Disintegration

Background: Disintegration Testing

Before the active ingredient(s) of an oral solid dose drug product can be absorbed into the body, the tablet or capsule in which they are contained must first disintegrate into smaller particles.

Chapters Ph. Eur. 2.9.1 and USP <701> and <2040> describe reproducible and standardised methods for quantifying the disintegration behaviour of solid dosage forms.

Disintegration

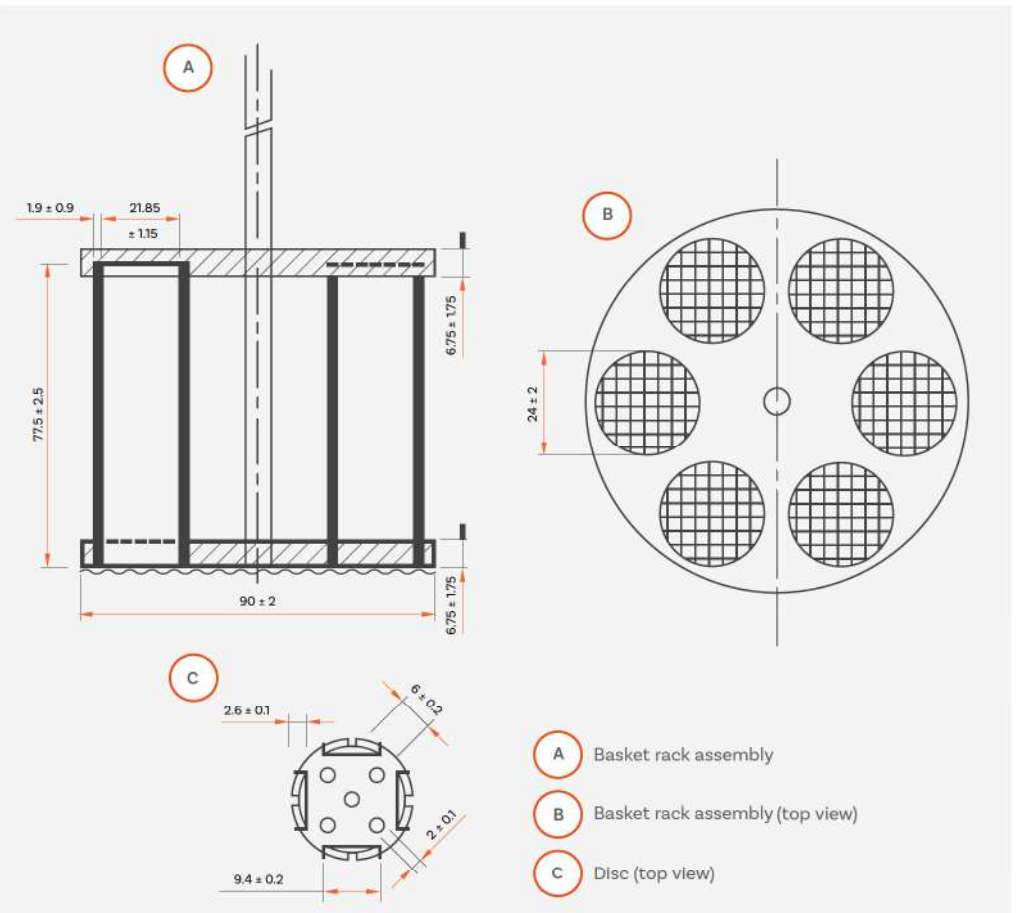
Test Apparatus & Method

Typically, the tablets and capsules to be tested are each 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 each tube is covered by a 2 mm sieve mesh. Large tablets, capsules and boluses may require a larger basket.

The basket assembly is raised and lowered in simulated gastric fluid at body temperature (37 °C) through a distance of 55 mm, at a constant stroke frequency of 30 cycles per minute. A plastic disc of precise geometry "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.



Disintegration: DTGi Series

Reproducible, standardised and affordable disintegration testing

The result of decades of innovation and experience in the field of pharmaceutical testing, the Copley DTGi series of disintegration testers simplifies testing within R&D and QC environments. Suitable for a wide range of tablet and capsule types (e.g. plain-coated tablets, delayed-release, gelatine etc.), the DTGi tester series is an affordable range of disintegration testers, that complies fully with specifications defined in Ph. Eur., USP and associated Pharmacopoeias.

Controlled via our intuitive touchscreen interface, the Copley DTGi Series features 1, 2, 3 and 4 station units as well as a 2-station independent control unit, ideal for testing tablets and capsules under varying conditions. The user-friendly design makes assessing disintegration characteristics a simple touch-of-a-button task.

- Ph. Eur. and USP compliant
- Integrated, precision temperature control and measurement
- Intuitive touchscreen control to simplify operation
- Single-point electronic temperature calibration
- One to four test station unit configurations, plus independent station control unit option
- Extensive data reporting output options
- Adjustable stroke frequency control for accelerated or high sensitivity testing
- Option to automate and remotely control DTGi systems

INNOVATIVE
COMPLIANT
TRUSTED

DTGi Series: Key Features

Quick-release baskets for rapid sample loading, unloading and cleaning

Intuitive touchscreen control with icon-based menu structure simplifies operation and clearly displays test parameters throughout run

Robust metal case with advanced corrosion protective coating

Basket rack assemblies are automatically lowered and raised to/from test media at start and end of test

Independent digital heater/ circulator maintains a constant temperature and minimises vibration

Easily removable leak-proof water bath with convenient drain tap eases bath water emptying

PT100 temperature probe monitors bath and media temperature

Maximum fill line indicator

Note:
A low-working noise level is generated by the equipment ensuring a comfortable working environment

DTGi Series: Touchscreen User Interface

Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters**:
  Speed (cycles per minute)
  Temperature (°C)
  Report output settings menu
- Status of **'Actual' v 'Set'** test **parameters clearly displayed** throughout testing
- **Test progress bar** provides clear and constant indication on run status
- Resistive touchscreen interface can be **operated with gloves on**
- Hygienic **wipe-clean** screen
- **Passcode-protected** temperature calibration
- High productivity - **easy system set-up and operation** minimises training burden.

Reporting

Extensive data output options are available as standard, including direct reporting to a printer or PC.

Reported parameters

- **Speed (cycles per minute)**
  Set
  Average
  Maximum
  Minimum
- **Temperature (°C)**
  Set
  Average
  Maximum
  Minimum
- **Test Duration (HH:MM:SS)**
  Set
  Actual
- **Calibration Data**
  Calibration date
  Temperature calibrated at (°C)

RS 232

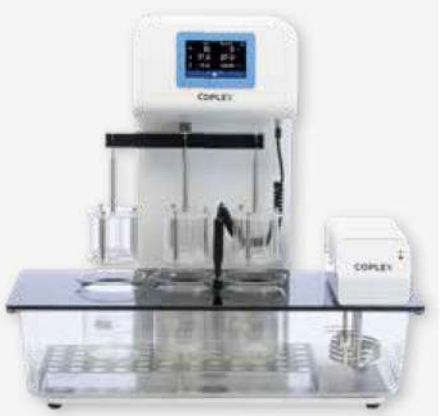
USB A

USB B

Compliance & Maintenance

- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available
- ✓ Passcode-protected single-point electronic temperature calibration
- ✓ Latest temperature calibration information stored and available to export/print

Choose your DTGi Disintegration System

		
DTG 100i	**DTG 200i**	**DTG 300i**
Cat. Number 1231	**Cat. Number** 1232	**Cat. Number** 1233
No. Test Stations 1	**No. Test Stations** 2	**No. Test Stations** 3
Tablet Capacity 6	**Tablet Capacity** 12	**Tablet Capacity** 18
Independent Station Control No	**Independent Station Control** No	**Independent Station Control** No
Unit Dimensions (w x d x h) 450 x 473 x 657 mm	**Unit Dimensions (w x d x h)** 450 x 473 x 657 mm	**Unit Dimensions (w x d x h)** 700 x 473 x 657 mm

DTG 400i

Cat. Number
1234

No. Test Stations
4

Tablet Capacity
24

Independent Station Control
No

Unit Dimensions (w x d x h)
700 x 473 x 657 mm

DTG 200i-IS

Cat. Number
1238

No. Test Stations
2

Tablet Capacity
12

Independent Station Control
Yes

Unit Dimensions (w x d x h)
515 x 473 x 657 mm

Independent Station Control: DTG 200i-IS

With the same standard features as the other DTGi systems, the DTG 200i-IS offers independent control over each test station, making it ideal for the following types of applications:

- Comparing one formulation directly against another
- Comparing the performance of a single formulation under different conditions
- Assessing delayed release or enteric coated tablets where samples must be immersed for specified periods of time in different media
- Allowing two users to run tests simultaneously

DTGi Series: Technical Specifications	
Pharmacopoeial Compliance	Ph. Eur. Chapter: 2.9.1 USP Chapter: <701> and <2040>
User Interface	Resistive touchscreen
Basket Rack Assembly	Automatically lowered and raised at beginning and end of test run
Stroke Frequency Range	10 - 50 strokes/min
Stroke Height	55 ± 1 mm
Heater Type	Independent digital heater/circulator
Heater Temperature Range	Ambient - 50 °C
Test Run Time	Up to 99 hours , 59 minutes, 59 seconds
Alarm(s)	**1.** End of testing (audible) **2.** Low bath water level warning on-screen indicator
Data Output	RS 232 USB A (for connection with a USB printer) USB B (for connection with a PC)

Temperature Calibration

Single-point electronic temperature calibration. Calibration of the DTGi Series temperature probe is simple, through the use of an electronic calibration key and passcode-protected calibration menu designed to guide users through the process without fuss. The latest temperature probe calibration information is stored and available to print/export when convenient to the user.

DTGi Series

Cat. No.	Description
1231	Disintegration Tester Model DTG 100i
1232	Disintegration Tester Model DTG 200i
1233	Disintegration Tester Model DTG 300i
1234	Disintegration Tester Model DTG 400i
1238	Disintegration Tester Model DTG 200i-IS
1205	Extra for Numbering and Certification (per basket)
1206	IQ/OQ/PQ Documentation Pack
1209	Electronic Temperature Calibration Key
1228	Qualification Tools
1229	Re-Calibration of Qualification Tools
1307	Printer (including USB cable)

Electronic Temperature Calibration Key

Choose your DTGi System Accessories

Copley offers a complete range of accessories for use with the DTGi 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. Certificates of Compliance can be supplied upon request.

DTGi Series Accessories

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 Polycarbonate Discs for Standard Basket
1213	Set of 6 Sieve Meshes for Standard Basket
1214	1000 mL Beaker

Accessories for Specialist Dosage Forms

Cat. No.	Description
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 Tubes for Special Basket
1220	Set of 3 Cylindrical Discs for Special Basket
1221	Sieve Mesh for Special Basket

Hygiene: Anti-Bacterial/Algae Treatment

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

Cat. No.	Description
1372	100 mL Bottle of Aqua Stabil