qualification Tools



▲ Basket fitted with Special Cover

▲ Special Basket for Large Tablets

Glass Tubes, Fluted Discs and Sieve Meshes ▲

DISINTEGRATION ACCESSORIES

STANDARD ACCESSORIES

Copley Scientific offers a complete range of accessories for use with the DTG series, from complete basket rack assemblies to individual tubes, discs and sieve meshes.

All parts are manufactured to tolerances that are equal to or better than those quoted in the respective Pharmacopoeias and carefully checked prior to despatch.

BASKET RACK ASSEMBLY COVER FOR HARD & SOFT GELATINE CAPSULES (as per USP Chapter <701>)

Converts standard basket to special covered version for testing hard or soft gelatine capsules according to USP Chapter <701>.

USP specifies that, when testing hard or soft gelatine capsules, the top of the basket rack assembly should be covered by a further sieve mesh (2 mm x 0.63 mm).

Comprises basket cover with integral sieve meshes, plus central locking device for easy assembly.

SPECIAL BASKET RACK ASSEMBLY FOR LARGE TABLETS & CAPSULES (as per Ph.Eur. Chapter 2.9.1 Test B and USP Chapter <2040>)

Special basket rack assembly for large tablets, capsules and boluses according to Ph.Eur. Chapter 2.9.1 Test B and for dietary supplements according to USP Chapter <2040>.

In this version, the six standard tubes are replaced with three tubes having an inside diameter of 33 mm.

Supplied complete with the special cylindrical discs specified in the Pharmacopoeia.

Can be supplied with Certificate of Compliance on request.

HYGIENE: ANTI-BACTERIA/ALGAE SOLUTION

Keep your water bath free of bacterial, algal or slime growth.

The addition of just 1 mL of Aqua-Stabil per litre of water, per month, will prevent the build-up of bacteria and algae keeping the water in your bath clear, safe and odour free.

Available in 100 mL bottles.

Cat. No. Description

1210	Standard Basket Rack Assembly
1205	Extra for Numbering and Certification (per basket)
1211	Set of 6 Glass Tubes for Standard Basket
1212	Set of 6 Fluted Discs for Standard Basket
1213	Set of 6 Sieve Meshes for Standard Basket
1214	1000 mL Beaker
1215	Basket Rack Cover for Hard & Soft Gelatine Capsules
1216	Extra for Numbering and Certification (per cover)
1217	Special Basket Rack Assembly for Large Tablets & Capsules
1218	Extra for Numbering and Certification (per basket)
1219	Set of 3 Glass Tubes for Special Basket
1220	Set of 3 Cylindrical Discs for Special Basket
1221	Sieve Mesh for Special Basket
1372	100 mL Bottle of Aqua-Stabil