

**COPLEY**



# Driving Results in Pharmaceutical Testing

TABLETS & CAPSULES • SUPPOSITORIES • TRANSDERMALS  
POWDERS & GRANULES • SEMISOLIDS

2020 EDITION

# About Us

## Copley: Driving Results for Over 70 Years

Founded in 1946 in Nottingham, UK, Copley remains family owned and managed. We are recognised as the world’s leading manufacturer of inhaler test equipment, in addition to being a trusted provider of test instrumentation for other pharmaceutical dosage forms.

We continue to work closely with industry groups and leading experts to bring relevant new products to market, with all equipment backed by expert training and lifetime support.

Committed to excellence, we aim to deliver exemplary service for an outstanding customer experience.

We deliver pharmaceutical testing equipment with the necessary accuracy and reproducibility hard-wired into its design by adopting the same Quality by Design (QbD) principles that our customers rely on to control product performance. Continuous improvement is a core element of this approach and we strive to exceed the expectations of the industry, not only by enhancing equipment performance but also through unrivalled service.

These commitments are exemplified by our investment in the **ISO 9001:2015 Quality Management System** for which we have certification to the latest standard for all aspects of our business, including equipment design.

### Copley customers benefit from:

- High quality pharmaceutical testing equipment, designed, manufactured and tested in the UK
- Product lifetime support from our friendly and experienced technical support team
- First-class training and education

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## The Copley Promise



- 
**Innovative**  
 Innovative product design features ensure ease-of-use and maximum productivity by streamlining work flows.
- 
**Compliant**  
 Products are certified to quality standards defined by global pharmacopoeias and regulators, ensuring data integrity.
- 
**Trusted**  
 Robust design and manufacture from a company with over 70 years’ experience guarantees product reliability and longevity.

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DTG 400i



Friabimat SA-400



HDT 1000

# Classification of Medicines

## Introduction

One of the clearest taxonomic guides for the classification of pharmaceutical dosage forms is to be found in Chapter <1151> of the US Pharmacopeia (USP) entitled “Pharmaceutical Dosage Forms”.

The guide is depicted in “Figure 1. Compendial taxonomy for pharmaceutical dosage forms”, a modified version of which appears below.

This proposes a three tier system with the first tier being based on the region of the body to which the drug is to be administered, i.e. gastrointestinal (oral), mucosal membrane (rectal, vaginal, oropharyngeal, ophthalmic, otic and urethral), skin surface (topical, transdermal), injection including implants (parenteral) or nasal/lungs (pulmonary).

The second tier describes the dosage form concerned, e.g. tablet, capsule, suppository, cream, ointment, transdermal patch, injection, inhaler, etc., whilst the third tier describes whether the dosage form concerned is designed for immediate, extended or delayed release.

It is the first tier classification which has been used as the basis for the Equipment Selection Guide to be found on page 7.

This lists the route of administration, the dosage form and test parameter concerned, the chapter relating to that test parameter in both European and US Pharmacopoeia (where applicable) and, in the final column, the page number in this catalogue where a description of the relevant test instrumentation can be found.



### TIER 1 Route of Administration

GASTROINTESTINAL / MUCOSAL / INHALATION / INJECTION / TOPICAL (DERMAL)

### TIER 2 Dosage Form

AEROSOLS / CAPSULES / CREAMS / EMULSIONS / FILMS / FOAMS / GASES  
 GELS / GRANULES / GUMS / IMPLANTS / INJECTIONS / INSERTS / IRRIGATIONS  
 LIQUIDS / LOZENGES / OINTMENTS / PASTES / PELLETS / PILLS / PLASTERS  
 POWDERS / SOAPS / SHAMPOOS / SOLUTIONS / SPRAYS / STRIPS  
 SUPPOSITORIES / SUSPENSIONS / SYSTEMS / TABLETS / TAPES

### TIER 3 Release Pattern

IMMEDIATE / EXTENDED / DELAYED

Equipment Selection Guide			
Route of Administration - Dosage Form	European Pharmacopoeia	United States Pharmacopoeia	Page No. (in this brochure)
<b>GASTROINTESTINAL</b> Tablets & Capsules - Disintegration	Chapter 2.9.1	Chapter 701	Pages 14-21
<b>GASTROINTESTINAL</b> Tablets & Capsules - Dissolution	Chapter 2.9.3	Chapter 711	Pages 26-39
<b>GASTROINTESTINAL</b> Tablets & Capsules - Friability	Chapter 2.9.7	Chapter 1216	Pages 42-47
<b>GASTROINTESTINAL</b> Tablets & Capsules - Breaking Force	Chapter 2.9.8	Chapter 1217	Pages 52-59
<b>GASTROINTESTINAL</b> Tablets & Capsules - Weight & Thickness	Chapter 2.9.5	Chapter 905	Pages 58
<b>GASTROINTESTINAL</b> Powders - Bulk & Tapped Density	Chapter 2.9.34	Chapter 616	Pages 67-73
<b>GASTROINTESTINAL</b> Powders - Flowability	Chapter 2.9.16 & 2.9.36	Chapter 1174	Pages 64-65
<b>GASTROINTESTINAL</b> Granules & Pellets - Friability	Chapter 2.9.41	---	Pages 48-49
<b>MUCOSAL MEMBRANE</b> Rectal - Drug Release	Chapter 2.9.2	Chapter 1004	Pages 86-89
<b>MUCOSAL MEMBRANE</b> Oropharyngeal, Ophthalmic, Otic & Urethral	Outside the scope of this brochure		
<b>MUCOSAL MEMBRANE</b> Vaginal - Drug Release	Chapter 2.9.22	---	Pages 89
<b>SKIN SURFACE - Semisolids</b> Drug Release - Permeation	---	Chapter 1724	Pages 76-83
<b>SKIN SURFACE</b> Transdermal Patches - Drug Release	Chapter 2.9.4	Chapter 724	Pages 37
<b>INJECTION</b> Injections & Implants	Outside the scope of this brochure		
<b>LUNGS</b> Inhalers	Chapter 2.9.18 & 0671	Chapter 601	See: Inhaler Testing Brochure
<b>LUNGS</b> Nebulisers	Chapter 2.9.44	Chapter 1601	See: Inhaler Testing Brochure
<b>NASAL</b> Inhalers & Sprays	Chapter 2.9.18 & 0676	Chapter 601	See: Inhaler Testing Brochure

# Organisations and their Roles

## Introduction

The ultimate responsibility for the safety, quality and efficacy of medicines and medical devices lies with the various national regulatory bodies designated to safeguard public health.

In Europe, Japan and in the USA this function is performed by the **European Medicines Agency (EMA)**, the **Ministry of Health, Welfare and Labor (MHWL)** and the **Food and Drug Administration (FDA)** respectively.

The regulatory authorities are supported in this role by the **Pharmacopoeias** whose job is to define the standards with which the drug formulation shall comply and the methods by which compliance will be adjudged.

In October 1999, the **International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)\*** published a single set of global specifications covering the **Test Procedures and Acceptance Criteria for new drug substances and products**.

The guidance takes the form of a number of universal tests/criteria considered generally applicable to:

- a) new drug substances and
- b) new drug products

together with a number of additional tests and acceptance criteria for specific substances and dosage forms, including solid oral drug products, liquid oral drug products and parenterals.

The additional tests for tablets (coated and uncoated) and hard capsules, for example, include:

- a) Dissolution
- b) Disintegration
- c) Hardness/Friability
- d) Uniformity of dosage units
- e) Water content and
- f) Microbial limits

The guideline on quality concerned (Q6A) was subsequently agreed and adopted by all of the parties involved, including the EMA, FDA and MHWL.

In 2002 the FDA launched a new initiative "Pharmaceutical cGMPs for the 21st Century" in which it proposed a new risk-based

approach to pharmaceutical manufacturing.

This initiative gave birth to **Process Analytical Technology (PAT)**, a framework for understanding and improving the processes involved in pharmaceutical development, manufacturing and quality control, described in FDA's Guidance of September 2004.

PAT operates on the premise that quality cannot be tested into products; rather, it should be built-in or by design.

The goal is to ensure final product quality by understanding and controlling the processes involved in the manufacturing operation.

*\* See Page 9 for further details*

### ICH Quality Guidelines

<b>Q1A - Q1F Stability</b>	<b>Q8 - Pharmaceutical Development</b>
<b>Q2 - Analytical Validation</b>	<b>Q9 - Quality Risk Management</b>
<b>Q3A - Q3D Impurities</b>	<b>Q10 - Pharmaceutical Quality System</b>
<b>Q4 - Q4B Pharmacopoeias</b>	<b>Q11 - Development and Manufacture of Drug Substances</b>
<b>Q5A - Q5E Quality of Biotechnological Products</b>	<b>Q12 - Lifecycle Management</b>
<b>Q6A - Q6B Specifications</b>	<b>Q13 - Continuous Manufacturing</b>
<b>Q7 - Good Manufacturing Practice</b>	<b>Q14 - Analytical Procedure Development</b>



## The Quality by Design (QbD)

approach agreed and now adopted by the EMA, FDA and the Japanese MHWL in the form of the five quality related guidelines, ICH Q8 to Q12, extends this philosophy to all parts of the product life cycle from product development, transfer through to manufacturing, manufacturing and finally product end.

ICH Q8 Pharmaceutical Development describes the suggested contents of a regulatory submission based on the QbD format.

ICH Q9 details a systematic approach to quality risk management, whilst ICH Q10 describes a new quality management system based on the complete product life cycle and referred to as the Pharmaceutical Quality System.

ICH Q11 provides a Guideline to the "Development and Manufacture of Drug Substances", including the type and extent of information to be submitted in regulatory dossiers, whilst Q12 provides a framework to facilitate the management of the entire "Pharmaceutical Product Lifecycle.

## 1. REGULATORY BODIES IN THE EUROPEAN UNION, JAPAN AND THE USA

In the USA, the regulatory function is performed by the **Food and Drug Administration (FDA)** with technical and scientific support being provided through two centers - the Center for Drug Evaluation and Research (CDER) in respect of medicines and the Center for Devices and Radiologic Health (CDRH) in respect of medical devices e.g. inhalers.

A similar function to the FDA is provided by the **Ministry of Health, Welfare and Labor (MHWL)** in Japan and the **European Medicines Agency (EMA)**, with support in the form of the **Committee for Medicinal Products for Human Use (CHMP)**, representing the various states making up the European Union (EU).

Other prominent bodies include the **Central Drugs Standard Control Organisation (CDSCO)** of India, the **China Food and Drug Administration (CFDA)**, **Health Canada** and **Swissmedic**.

## 2. INTERNATIONAL REGULATION AND HARMONISATION

The International Centre for Harmonisation (ICH) mentioned on Page 8 is a unique organisation consisting of representatives from the regulatory authorities in the European Union (EMA), Japan (MHLW) and the USA (FDA), and experts from the pharmaceutical industry in the three regions, in a single forum.

The purpose of the ICH is to promote greater harmonisation in the ways in which the individual regulatory bodies regulate new drugs such that the medicine reaches the patient economically and with the minimum delay whilst maintaining the standards of safety, quality and efficacy necessary to safeguard public health.

Current goals include finalisation of ICH Q13 (Continuous Manufacturing of Drugs) and ICH Q14 (Analytical Procedure Development).

**Note:** A similar organisation, the **Global Harmonisation Task Force (GHTF)**, exists for medical devices.

## Organisations and their Roles

### 3. DRUG SAFETY, QUALITY AND EFFICACY – THE PHARMACOPOEIAS

The main role of the Pharmacopoeias is to define the standards with which medicines must comply and the methods by which compliance will be adjudged.

As with the regulatory groups, the leading Pharmacopoeias tend to be those of the European Union, Japan and the USA.

#### a) European Pharmacopoeia

This is published by the Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM).

In the **European Pharmacopoeia (Ph.Eur.)**, the main information relating to a drug product is contained in the general monograph relating to the dosage form concerned (see “Monographs on Dosage Forms”).

This normally gives a definition of the dosage form e.g. tablets,

together with notes as to its production and, where applicable, the test procedures, storage conditions and labelling requirements relevant to that type of product, with cross references to appropriate methods of testing e.g. Uniformity of Dosage Units (2.9.40).

The EDQM is also responsible for “**Pharmeuropa**”, a quarterly publication which contains “Draft Monographs and General Texts for Comment” together with the latest news on “International Harmonisation”.

#### b) United States Pharmacopoeia

Hitherto, the **United States Pharmacopoeia (USP)** has adopted a similar approach to Ph.Eur. with details of the test procedures to be employed together with all of the other relevant information in product specific monographs with cross references to the appropriate methods of testing e.g. Uniformity of Dosage Units <905>.

A separate chapter, Pharmaceutical Dosage Forms <1151>, gives a general description and definition of the more common dosage forms together with the general principles in their compounding and manufacturing.

However, in USP 38 the Pharmacopoeia has introduced a series of new chapters, <1> through to <5>, entitled **General Requirements for Tests and Assays**, which provide general information and the critical quality attributes applicable to the various dosage forms based on their **route of administration** (see Table on Page 11).

The five chapters concerned detail the test procedures relevant to each dosage form, divided between those relating to product **quality** and those to product **performance**, with cross references to the methods of testing as appropriate.

Product quality tests assess physical, chemical and microbial attributes.

Product performance tests assess drug release from the dosage form concerned or, in the case of aerosols, particle size distribution.

Like Ph.Eur., USP also produces a bi-monthly publication entitled “Pharmacopeial Forum”, which contains discussion documents relating to new and/or amended chapters and monographs.

### NEW USP 38 CHAPTERS <1> to <5>

Route of Administration	Site of Release	Typical Dose Forms	Product Tests for Quality	Product Tests for Performance
Injections & Implanted Drug Products (Parentals) Chapter <1>	Body tissues and fluids	Injections, particles, liposomes, implants, stents	<1>	<1001> Under development
Oral Drug Products Chapter <2>	Oral	Tablets and Capsules, Liquids	<2>	<701> <711>
Topical and Transdermal Drug Products Chapter <3>	Skin	Semisolids, Transdermal Patches	<3>	<724> <1724>
Mucosal Drug Products Chapter <4>	Ear, eye, nose, throat, urether, vagina, rectum	Various see <4>	<4>	<1004>
Inhalation and Nasal Drug Products Chapter <5>	Lung, nasal cavity	Aerosols, sprays, powders	<5>	<601>, <602> <603>, <604>, <1601>, <1602>



# 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

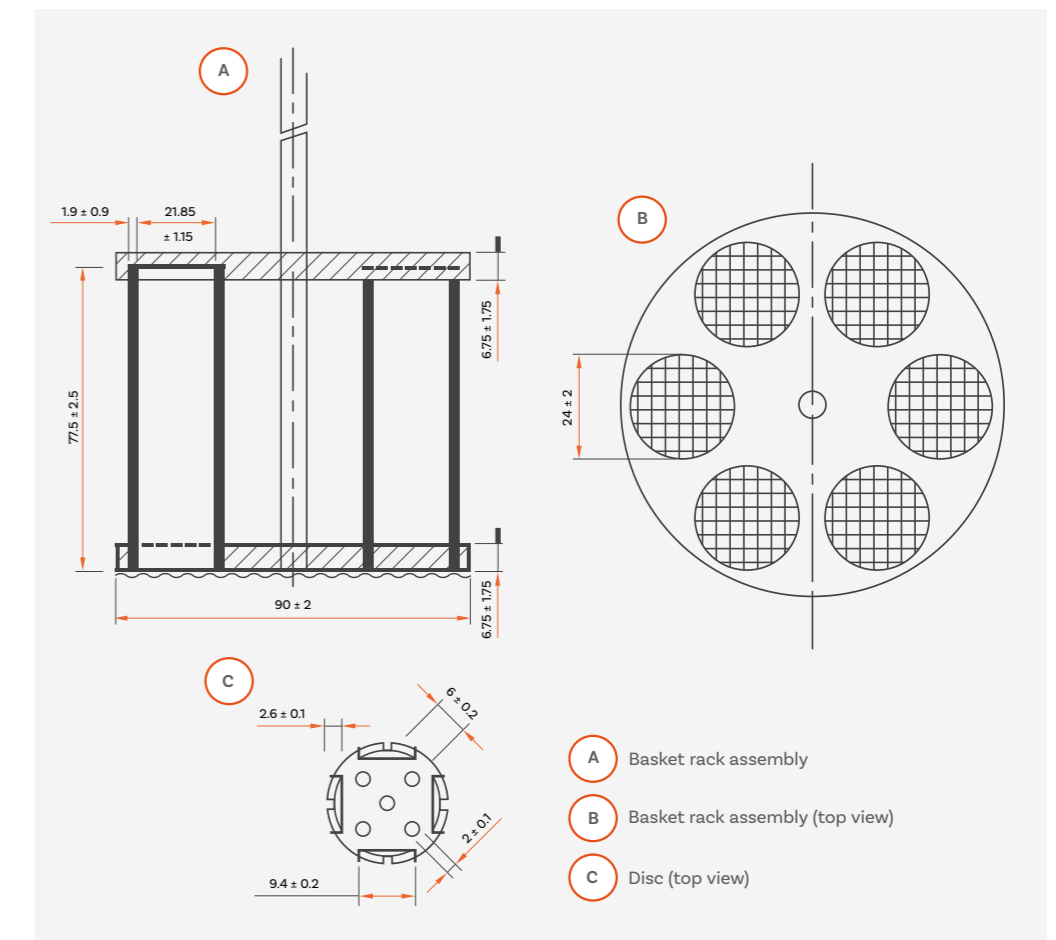
Typically, the tablets and capsules to be tested are each placed in one of six vertical tubes each measuring approx. 77.5 mm long x 21 mm inside diameter, positioned in a circular basket arrangement.

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



## 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



- A Setting a test parameter
- B Set v Actual test parameters (before test run)
- C Set v Actual test parameters (during test run, with test progress bar)
- D Settings menu
- E Passcode-protected temperature calibration process
- F Temperature calibration
- G Report output settings menu

## 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.

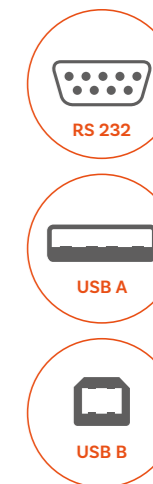


## Reporting

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)



## 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**

**Cat. Number**  
1231

**No. Test Stations**  
1

**Tablet Capacity**  
6

**Independent Station Control**  
No

**Unit Dimensions (w x d x h)**  
450 x 473 x 657 mm



**DTG 200i**

**Cat. Number**  
1232

**No. Test Stations**  
2

**Tablet Capacity**  
12

**Independent Station Control**  
No

**Unit Dimensions (w x d x h)**  
450 x 473 x 657 mm



**DTG 300i**

**Cat. Number**  
1233

**No. Test Stations**  
3

**Tablet Capacity**  
18

**Independent Station Control**  
No

**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

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



## 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



# Dissolution

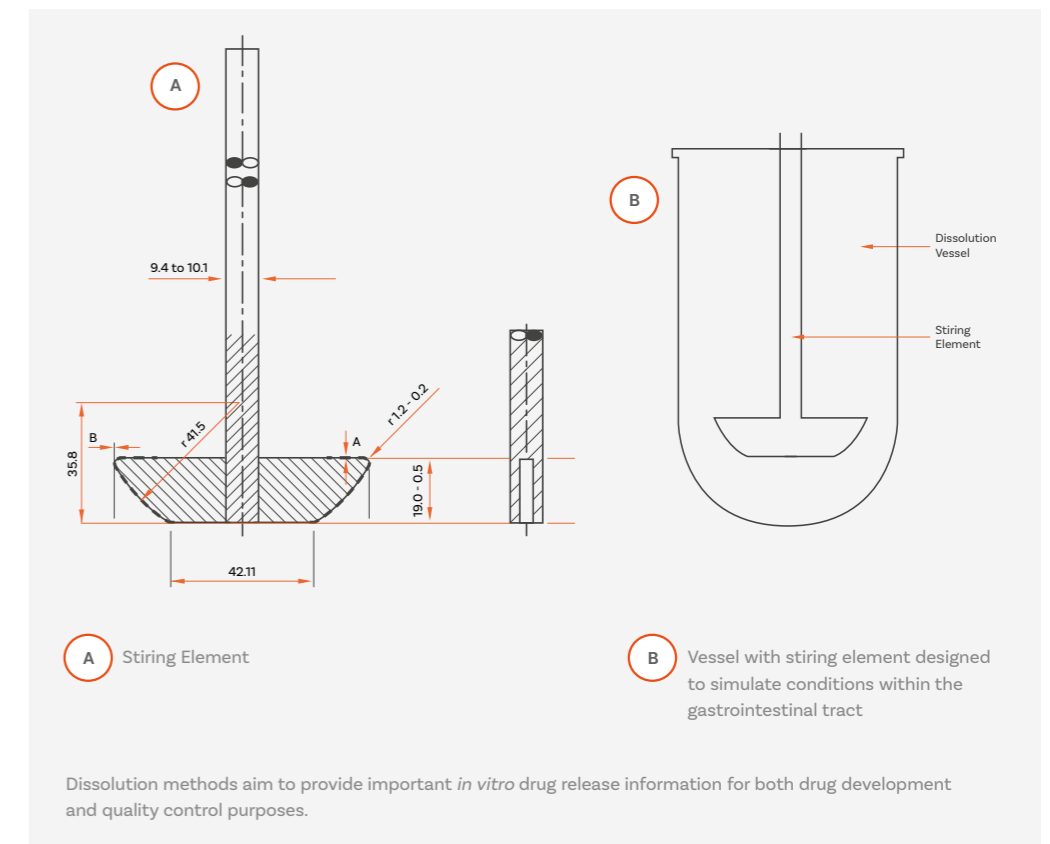
## Background: Dissolution Testing

Optimising the amount of a drug available to the body following administration, i.e. its bioavailability, remains one of the greatest challenges the pharmaceutical industry faces. Inadequacies in bioavailability can mean a treatment is ineffective or even potentially dangerous (e.g. overdose).

The effectiveness of tablets or capsules administered orally relies on the drug dissolving in the fluids of the gastrointestinal tract prior to absorption into the systemic circulation. It is widely acknowledged that the rate at which the drug dissolves is critical to its therapeutic efficacy and as such, is considered a Critical Quality Attribute (CQA) in both the formulation process and final quality control.

Determining bioavailability via *in vivo* drug release analysis studies (e.g. urine or plasma analysis) can be impractical, particularly when such techniques are required on a routine basis. To overcome such issues, official *in vitro* dissolution tests have been rigorously and comprehensively defined in the respective Pharmacopoeias and are essential for:

- Predicting *in vivo* drug bioavailability
- Assessing bioequivalence and its application in scale-up and post-approval changes
- Optimising therapeutic effectiveness during development and stability assessment
- Ensuring uniformity between production lots



Initially developed for oral dosage forms, the role of the 'dissolution test' has now been expanded to the 'drug release' of various other forms such as semisolids topical and transdermal systems (see page 74).

# Dissolution

## Test Apparatus & Method

The progressive optimisation of dissolution testing for different pharmaceutical forms has led to the introduction of a range of different apparatuses and techniques as detailed in Ph. Eur Chapters 2.9.3, 2.9.4 and USP Chapters <711> and <724>.

The most commonly used apparatus defined by the Pharmacopoeias to measure the dissolution rate of solid dose forms are the **basket** and **paddle**.

The basic dissolution apparatus consists of a covered cylindrical vessel with a hemispherical bottom, typically holding 1000 mL of simulated gastric juice.

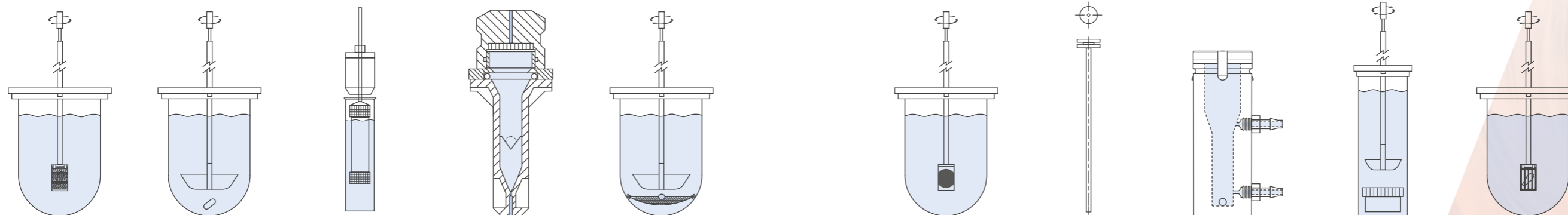
The vessel is immersed in a water bath capable of maintaining the temperature of the vessel contents at 37°C. For the basket method, the tablet or capsule is constrained in a cylindrical basket, constructed of sieve mesh, of defined proportions. The basket is attached to a metal drive shaft, positioned so that the bottom of the basket is 25 mm from the bottom of the vessel.

With the **paddle** method, the basket is replaced by a paddle and the sample to be tested is allowed to sink to the bottom of the vessel. During a test run, a motor is used to rotate the shaft at a speed specified by the appropriate Pharmacopoeias.

The **paddle over disk** technique is used for the determination of the drug release rate from transdermal patches. It is described in the Ph. Eur. under Chapter 2.9.4 and under Chapter <724> as Method 5 in the USP. Using a suitable adhesive, the transdermal patch is simply mounted on a disk designed to hold it at the bottom of the vessel. The **rotating cylinder** (Ph. Eur. Chapter 2.9.4, USP Method 6) is an alternative to the paddle over disk method.

Samples of the dissolution medium are taken at predefined time intervals to determine the percentage of dissolved drug present – typically using a UV/Vis Spectrophotometer or high-pressure liquid chromatography (HPLC). Dissolution of all but the most specialised oral pharmaceutical dosage forms can be tested with either the basket or paddle methods.

Other techniques specified in the USP for dissolution testing include: Reciprocating Cylinder (Apparatus 3), Flow-Through Cell (Apparatus 4) and Reciprocating Holder (Apparatus 7). These are not routinely required except for highly specialised dosage forms.



Basket	Paddle	Reciprocating Cylinder	Flow-Through Cell	Paddle Over Disk		Cylinder	Reciprocating Holder	Vertical Diffusion Cell	Special Immersion Cell	Special Suppository Basket
Ph. Eur. 2.9.3	Ph. Eur. 2.9.3	Ph. Eur. 2.9.3	Ph. Eur. 2.9.3	Ph. Eur. 2.9.4		Ph. Eur. 2.9.4	-	-	-	-
USP App 1 <711>	USP App 2 <711>	USP App 3 <711>	USP App 4 <711>	USP App 5 <724>		USP App 6 <724>	USP App 7 <724>	USP <1724>	USP <1724>	-

# Dissolution: DISi Series

## Expertly engineered systems for everyday dissolution testing

Meeting the latest specifications as laid down in the European, United States and associated Pharmacopoeias, the DISi Series from Copley is a range of reliable and cost-efficient dissolution tester systems designed with the highest standards of solid dosage testing performance in mind.

Ideal for use in both R&D and QC environments, the DISi Series is equipped with precision ground shafts that will accept any of the baskets, paddles or rotating cylinders described in the Ph. Eur., USP and associated Pharmacopoeias.

Designed to minimise user training and reduce the burden of routine equipment maintenance, the DISi Series simplifies the dissolution testing process, without compromising on data quality.



Ph. Eur. and USP compliant



Integrated, precision temperature control and measurement



Intuitive touchscreen control to simplify operation



Single-point electronic temperature calibration



Six and eight test station unit configurations available



Extensive data output options



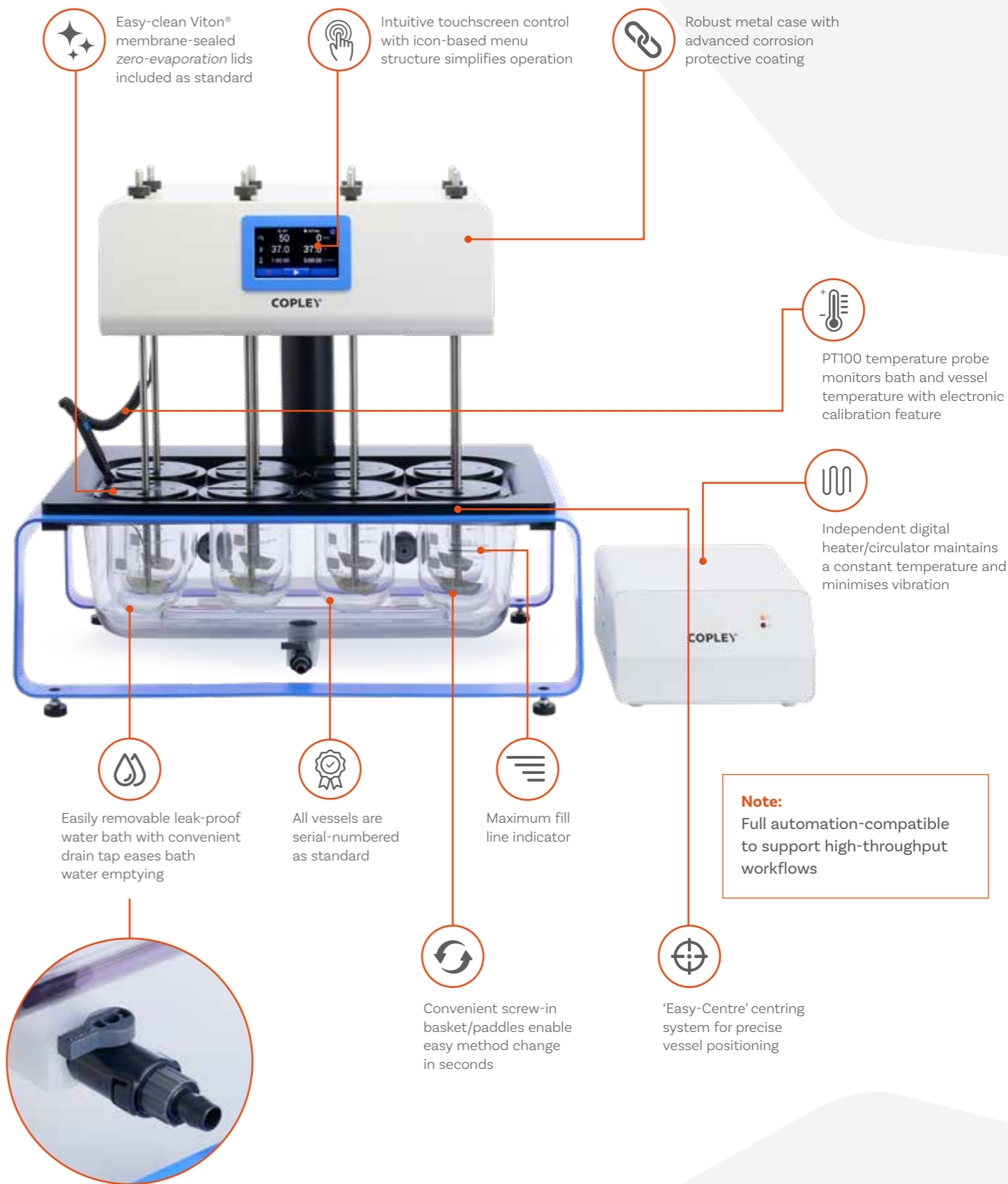
Wide speed range to accommodate broad scope of methods



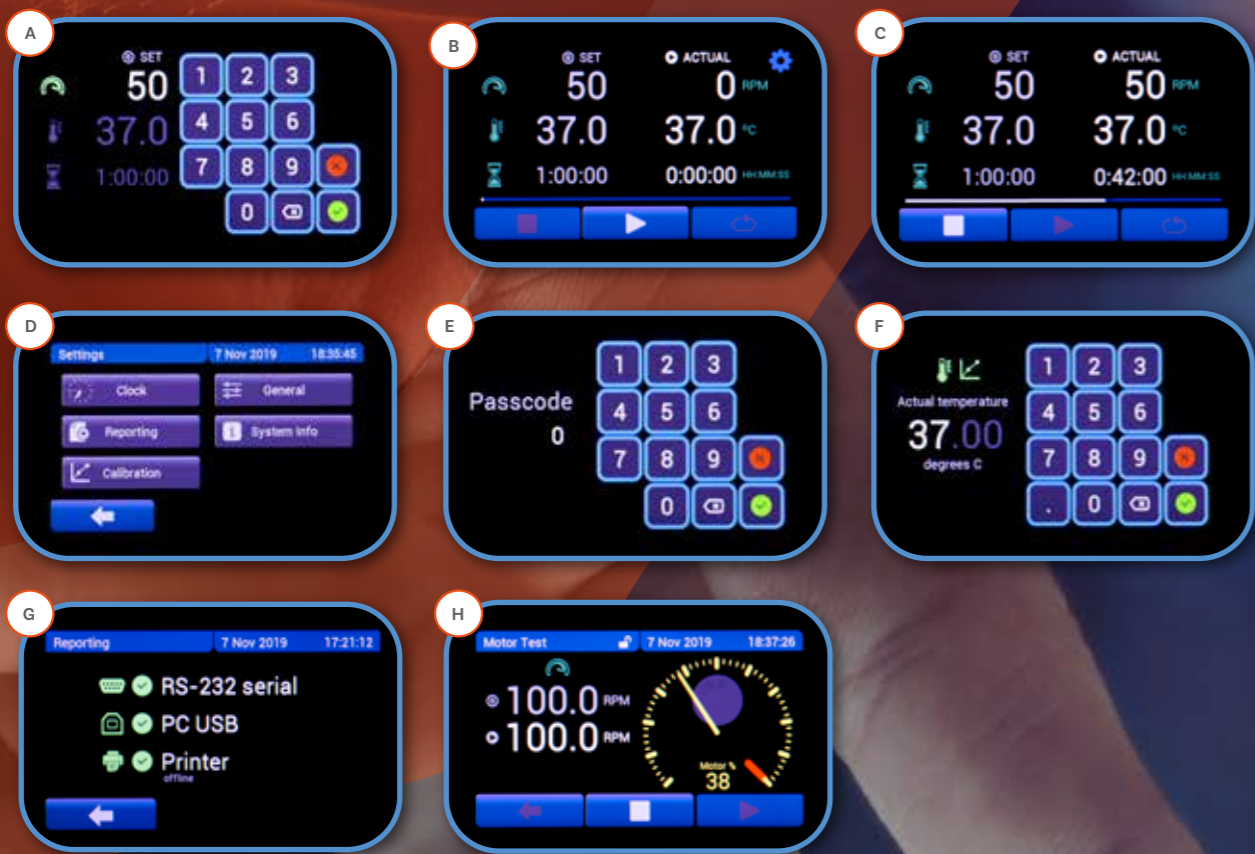
Option to automate and remotely control DISi Systems



## DISi Series: Key Features



# DISi Series: Touchscreen User Interface



- A** Setting a test parameter
- B** Set v Actual test parameters (before test run)
- C** Set v Actual test parameters (during test run, with test progress bar)
- D** Settings menu
- E** Passcode-protected temperature calibration process
- F** Temperature calibration
- G** Report output settings menu
- H** Motor speed (RPM) verification

### Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters**:  
Speed (revolutions per minute)  
Temperature (°C)  
Test duration (HH:MM:SS)
- Status of **'Actual' v 'Set'** test **parameters clearly displayed** throughout testing
- **Test progress bar** provides clear and constant indication of 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

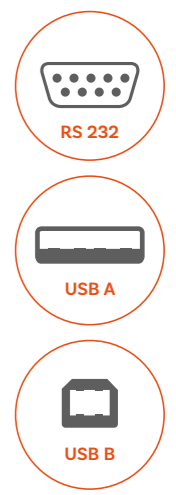


### Reporting

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

#### Reported parameters

- **Speed (revolutions 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)



### 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 DISi Dissolution System



## DIS 600i

With bench space a premium in many laboratories, the DIS 600i is one of the most compact dissolution testers available on the market today.

### Cat. Number

1336

### No. Stirred Vessels

6

### Ph. Eur. and USP Test Methods Supported

1, 2, 5, 6

### Heater

Low vibration integrated digital heater/circulator

### Unit Dimensions (w x d x h)

728 x 495 x 689 mm



## DIS 800i

Maximising visibility and access to the critical sampling area above the bath, the DIS 800i represents the very latest in tablet dissolution testing technology.

### Cat. Number

1338

### No. Stirred Vessels

8

### Ph. Eur. and USP Test Methods Supported

1, 2, 5, 6

### Heater

Low vibration independent external digital heater/circulator

### Unit Dimensions (w x d x h)

728 x 495 x 689 mm (unit)  
260 x 330 x 150 mm (heater)

## DISi Series: Technical Specifications

<b>Pharmacopoeial Compliance</b>	Ph. Eur. Chapters: 2.9.3, 2.9.4 USP Chapters: <711> <724>
<b>User Interface</b>	Resistive touchscreen
<b>Speed Range</b>	20 - 220 rpm +/- 2%
<b>Heater Accuracy</b>	± 0.1°C
<b>Heater Temperature Range</b>	Ambient - 50°C
<b>Vibration Elimination</b>	Low vibration heaters
<b>Test Run Time</b>	Up to 99 hours, 59 minutes, 59 seconds
<b>Alarm(s)</b>	1. End of testing (audible) 2. Low bath water level warning on-screen indicator
<b>Data Output</b>	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 DISi 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.

### DISi Series

Cat. No.	Description
1336	Dissolution Tester DIS 600i (incl. 6 Drive Shafts)
1338	Dissolution Tester DIS 800i (incl. 8 Drive Shafts)
1209	Electronic Temperature Calibration Key
1309	IQ/OQ/PQ Documentation Pack
1307	Printer (including USB cable)



Electronic Temperature Calibration Key



## Choose your DISi System Accessories

All DISi Series are equipped with precision-ground shafts that will accept any of the baskets, paddles or rotating cylinders described in the Pharmacopoeias. Each clutch can be raised, lowered or engaged independently of the drive head, ensuring users have maximum accessibility to the vessels, whilst also making the systems suitable for staggered starts.

Each element can be supplied with a Teflon coating for additional protection against aggressive media, if required and can be laser numbered and certified upon request.



## Baskets, Paddles & Rotating Cylinders



### Basket Stirring Elements (Ph. Eur. /USP Method 1)

Cat. No.	Description
1302B	Set of 6 Baskets (Ph.Eur./USP Method 1)
1302A	Set of 8 Baskets (Ph.Eur./USP Method 1)
1302	Basket <b>only</b> in 316 Stainless Steel (40 mesh)
1317	Basket Holder in 316 Stainless Steel
1331	3-Prong Retention Spring in Hardened 17-7 Steel
1333	Basket Stirring Element <b>complete</b> with Drive Shaft

### Paddle Stirring Elements (Ph. Eur. /USP Method 2)

Cat. No.	Description
1304B	Set of 6 Paddles (Ph.Eur./USP Method 2)
1304A	Set of 8 Paddles (Ph.Eur./USP Method 2)
1304	Paddle <b>only</b> in 316 Stainless Steel
1341	Paddle Stirring Element <b>complete</b> with Drive Shaft
1343	Paddle Stirring Element <b>complete</b> - Teflon Coated

### Dissolution Drive Shaft

Cat. No.	Description
1329	316 Stainless Steel Drive Shaft only

### Capsule Sinkers & Weights

Cat. No.	Description
1356	Set of 6 316 Stainless Steel Sinkers
1356A	Set of 8 316 Stainless Steel Sinkers
1345	Set of 6 USP/Ph.Eur. Alternative Sinkers
1345A	Set of 8 USP/Ph.Eur. Alternative Sinkers
1348	Wire, 316 Stainless Steel (50 ft length)
1357	Set of 6 3-Prong Plastic Sinkers



## Vessels

Compliant with Ph. Eur. and USP specifications, all DISi Series vessels feature unique Easy-Centre systems ensuring perfect positioning every time. Locking the vessel into the correct position relative to the drive shaft, the fixture ensures that the vessels will not become loose or float, even when empty. UV-resistant vessels are also available for products sensitive to UV.

Easy-clean Viton® membrane-sealed low evaporation lids are included as standard with each vessel.



### Vessels

Cat. No.	Description
1344	Vessel, 1000 mL
1346	Vessel, 1000 mL, with "Easy-Centre"
1352	Amber Vessel, 1000 mL
1349	Amber Vessel, 1000 mL, with "Easy-Centre"
1366	"Easy-Centre" Vessel Ring

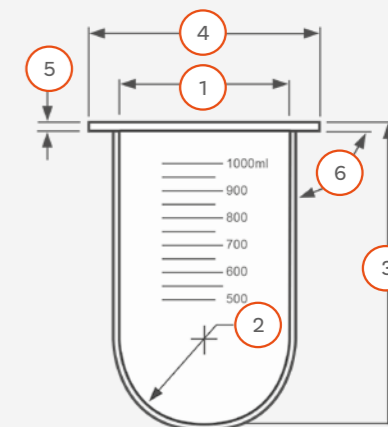
### EMC Ultra-Precision Dissolution Vessels

With dimensional tolerances a factor of 2 higher than those specified in the FDA Enhanced Mechanical Calibration, the EMC Ultra-Precision Dissolution Vessel brings even higher levels of accuracy to dissolution testing.

All relevant parts are individually serialised as standard.



1. Inside Diameter	101.19 +/- 0.13 mm
2. Inside Spherical Radius	50.59 +/- 0.13 mm Radius
3. Height (Inside Spherical Radius to top)	154.75 +/- 0.50 mm
4. Flange OD	120.00 +/- 0.50 mm
5. Flange Thickness	3.50 +/- 0.50 mm
6. Perpendicularity (Inside Vessel Dia. to Flange Underside)	0.50° Max



Cat. No.	Description
1398	EMC Dissolution Vessel, 1000 mL, with "Easy-Centre"



Vessel Cover for DIS 600i/800i

Automatic Tablet Drop Vessel Cover for DIS 600i/800i

### Vessel Covers

Cat. No.	Description
1354	Vessel Cover for DIS 600i/800i
1393	Automatic Tablet Drop Vessel Cover (Set of 6 for DIS 600i)
1394	Automatic Tablet Drop Vessel Cover (Set of 8 for DIS 800i)
1355	Plug for Vessel Cover

## Automatic Tablet Drop

Eliminate the need for time-lag correction factor calculations with the Automatic Tablet Drop system. Guaranteeing simultaneous tablet ejection at the start of the test run, synchronised sampling is simplified.

### Automatic Tablet Drop

#### Cat. No. Description

- 1393** Automatic Tablet Drop Vessel Cover (set of 6 for DIS 600i)  
**1394** Automatic Tablet Drop Vessel Cover (Set of 8 for DIS 800i)



## Sampling Probes

Choose from a range of dissolution sampling probe systems, optimised for different user requirements:

- 1. Manual sampling cannula:** with a Luer fitting to accept a 20 mL syringe, bent at the top to enable easy positioning within the dissolution vessel.
- 2. Resident probe:** designed to be left *in-situ* in the dissolution vessel for the duration of the test and is height adjustable, in accordance with differing methods described in the pharmacopoeias. 3 different types are available:
  - a.** For automated systems: fitted with Omnifit fittings used in conjunction with the return line inserts
  - b.** For automated systems: fitted with Omnifit fittings
  - c.** For manual sampling (with Luer fittings)



### Sampling Probes

#### Cat. No. Description

- 1313** Manual Sampling Cannula Assembly complete (each)  
**1314** Resident Probe with Luer Fitting (each)  
**1315** Resident Probe with Omnifit Fitting (each)  
**1316** Return Line Insert (each)

### Filters (Polyethylene)

#### Cat. No. Description

- 1358** Pack of 50 Filters (20 micron)  
**1359** Pack of 50 Filters (10 micron)  
**1360** Pack of 50 Filters (4 micron)

### Sundries

#### Cat. No. Description

- 1365** Carrying Case for 8 Baskets/Paddles and Shafts  
**1339** Carrying Rack for 4 Vessels  
**1367** Pack of 8 Peristaltic Pump Tubes (Green/Green)  
**1368** Pack of 8 Peristaltic Pump Tubes (Purple/White)  
**1369** 8-Channel Colour Coded Ribbon Tubing (per metre)  
**1370** Pack of 10 Connectors  
**1321** Storage Rack for 8 Baskets or Paddles

### Laser Numbering and Certification (each)

#### Cat. No. Description

- 1332** Certification of 316 Stainless Steel Drive Shaft  
**1310** Certification of Basket in 316 Stainless Steel (40 Mesh)  
**1335** Certification of Basket Stirring Element complete  
**1318** Certification of Paddle only in 316 Stainless Steel  
**1342** Certification of Paddle Stirring Element complete  
**1350** Certification of Vessel, 1000 mL

### Performance Verification Testing (PVT)

Formulated to produce reproducible results under standard dissolution test conditions, these standard drug references supplied by USP (Rockville, Maryland, USA) can be used to help verify the source of anomalies.

#### Cat. No. Description

- 1373** Pack of 30 Prednisone Tablets - USP Disintegrating  
**1375** Prednisone Reference Standard (250 mg pack)



## DISi Series: Qualification & Maintenance

### DISi Series: Qualification Tools

To calibrate all other aspects of the DISi Series, our complete range of calibration and qualification tools can be used to safeguard compliance with the appropriate pharmacopoeial, regulatory guidance and Enhanced Mechanical Calibration (EMC) requirements.



For further information about the full range of Copley Qualification Services available see Page 96



### 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
1508	Calibration Tool Kit complete
1516	Re-calibration of Calibration Took Kit complete

## Special Applications

### Transdermal Patch Testing

Copley offers equipment for three different methods for the determination of the rate of drug release from transdermal patches.

#### 1. Paddle Over Disk



A modification of Method 2 (Paddle), the *Paddle Over Disk* technique is suitable for patches up to a maximum of 16 mm outside diameter. Using a suitable adhesive, the transdermal patch is simply, mounted on the disk, release side up.

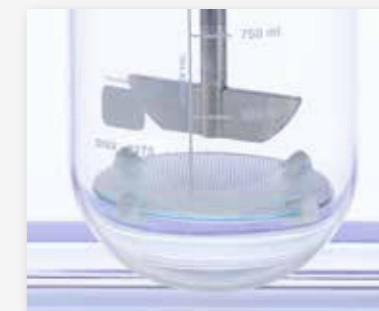
#### 2. Rotating Cylinder



An alternative approach employs the same dissolution equipment as USP Method 1 (Ph. Eur 2.9.4 Method 3) with the basket replaced by a cylinder stirring element. In this method, the adhesive side of the transdermal patch is placed on an inert, porous cellulosic material. This is then attached to the exterior of the cylinder using a suitable adhesive.

An extension piece is included in the kit for larger patches.

#### 3. Watch Glass / Patch



A second larger version of the disk comprising a 90 mm diameter watch glass-patch-PTFE assembly is available for larger patches.

### Transdermal Patch Testing

Cat. No.	Description
1384	Standard disk according to USP Method 5
1384A	Watch Glass/patch/PTFE Assembly to USP Method 5
1385	Hollister Medical Grade Adhesive (90 gm spray)
1386	Cylinder Stirring Element including Extension (USP Method 6)
1386B	Height Gauge for Cylinder Stirring Element
1387	Cuprophane Flat Sheets, 128 x 345mm, Pack of 10



## Intrinsic Dissolution

Based on the same principles as the Rotating Disk apparatus as described in USP Chapter <1087>, Copley offers punch and die kits, together with a hand operated press for intrinsic dissolution methods.

### Intrinsic Dissolution

Cat. No.	Description
1364	Punch and Die Set Kit (each)
1364A	Hand Operated Press



## Small Volumes

For dosage forms with small quantities of drug, or extended release where much lower concentrations are required than that provided by the standard 1000 mL vessel, 100 mL and 200 mL conversion kits are available.

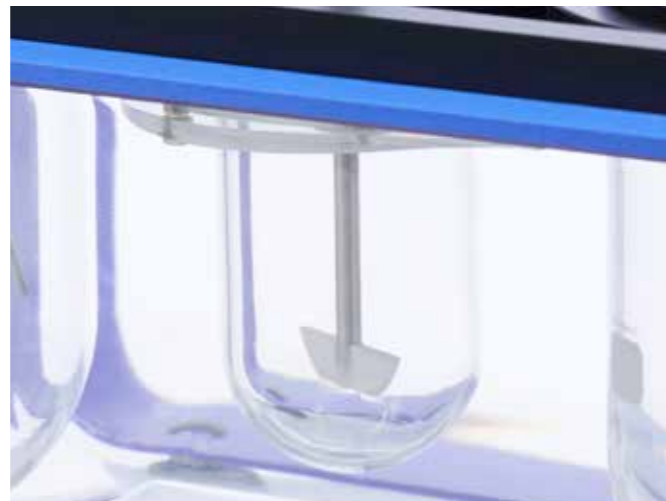
Each conversion kit comprises:

- ✓ Mini Vessel (100 mL or 200 mL)
- ✓ Mini Paddle
- ✓ Vessel Cover
- ✓ Centring Ring Assembly



### Small Volume Conversion Kits

Cat. No.	Description
1371-100	Conversion Kit for Small Volumes – 100 mL
1371-200	Conversion Kit for Small Volumes – 200 mL



## Special Baskets

For solid dosage forms that have a tendency to block the standard 40 mesh basket, a basket with a coarser mesh is available to retain the dosage form in the basket, whilst allowing media penetration without clogging.

### Special Baskets

Cat. No.	Description
1361	Basket only in 316 Stainless Steel (20 Mesh)
1362	Basket only in 316 Stainless Steel (10 Mesh)



## Basket for Suppository Dissolution

Oil-based suppositories give unacceptable and unreproducible results, since the suppository base tends to block the filter mesh.

With the same basic basket specification as the USP standard, the special suppository basket provides the equivalent porosity to a basket of 10 mesh, allowing suppository dissolution testing to take place unimpeded.

### Basket for Suppository Dissolution

Cat. No.	Description
1363	Special Suppository Basket



# Friability

## Background: Friability Testing

Friability is the tendency for a tablet to chip, crumble or break following compression and can occur due to shock or abrasion during subsequent manufacturing steps, packaging or shipping. Normally limited to uncoated tablets and surfaces, it is a tendency that can significantly erode tablet quality.

Tablets need to be hard enough so that they do not break up in the bottle, to safeguard product stability and dose uniformity, but sufficiently friable to disintegrate in the gastrointestinal tract and release the active(s).

Chapters Ph. Eur. 2.9.7 and USP <1216> describe reproducible and standardised methods and equipment to determine the friability of a tablet.

## Friability

### Test Apparatus & Method

A standard friability drum has an inside diameter of 287 mm and a depth of 38 mm. Each drum is fitted with a curved baffle which subjects tablets to a drop of 156 mm during rotation.

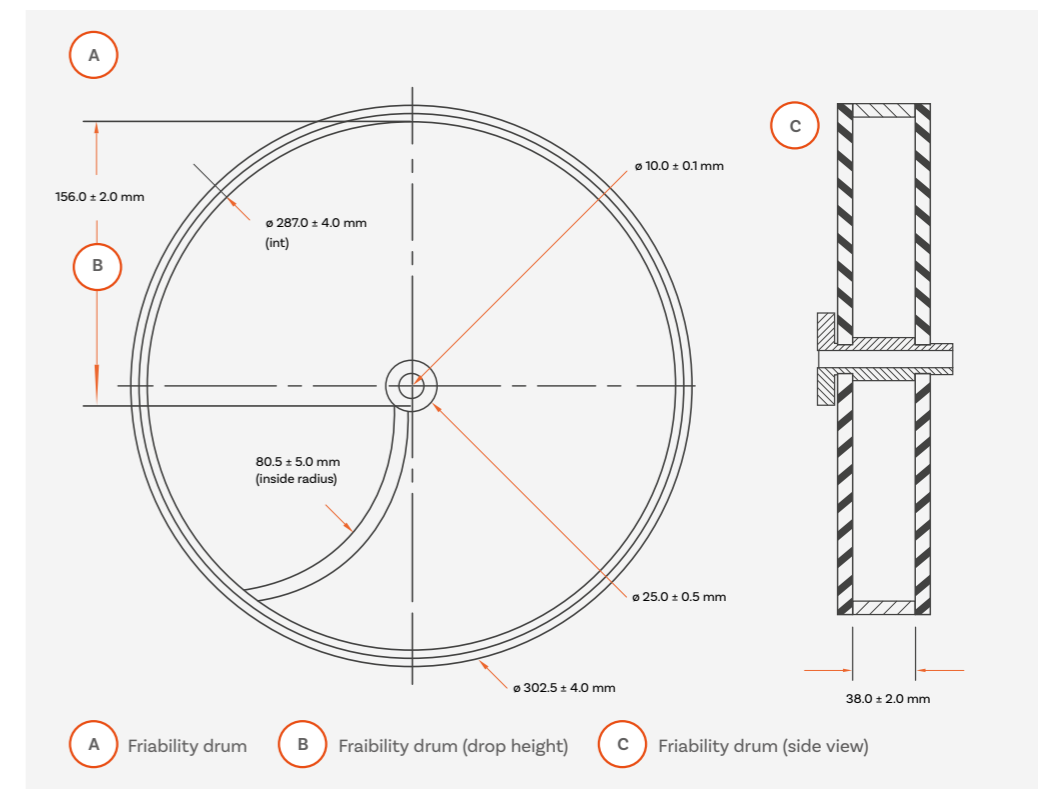
The sample (normally 10 tablets) to be tested is first weighed and then placed into the drum. The drum is then rotated 100 times at a speed of 25 rpm. Any loose dust from the sample is removed and the sample re-weighed.

Friability of a sample is defined in terms of percentage (%) weight loss (loss in weight expressed as a % of the original sample weight). A maximum weight loss of no more than 1% is considered acceptable for most tablets.

Attrition caused by tablets rubbing together can also be measured using this method with a special abrasion drum.

For coated tablets, granules and spheroids, friability cannot be determined using a conventional friability tester, as the dosage form is too hard for meaningful weight loss measurements. Alternative equipment that oscillates the sample at high frequencies is available for this purpose (see Ph. Eur. 2.9.41).

The abrasive forces generated by the horizontal shaking movement of the oscillating arm of this equipment allows users to easily optimise test conditions for each type of formulation with simple-to-use programmable controls.



# Friability: FRVi Series

## Advanced friability testers for all tablet types

Providing highly reproducible and cost-efficient friability testing, the FRVi series of friability testers from Copley allow analysts to easily characterise the critical tendency of tablets to chip, crumble or break.

Based on an original design by Roche, the Copley FRVi Series friability tester is an established standard within the pharmaceutical industry. Equipped with advanced design features, ranging from convenient sample loading and unloading to an integrated friability calculator, the FRVi Series streamlines the workflow associated with routine friability testing.



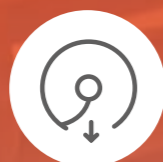
Ph. Eur. and USP compliant



Extensive data output options



Intuitive touchscreen control to simplify operation



Convenient drum emptying function



Integrated calculation of % tablet weight loss



Built-in 10° angling device for larger tablets



## FRVi Series: Key Features



# FRVi Series: Touchscreen User Interface



- A Setting a test parameter
- B Set v Actual test parameters (before test run)
- C Set v Actual test parameters (during test run, with test progress bar)
- D Settings menu
- E Friability calculation screen
- F Report output settings menu
- G Motor speed (RPM) verification

## Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters**:
  - Speed (revolutions per minute)
  - Total revolutions
  - Test duration (HH:MM:SS)
- 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
- High productivity - **easy system set-up and operation** minimises training burden
- **Calculation** of Friability Ratio



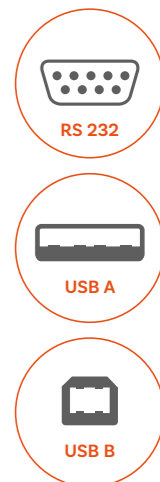
Built-in 10° switching leg for testing larger tablet and capsule types

## Reporting

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

### Reported parameters

- **Speed (revolutions per minute)**
  - Set
  - Average
  - Maximum
  - Minimum
- **Number of revolutions**
  - Set
  - Actual
- **Friability calculations**
  - Start weight (g)
  - End weight (g)
  - Friability (%)



## Compliance & Maintenance



- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available

## Choose your Friability System

		
<b>FRV 100i</b>	<b>FRV 200i</b>	<b>Friabimat SA-400</b>
<b>Cat Number</b> 1431	<b>Cat Number</b> 1432	<b>Cat Number</b> 1450
<b>Pharmacopoeial Compliance</b> Ph. Eur. 2.9.7 USP <1216>	<b>Pharmacopoeial Compliance</b> Ph. Eur. 2.9.7 USP <1216>	<b>Pharmacopoeial Compliance</b> Ph. Eur. 2.9.41-2 (Method B)
<b>Tablet Types</b> Uncoated tablets	<b>Tablet Types</b> Uncoated tablets	<b>Tablet Types</b> Hard tablets, Granules
<b>Test Station Capacity</b> 1 drum	<b>Test Station Capacity</b> Up to 2 drums	<b>Test Station Capacity</b> 1 oscillating container
<b>Unit Dimensions (w x d x h)</b> 316 x 343 x 325 mm	<b>Unit Dimensions (w x d x h)</b> 407 x 343 x 325 mm	<b>Unit Dimensions (w x d x h)</b> 440 x 300 x 220 mm

### FRVi Series: Friability Calculator

The integrated friability calculator removes the need for manual tablet weight loss calculations, reducing the risk of analyst calculation error and improving data accuracy.

Simply inputting start and end weight allows for automatic calculation of percentage (%) friability.

Friability results together with the test report are easily output to PC and printer.

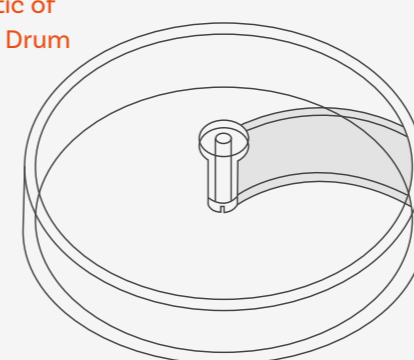


## FRVi Series: Friability & Abrasion Drums

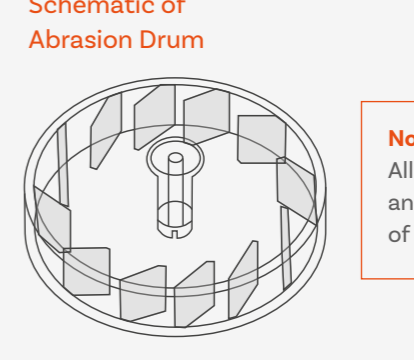
Fitted with an aperture for convenient sample loading and unloading, the FRVi Series drums automatically revolve to face the operator for easy sample loading. Upon test completion, simply tapping the 'empty drum' icon on the touchscreen empties the drum contents into the waiting collection tray(s), ready for weighing.

With a choice of either USP Friability and/or Abrasion drums, the versatile FRVi Series allows direct comparisons between the two parameters under identical test conditions.

Schematic of Friability Drum



Schematic of Abrasion Drum



**Note:**  
All drums are interchangeable and can be fitted to any side of the unit

FRVi Series: Technical Specifications	
<b>Pharmacopoeial Compliance</b>	Ph. Eur. 2.9.7 USP <1216>
<b>User Interface</b>	Resistive touchscreen
<b>Test Duration Parameters</b>	Time or Revolutions of the Drum(s)
<b>Drum Rotational Speed Range</b>	10 - 60 rpm (± 1 rpm)
<b>Rotational Limit</b>	Up to 60,000 rotations
<b>Test Run Time</b>	Up to 99 hours, 59 minutes, 59 seconds
<b>Data Output</b>	RS 232 USB A (for connection with a USB printer) USB B (for connection with a PC)
<b>Alarm</b>	End of testing (audible)

FRVi Series & Accessories			
Cat. No.	Description	Cat. No.	Description
1431	Friability Tester FRV 100i (Variable Speed - 1 Drum)	1405	Extra for Numbering & Certification (per drum)
1432	Friability Tester FRV 200i (Variable Speed - 2 Drums)	1406	IQ/OQ/PQ Documentation Pack
1407	Abrasion Drum (Optional extra)	1410	Qualification Tools
1408	Friability Drum (Spare)	1412	Re-calibration of Qualification Tools

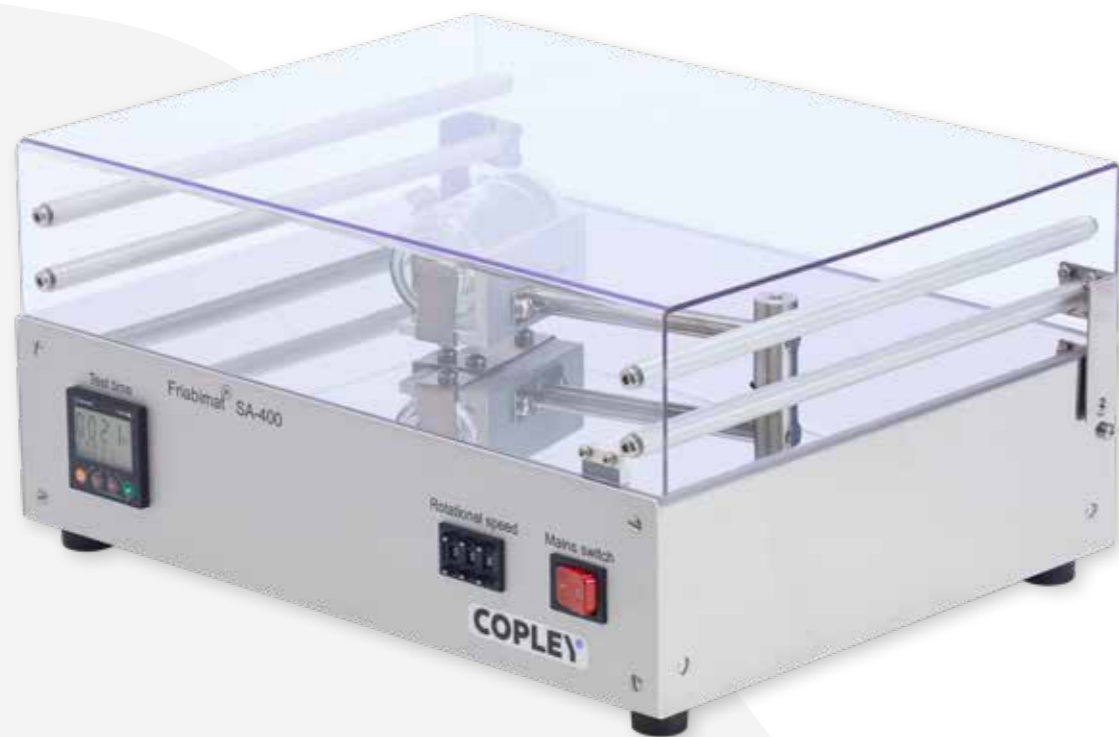


## Friability: Friabimat SA-400

For the hardest and most robust solid dosage forms which fall outside the scope of the conventional friability tester a higher-energy input instrument is needed to generate quantifiable changes in surface mass. The Friabimat, as described in Ph. Eur. 2.9.41, has been designed to generate the necessary abrasive forces required to define the friability characteristics of these types of dosage forms.

Not only useful for determining the friability of hard pellets and granules, the Friabimat is suitable for detecting variations in mechanical properties between

different formulations and batches, making it a convenient tool for both research and development and quality control applications.



### Friabimat SA-400: Technical Specifications

<b>Pharmacopoeial Compliance</b>	Ph. Eur. 2.9.41.-2 (Method B)
<b>Shaking rate</b>	0 - 400 oscillations per minute
<b>Test Run Time</b>	Up to 9,999 seconds
<b>Test Station Capacity</b>	1 Oscillating Container
<b>Dimensions (w x d x h)</b>	440 x 300 x 220 mm



Friabimat with safety lid open



Oscillating Container

### Friabimat SA-400: Key Features



Quantifiable abrasion of hard tablets, granules and pellets



Stainless steel case ideal for production environments



Clear acrylic lid with magnetic interlock to ensure safe operation



Option: Oscillation frequency verification certificate

### Friabimat SA-400 Accessories

Cat. No.	Description
1450	Friabimat Model SA-400 including 1 Glass Container
1451	Oscillation Frequency Verification Chart
1452	Pack of 100 Spare Glass Containers
1453	IQ/OQ/PQ Documentation Pack
1455	Qualification Tools
1456	Re-Calibration of Qualification Tools
1454	355 Micron Sieve

# Hardness

## Background: Hardness Testing

Together with friability, hardness (or breaking force) is a defining physical characteristic for a tablet. High hardness values may indicate for example, longer disintegration and dissolution times, compromising the speed of drug delivery.

On the other hand, if hardness is too low, then friability may be also high, giving rise to poor product stability and compromised dose uniformity.

By examining correlations between hardness, disintegration, dissolution and friability, a dosage form with optimum characteristics can be produced.

Chapters Ph. Eur. 2.9.8 **Resistance to Crushing of Tablets** and USP Chapter <1217> **Tablet Breaking Force** describe standardised methods for the assessment of tablet hardness.

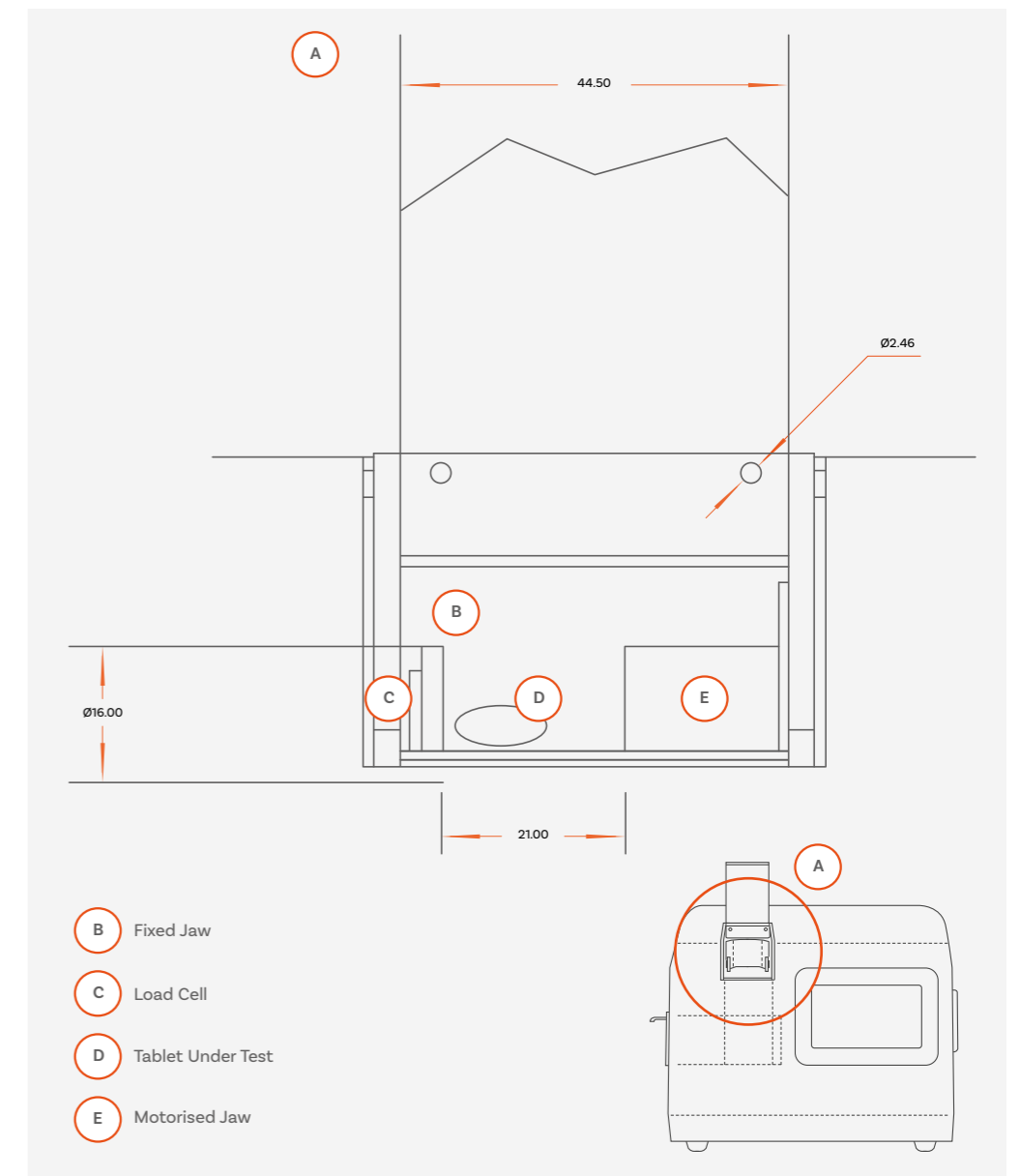
## Hardness

### Test Apparatus & Method

A tablet is placed between two platens (jaws), one of which is attached to a force gauge with load cell and the other to a motor which provides the mechanical drive.

The motorised jaw drives forward pressing the tablet against the fixed jaw until the tablet breaks. The motorised jaw then retracts and the load force required to break the tablet is recorded.

The units of force normally employed to quantify breaking force are Kiloponds (Kilogram-Force) or Newtons.



# Hardness: TBF 100i

## Rapid, no-fuss tablet hardness testers

Combining the economy of a simple, easy to use hardness tester with the accuracy of microprocessor-controlled data collection, the compact TBF 100i hardness tester delivers precise tablet hardness and diameter measurements. Tablet thickness and weight can also be recorded (optional).

Offering high tablet throughput, the intuitive touchscreen user interface of the TBF 100i streamlines test set-up procedures for users, whilst the built-in data processor provides analysts with tablet breaking force statistical analyses at the touch of a button.



Ph. Eur. and USP Compliant



Choice of breaking force measurement units



Intuitive touchscreen control to simplify operation



Force application: constant speed



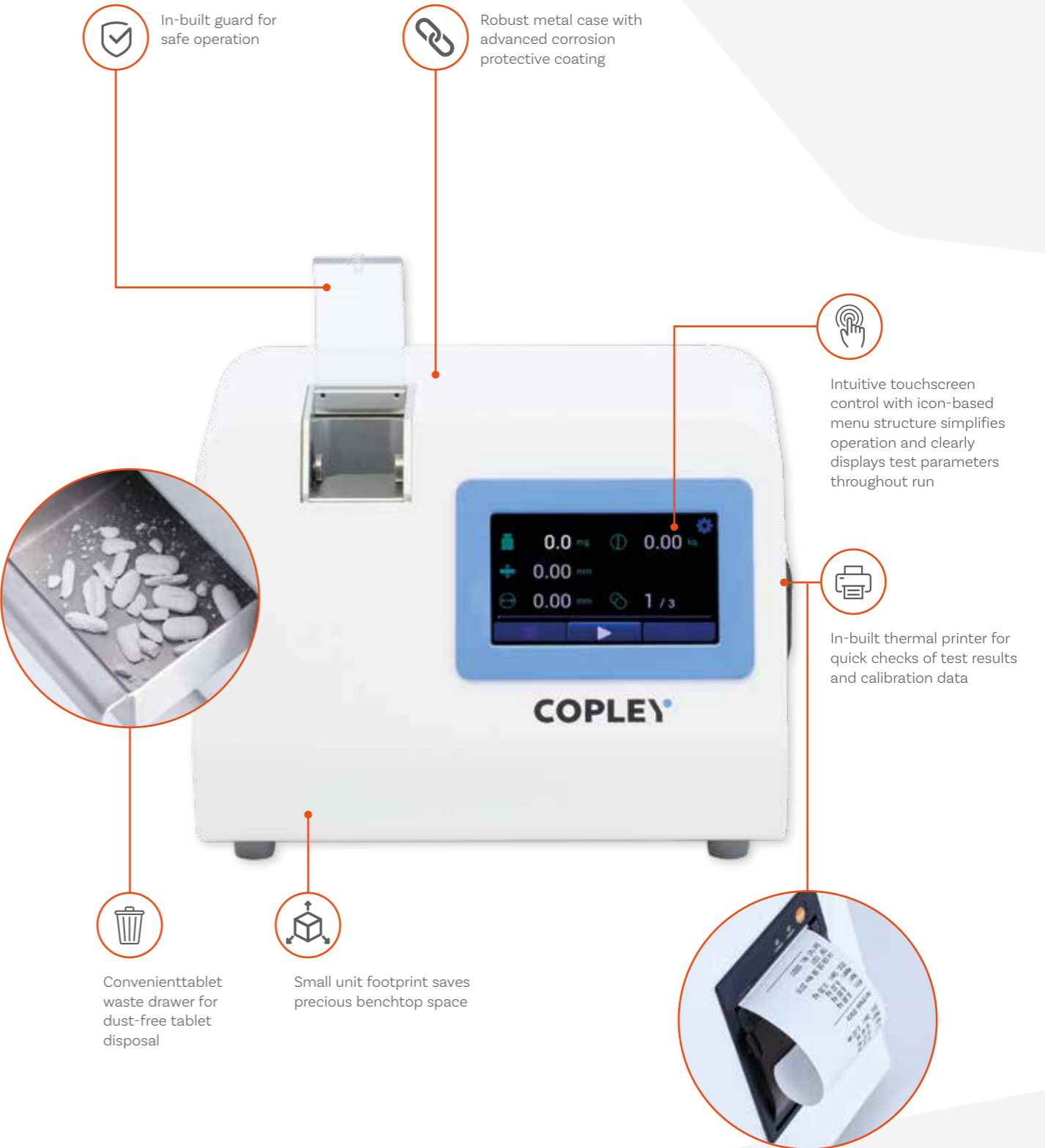
Option: Manual or automated entry of tablet weight & thickness data



Extensive data reporting output options



## TBF 100i: Key Features



# TBF 100i: Touchscreen User Interface



- A Before testing (batch mode enabled)
- B After test completion (batch mode enabled). Progress bar indicates test run complete.
- C Tablet hardness statistics
- D Settings menu (I)
- E Settings menu (II)
- F Test speed setting screen
- G TBFi interface settings menu
- H Calibration menu

## Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters:**
  - Rate of force application (mm/min)
  - Force measurement unit (N, kp, kgf, or lbs)
  - Tablet Batch size
- **Key tablet measurements clearly displayed on-screen to user**
  - Tablet weight (if applicable)
  - Tablet thickness (if applicable)
  - Tablet diameter (if enabled)
  - Tablet hardness
- **Batch progress displayed during batch testing run** provides clear indication on throughput status
- Resistive touchscreen interface can be **operated with gloves on**
- Hygienic **wipe-clean** screen
- High productivity - **easy system set-up and operation** minimises training burden



TBF 100i with calibration rig

## Reporting

Extensive data output options are available as standard, including direct printing from the TBF 100i and direct reporting to a PC.

### Reported parameters

- **Individual Tablet Results**
  - Diameter (if enabled)
  - Hardness
  - Weight (if applicable)
  - Thickness (if applicable)



- **Tablet Batch Statistics**
  - Batch minimum, maximum, mean and standard deviation of:*
  - Diameter
  - Hardness
  - Weight
  - Thickness

- **Calibration Data**
  - Calibration date
  - Temperature calibrated at (°C)

## Compliance & Maintenance



- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available
- ✓ Passcode-protected static calibration routine
- ✓ Optional calibration rig available
- ✓ Latest calibration information stored and available to export/print

# Choose your Tablet Hardness Tester



**TBF 100i**

**Cat. Number**  
2532

**Pharmacopoeial Compliance**

Ph. Eur. 2.9.8  
USP <1217>

**Tablet Measurements**

Breaking force • Diameter  
Weight\* • Thickness\*

**Statistics Reporting**

Yes

**Max. Tablet Diameter**

36 mm

**Force Range**

0-490 N

**Batch Testing**

Yes

**Portable**

No

**Unit Dimensions (w x d x h)**

283 x 237 x 208 mm



**TH3/200**

**Cat. Number**  
7801

**Pharmacopoeial Compliance**

Ph. Eur. 2.9.8  
USP <1217>

**Tablet Measurements**

Breaking force

**Statistics Reporting**

No

**Max. Tablet Diameter**

30 mm

**Force Range**

0-200 N (+/- 0.04 N)

**Batch Testing**

No

**Portable**

Yes

**Unit Dimensions (w x d x h)**

82 x 380 x 90 mm



**TH3/500**

**Cat. Number**  
7802

**Pharmacopoeial Compliance**

Ph. Eur. 2.9.8  
USP <1217>

**Tablet Measurements**

Breaking force

**Statistics Reporting**

No

**Max. Tablet Diameter**

30 mm

**Force Range**

0-500 N (+/- 0.1N)

**Batch Testing**

No

**Portable**

Yes

**Unit Dimensions (w x d x h)**

82 x 380 x 90 mm

**TBF 100i: Technical Specifications**

<b>User Interface</b>	Resistive touchscreen
<b>Max. Tablet Diameter</b>	36 mm
<b>Force Range</b>	0 - 490 N
<b>Force Application</b>	Constant speed 1 - 50 mm/min
<b>Hardness Units</b>	N, kp, kgf, lbs
<b>Testing Throughput</b>	~ 5-8 tablets per minute* <small>*depending on hardness/diameter of tablet under test</small>
<b>Fracture Detect Percentage</b>	Adjustable between 30% - 90%
<b>Data Output</b>	RS 232 USB type B (for communications with a PC) In-built thermal printer
<b>Waste Drawer</b>	Integrated

**TBF 100i**

Cat. No.	Description	Cat. No.	Description
2532	Tablet Hardness Tester Model TBF 100i	2505	IQ/OQ/PQ Documentation Pack
2503	Calibration Rig	2511	Re-Calibration Certificate
2504	Set of Calibration Weights for TBF 100i (4 x 10 kg, 2 x 5 Kg)	2506	Pack of 10 Paper Rolls
2510	Other Qualification tools		
2512	Re-calibration of Qualification Tools		



TBF 100i with open guard

\*Optional with balance and/or thickness gauge

## Choose your TBF 100i Accessories

### Tablet Weight & Thickness

With the addition of a balance and/or Mitutoyo micrometer for measuring thickness, the TBF 100i becomes a complete system for measuring the hardness, diameter, weight and thickness of tablets. This configuration is a highly efficient, cost-effective alternative to more sophisticated commercial systems for measuring these critical tablet parameters.

Alternatively, tablet weight and thickness can be entered into the TBF 100i system manually.



Mitutoyo Measuring Gauge



Sartorius Balance Model Quintix 224-1 CEU



### TBF 100i Accessories

Cat. No.	Description
2507	Sartorius Balance Model Quintix 224-1 CEU (including cable)
2508	Mitutoyo Thickness Measuring Gauge

## Hardness: TH3 Tester

Ideal for use in the production area for a quick check of compression force, the TH3 is a portable and simple-to-use tablet hardness tester.

Using a multi-turn, low-friction hand wheel to apply the load, the TH3 is available with two load ranges, which can apply up to 200 N or 500 N (TH3/200 and TH3/500 respectively). The resulting breaking force is displayed clearly on the LCD with a wide choice of data output options.

With easy calibration verification, this tester offers easy and convenient tablet hardness testing in busy production environments.

### TH3: Key Highlights



Easy calibration verification



Choice of force measurement unit (N, g, lbs, oz)



Clear LCD display



Portable unit with debris collection tray



Extensive data reporting output options



Measures tablets < 30mm diameter

### Reporting

The TH3 is provided with RS-232, Mitutoyo and analogue data output as standard. All displayed readings including breaking force in Newtons, grams, pounds or ounces, can be transmitted to external devices, including PCs and printers.

### TH3 Series

Cat. No.	Description
7801	Tablet Hardness Tester Model TH3/200
7802	Tablet Hardness Tester Model TH3/500
7803	Re-Calibration Certificate
7804	Calibration Verification Hanger & Weight
4902	Mini Processor for TH3 Tester
9005	Compact Printer (Force Gauge)

# Powders

## Background: Powders

A pharmaceutical powder is a dry, bulk solid composed of many very fine particles normally classified dependent on particle size between coarse and very fine (see USP Chapter <811> Powder Fineness).

Whilst powders themselves are not widely employed as a dosage form in their own right, they are often used in the preparation of other forms such as tablets, capsules and inhaled products and are frequently added to other ingredients to make semisolids such as creams, ointments and pastes.

It is this widespread use of powders in the pharmaceutical industry that has led to a proliferation of test methods for measuring powder flow and density.

USP <1174> and Ph. Eur. 2.9.36 list four well-defined methods for powder testing proposed to bring some degree of test methodology standardisation:

- Flow through an orifice
- Angle of repose
- Shear cell
- Compressibility index and Hausner ratio

## Powders: Flowability

Powder flow depends on several factors, some of which relate to the powder material and some to the actual manufacturing processes, its ability, for example, to flow from a container (hopper, funnel, cylinder, etc.) or its compressibility in forming a tablet. The Pharmacopoeias recommend three methods for testing powder flow:

### 1. Flow Through an Orifice

Measuring the ability and the time taken for a powder to flow through an orifice of known size is a useful method of quantifying powders. As the name suggests, this technique is only applicable to free-flowing powders, not cohesive materials. Methods vary but can be classified on the basis of three basic experimental variables:

- Type of container employed (hopper, funnel, cylinder, etc.)
- Size and shape of the orifice employed
- Method of measuring powder flow rate

### 2. Angle of Repose

The Angle of Repose is the angle (relative to the horizontal base) of the conical pile produced when a granular material is poured onto a horizontal surface. It is related to the density, surface area and coefficient of friction of the material concerned and indicative of flow in accordance with the values shown in the table overleaf.



## Powders: Flowability

Flow Properties & Angle of Repose	
Flow Property	Angle of Repose
Excellent	25 - 30
Good	31 - 35
Fair - aid not needed	36 - 40
Passable - may hang up	41 - 45
Poor - must agitate, vibrate	46 - 55
Very poor	56 - 65
Very, very poor	> 66

### 3. Shear Cell

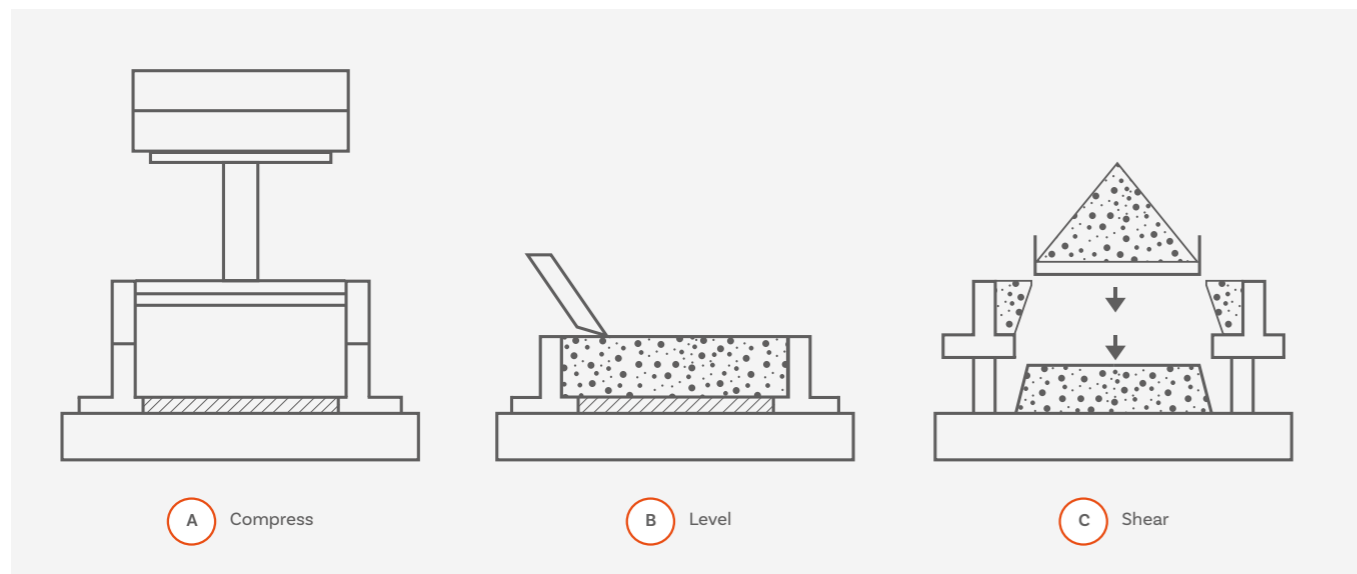
Measures the force required to shear a circular disk through a prepared sample of bulk material.

It comprises 2 stages:

- (a) Sample consolidation (bulk density measurement)
- (b) Failure inducement (shear strength)

Shear Cell methodology widely used in the pharmaceutical industry to determine the flow properties of fine-grained powders and bulk solids and how they will behave in bins, hoppers, feeders and other handling equipment.

The ability of a powder to flow through such devices is dependent on the bulk density of the material concerned and its shear strength.



## Powders: Bulk and Tapped Density

The bulk density of a powder is expressed in terms of grams per mL by dividing the weight of a given “untapped” powder sample by its volume.

It is important to ensure that no settlement occurs during preparation such that the density of the powder concerned is “as poured” and therefore includes the contribution made by the volume of the interparticulate void.

Tapped Density, on the other hand, is the density attained after “tamping down”. This is normally measured using an instrument that lifts and drops a measuring cylinder or similar vessel containing the powder through a fixed distance.

The Tapped Density in grams per mL can now be calculated by dividing the sample weight by the final tapped volume.

### Compressibility Index and Hausner Ratio

Measures of the ability of the powder to flow and its compressibility can now be given in the form of (a) the Hausner Ratio or (b) the Compressibility Index” (see below).

#### a. Hausner Ratio

$$= \text{Tapped Density} / \text{Bulk Density}$$

#### b. Compressibility Index

$$= \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

In a free flowing powder, inter-particulate interaction is less significant and unsettled and tapped densities will be closer in value. In poorly flowing powders, the inverse is to be expected. It follows that the closer the Hausner ratio is to 1, the better the flow. Powders with poor flow generally have a ratio of greater than 1.25.

Scale of Flowability		
Compressibility Index (%)	Flow Character	Hausner Ratio
< 10	Excellent	1.00 - 1.11
11 - 15	Good	1.12 - 1.18
16 - 20	Fair	1.19 - 1.25
21 - 25	Passable	1.26 - 1.34
26 - 31	Poor	1.35 - 1.45
3 - 37	Very poor	1.46 - 1.59
> 38	Very, very poor	> 1.60



## Powders: Flowability Testers

The Flowability Tester BEP2 has been specifically designed to address the specifications in and comments raised by the Ph. Eur. and USP on Powder Flow.

The Flowability Tester BEP2 from Copley provides a range of options for testing pharmaceutical powders including three of the four methods quoted in the Pharmacopoeias – flow through an orifice, angle of repose and shear cell – in a single, cost effective unit.



### BEP2 with Cylinder Attachment

Comprising a stainless-steel cylinder measuring 76 mm long x 57 mm and a capacity of 200 mL, each attachment comes complete with 20 interchangeable stainless-steel disks each with a precision drilled hole between 4 mm and 36 mm.

The cylinder attachment can be used in two different ways:

- i. For quantitative flowability tests based on mass vs time
- ii. To determine the intrinsic flowability of a powder via a flowability index based on comparative measurements.



### BEP2 with Funnel Attachment

The stainless-steel flow funnel is designed to simulate flow in a hopper or other similar production situation.

Supplied with 10 mm, 15 mm and 25 mm aperture quick-change nozzles it is manufactured from pharmaceutical grade 316 stainless steel. Testing is carried out with an easy-to-use shutter.



A BEP2 with Funnel and Balance/Timer Attachments

B BEP2 with Cylinder and Balance/Timer Attachments

Remove the hassle of a stopwatch by adding our balance and timer attachment to the shutter mechanism to simplify and streamline mass vs time tests including:

- |   |   |
|---|---|
| a) Flow time of a predetermined sample weight | c) Weight of a sample in a predetermined time |
| b) Flow time of a predetermined sample volume | d) Time against sample weight (weight/time).  |



### BEP2 with Funnel and Shear Cell Attachments

The Copley cylindrical shear cell attachment is ideal for determining flow properties based on the bulk density and shear strength of fine-grained powders and bulk solids.

Providing important information on a given material's behaviour in bins, hoppers, feeders and other handling equipment, the Copley shear cell enables precise control of test parameters for a wide range of flowability measurements.

### BEP2 with Funnel and Angle of Repose Attachments

Providing a simple method for assessing the friction characteristics of powders, the Copley angle of repose attachment is ideal for predicting manufacturing issues associated with resistance to movement between particles.

Comprises a 100 mm diameter circular test platform together with a digital gauge. Powder heights of up to 300mm can be easily read from the clear gauge display. Dividing this value by 50 calculates the angle of repose.





Manually operated Stirrer for Funnel Attachment



Shear Cell with Weight



Anti-Static Grounding Kit for BEP2



Interchangeable Disks for Cylinder Attachment

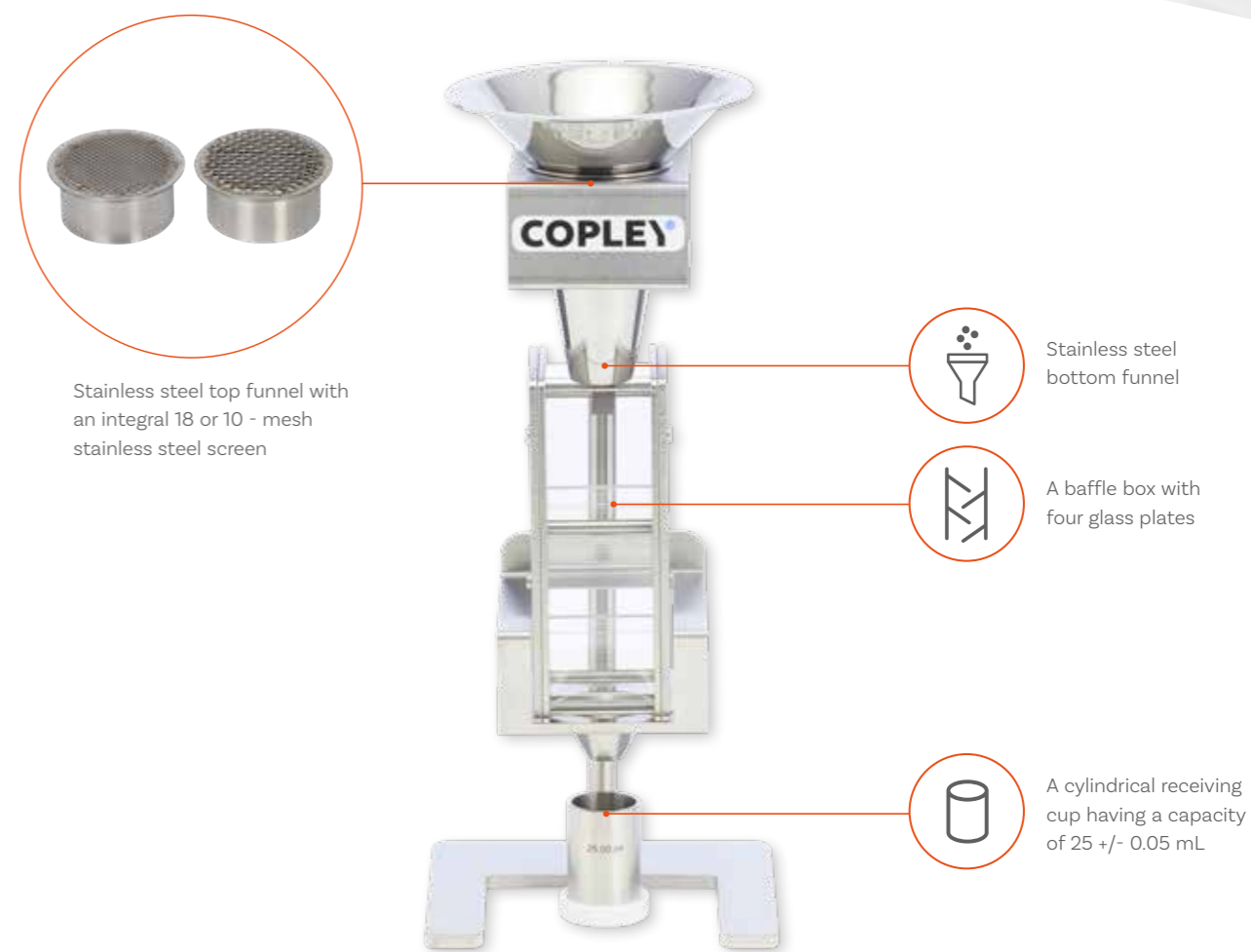
### Flowability

Cat. No.	Description
1650	Flowability Tester Model BEP2 Stand and Upright
1651	Cylinder Attachment
1652	Funnel Attachment
1656	Manually operated Stirrer for Funnel Attachment
1653	Balance/Timer Attachment
1654	Angle of Repose Attachment*
	*Requires the Funnel Attachment (Cat No. 1652) to operate
1655	Shear Cell Attachment*
	*Requires the Funnel Attachment (Cat No. 1652) to operate
1657	Anti-Static Grounding Kit for BEP2
1658	IQ/OQ Documentation Pack
1659	Qualification Tools
1660	Re-calibration of Qualification Tools

## Powders: Bulk Density Tester

The Bulk Density Tester (Scott Volumeter) is described in Ph. Eur. and USP and is designed for measuring the bulk density of fine powders and similar products.

The bulk density of powders can be extremely difficult to measure since the slightest disturbance may result in a change in the results. This is the result of the relationship between the particles that constitute the powder bulk. This same relationship affects the ability of the powder to flow. The Scott Volumeter obviates this problem.



### Scott Volumeter

Cat. No.	Description
6301	Scott Volumeter with 18-mesh screen (USP <616> Method 2)
6302	Alternative filter insert with 10-mesh screen
6303	Volume Certification of the Receiving Cup
6305	Spare Receiving Cup
6306	Spare set of Glassware (4 x Baffles + 1 Front and Rear Plate)

# Powders: Tapped Density Testers

A high reliability solution for routine measurement of the tapped density of powders, granules and similar products, the Copley JVi testers are the only single tapped density systems on the market that offer all three methods specified in Eur. Ph. and USP .

Available with either one or two test stations, the JVi tapped density series provides detailed reports, including Hausner ratio calculations for a wide range of industrial standards.



Ph. Eur. and USP Compliant



Adjustable stroke frequency control for accelerated or high sensitivity testing



Intuitive touchscreen control to simplify operation



One to two test station unit configurations



Supports Methods 1, 2 and 3



Extensive data reporting output options



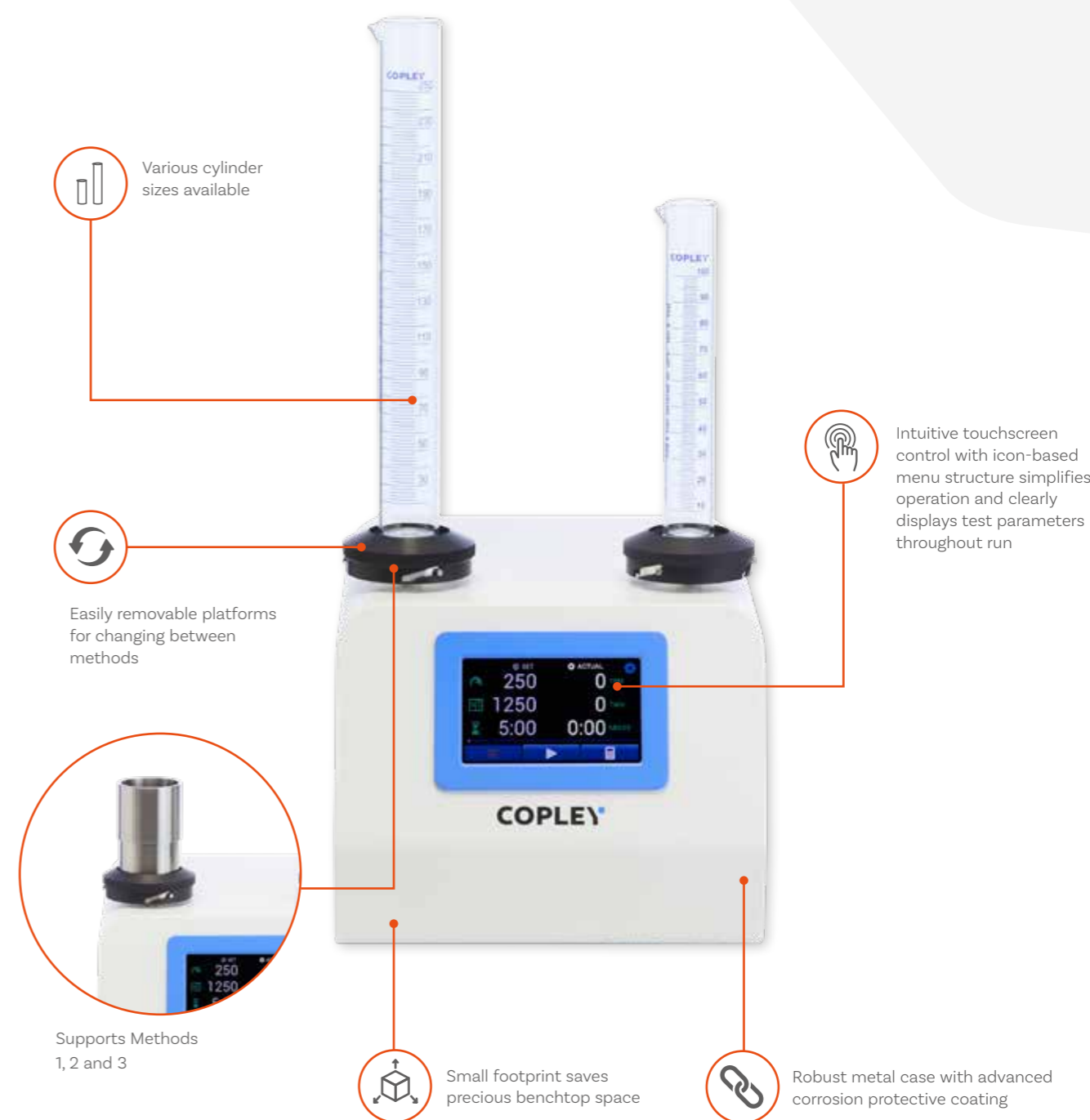
Integrated calculation of bulk density, tapped density, Hausner ratio and compressibility index



Option to automate and remotely control JVi systems



## JVi Series: Key Features



Various cylinder sizes available

Easily removable platforms for changing between methods

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

Supports Methods 1, 2 and 3

Small footprint saves precious benchtop space

Robust metal case with advanced corrosion protective coating

# JVi Series: Touchscreen User Interface

- A** Setting a test parameter
- B** Calculation screen (before data entry)
- C** Set v Actual test parameters (before test run)
- D** Set v Actual test parameters (during test run), with test progress bar
- E** Calculation screen (after data entry)
- F** Settings menu
- G** Report output settings menu
- H** Motor speed (TPM) verification

## Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters:**
  - Test speed
  - Number of taps
  - Test duration
- 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
- High productivity - **easy system set-up and operation** minimises training burden.
- **Calculation of:**
  - Bulk Density
  - Tapped Density
  - Hausner Ratio
  - Compressibility Index

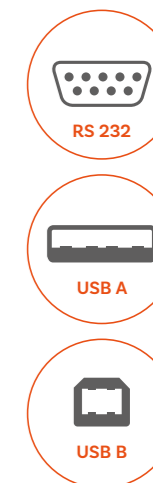


## Reporting

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

### Reported parameters

- **Speed (taps per minute)**
  - Set
  - Average
  - Maximum
  - Minimum
- **Number of taps**
  - Set
  - Actual
- **Calculations**
  - Start weight/volume (g/mL)
  - End weight/volume (g/mL)
  - Bulk Density (g/mL)
  - Tapped Density (g/mL)
  - Hausner Ratio
  - Compressibility Index (%)



## Compliance & Maintenance



- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available

# Choose your JVi Tapped Density System



**JV 100i**

**Cat Number**  
1631

**Test Station Capacity**  
1 Cylinder

**Eur. Ph and USP Test Methods Supported**  
1, 2, 3

**Unit Dimensions (w x d x h)**  
260 x 347 x 562 mm (with 250 mL cylinder)



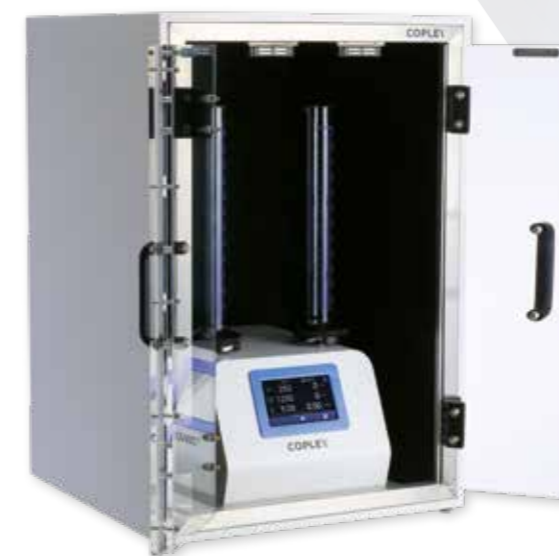
**JV 200i**

**Cat Number**  
1632

**Test Station Capacity**  
2 Cylinders

**Eur. Ph and USP Test Methods Supported**  
1\*, 2, 3  
\* Only one station available for this method

**Unit Dimensions (w x d x h)**  
260 x 347 x 562 mm (with 250 mL cylinders)



Acoustic Cabinet  
reduces the noise level  
produced by the JVi series unit



JV 200i with Method 3 platform

## JVi Series: Technical Specifications

<b>Pharmacopoeial Compliance</b>	Ph. Eur. 2.9.34 USP <616>
<b>User Interface</b>	Resistive touchscreen
<b>Test Duration Parameters</b>	Time or Taps
<b>Testing Run Time</b>	Up to 99 hours, 59 minutes, 59 seconds
<b>Test Station Capacity</b>	Up to 2 stations (1 left, 1 right)
<b>Data Output</b>	RS 232 USB Type A (for a USB printer) USB Type B (for communications with a PC)
<b>Methods Supported Details</b>	Method 1: 14 mm @ 300 taps/min Method 2: 3 mm @ 250 taps/min Method 3: 3 mm, 14 mm - 50/60 taps/minute
<b>Alarm</b>	End of testing (audible)

## JVi Series

Cat. No.	Description	Cat. No.	Description
1631-1	Tapped Density Tester JV 100i - Method 1, 250 mL Cylinder	1604	250 mL Measuring Cylinder (spare)
1631-2	Tapped Density Tester JV 100i - Method 2, 250 mL Cylinder	1605	100 mL Measuring Cylinder (option)
1631-3	Tapped Density Tester JV 100i - Method 3 - 3mm Drop	1635	Tapped Density Method 3 Cup
1631-4	Tapped Density Tester JV 100i - Method 3 - 14mm Drop	1643	Platform for use with 250 mL Cylinder - Method 1
1632-2	Tapped Density Tester JV 200i - Method 2, 250 mL Cylinders	1644	Platform for use with 250 mL Cylinder - Method 2
1632-3	Tapped Density Tester JV 200i - Method 3 - 3mm Drop	1641	Platform for use with 100 mL Cylinder - Method 1
1632-4	Tapped Density Tester JV 200i - Method 3 - 14mm Drop	1642	Platform for use with 100 mL Cylinder - Method 2
1603	IQ/OQ/PQ Documentation Pack	1645	Platform for use with Cup - Method 3 - 3mm Drop
1616	Qualification Tools	1646	Platform for use with Cup - Method 3 - 14mm Drop
1617	Re-calibration of Qualification Tools	1636	Acoustic Cabinet for JV100i / 200i
		1609	50 mL Measuring Cylinder Kit
		1610	25 mL Measuring Cylinder Kit
		1611	10 mL Measuring Cylinder Kit
		1612	5 mL Measuring Cylinder Kit

# Semisolids

## Background: Semisolids Testing

Most pharmaceutical dosage forms applied directly to the skin for topical action are classified as semisolid, a group of products which include ointments, creams and gels. They are typically applied for immediate, localised relief.

These products are typically hydrocarbon-based or oil-in-water emulsions incorporating additional ingredients such as emulsifiers, stabilisers, pH buffers, preservatives, absorption promoters and perfumes.

USP Chapter <1724> details the performance testing required for semisolid drug products.

## Semisolids

### Test Apparatus & Method

There are three different apparatuses for the *in vitro* determination of drug release from semisolid drug dosage forms:

- Vertical Diffusion Cell (VDC)
- Immersion Cell
- Flow Through Cell (Apparatus 4)

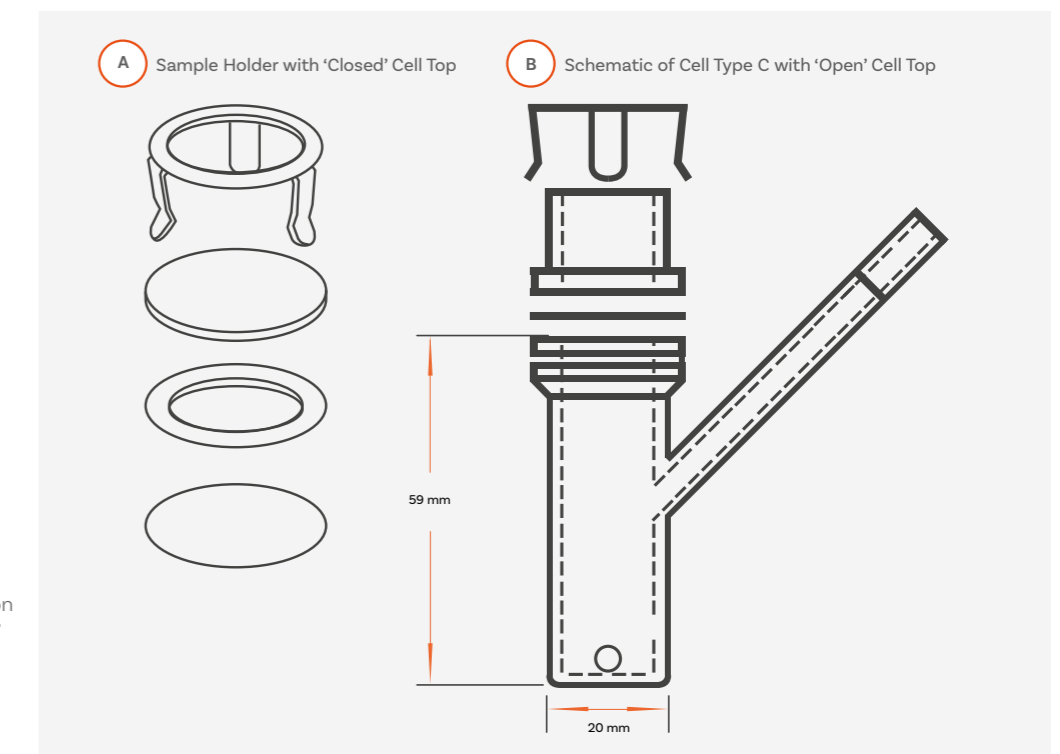
Due to its simplicity and reproducibility, the VDC, or Franz Cell, is typically the apparatus of choice.

The VDC comprises two parts: (a) the donor chamber containing the sample to be tested and (b) the receptor chamber containing the receptor medium.

The two parts are separated by an inert, highly permeable support membrane that acts as a conduit through which diffusion occurs.

The receptor chamber temperature is usually set to 32°C, to simulate normal skin conditions. At least 6 samples should be taken over a 6-hour period and analysed using HPLC or a similar analytical technique.

Results are calculated and expressed as the amount of drug released per unit membrane area ( $\text{mcg}/\text{cm}^2$ ) vs square root of time. This should yield a straight line. The slope of the line (regression) represents the release rate of the product.



Annex 1 of the EMA 'Guideline on quality of transdermal patches' suggests the use of the VDC for permeation studies on transdermal patches

# Vertical Diffusion Cell System: HDT 1000

## Simple, reproducible semisolid drug release measurement

With precision heating and integrated powerful magnetic stirrers, Copley's compact HDT 1000 test system offers full control over all test parameters and has become the benchmark vertical diffusion cell test system for many labs.

Using an innovative heating block approach, the HDT 1000 eradicates the difficulties and the "spaghetti" of tubing associated with water-jacketed cell systems and accommodates either endpoint, discrete manual or fully automatic sampling techniques. A dedicated stirrer mounted beneath each station ensures thorough mixing throughout testing for accurate sampling.



USP compliant



Innovative dry heating system simplifies test set-up



Precision control over all test parameters



Powerful magnetic stirrers ensure consistent mixing during testing



Novel cell clamps simplify cell preparation and sample collection



Small benchtop footprint saves precious benchtop space



## HDT 1000: Key Features



## Choose your HDT System



**HDT 1000**  
For higher throughput semisolids testing

**Cat. Number**  
7290

**Pharmacopoeial Compliance**  
USP <1724>

**User Interface**  
Touchpad and LED display

**Cell Capacity**  
Up to 10 diffusion cells

**Heating System**  
Dry heating block

**Temperature Range**  
Ambient - 150°C

**Stirrer Speed Range**  
400 - 2,000 rpm

**Sampling Technique Compatibility**  
End-point  
Discrete manual  
Fully automatic

**Unit Dimensions (w x d x h)**  
80 x 325 x 145 mm



**HDT 1**  
Basic, low cost test system for entry-level semisolids testing

**Cat. Number**  
7276

**Pharmacopoeial Compliance**  
USP <1724>

**User Interface**  
Touchpad and LED display

**Cell Capacity**  
1 single diffusion cell

**Heating System**  
Water bath

**Temperature Range**  
Ambient to 300°C

**Stirrer Speed Range**  
200 - 1,300 rpm

**Sampling Technique Compatibility**  
End-point  
Discrete manual  
Fully automatic

**Unit Dimensions (w x d x h)**  
190 x 300 x 100 mm

## Choose your HDT Accessories

### Cells

All cells supplied with Copley's Vertical Diffusion Cell systems are designed to simplify cell preparation and sample collection procedures.

For USP Models 'A', 'B' and 'C', vertical diffusion cells are supplied complete with individual cell tops for both 'closed or occluded' operation (as per Model 'A') and 'open' operation (as per Models 'B' and 'C' respectively), maximising the versatility of the HDT series.

To accommodate 'full thickness' membranes or skin, and in contrast to the Type 'B' and 'C' cells, which use a 3-pronged spring clip, a screw-type cell closure mechanism has been developed for the skin specific

cell that ensures proper contact between the sample and the receptor medium. All components of the cell are made from FDA-approved inert materials and a side sampling arm facilitates easy filling, sample withdrawal and media replacement.

Samples are separated from the receptor media by a synthetic inert and highly permeable support membrane.



### HDT

Cat. No.	Description
7290	10 Cell Vertical Diffusion Cell Test System HDT 1000 (excl. cells)
7276	Single Cell Vertical Diffusion Cell Test System HDT 1 (excl. cells)
7298	Vertical Diffusion Cell 11.28 mm x 7 mL Type 'B' (in Glass)
7299	Vertical Diffusion Cell 15 mm x 11 mL Type 'C' (in Glass)
7302	Vertical Diffusion Cell 15 mm x 12 mL for Skin (in Glass/Tecapro)
7295	Syringe 2 mL complete with Luer and sampling tube (Pk 10)
7296	Syringe 20 mL complete with Luer and media filling tube
7297	Parafilm Laboratory Film (250' x 2")
7289	Storage Rack for 10 Vertical Diffusion Cells (Types 'B', 'C' and Skin)
7277	IQ/OQ/PQ Documentation Pack for HDT 1/1000
7272	Qualification Tools for HDT 1/1000
7282	Re-calibration of Qualification Tools for HDT1/1000





# Cell Specification



**Type 'B' Cell**

**Cat. Number**  
7298

**Sample Holder Type**  
Clip

**Sample Holder Material**  
Glass

**Receptor Material**  
Glass

**Operation**  
Open, Closed/Occluded

**Receptor Volume**  
7 mL

**Max Membrane/Skin Thickness**  
Open 0.5 mm  
Closed/Occluded 0.5 mm



**Type 'C' Cell**

**Cat. Number**  
7299

**Sample Holder Type**  
Clip

**Sample Holder Material**  
Glass

**Receptor Material**  
Glass

**Operation**  
Open, Closed/Occluded

**Receptor Volume**  
11 mL

**Max Membrane/Skin Thickness**  
Open 0.5 mm  
Closed/Occluded 0.5 mm



**Skin Cell**

**Cat. Number**  
7302

**Sample Holder Type**  
Screw

**Sample Holder Material**  
Tecapro

**Receptor Material**  
Glass

**Operation**  
Open, Closed/Occluded

**Receptor Volume**  
12 mL

**Max Membrane/Skin Thickness**  
Open 4.0 mm  
Closed/Occluded 2.5 mm

# Membranes

Copley offers a range of three synthetic membranes:

- **PVDF**  
A hydrophilic polymeric membrane  
Pore size: 0.45 microns.
- **Supor Polyethersulfone**  
A hydrophilic polyethersulfone membrane with a 0.45 m pore size. These membranes have reduced protein binding and fewer leachables than Tuffryn membranes.
- **Strat-M Membranes**  
Newer, multi-layered membrane offering higher correlation to human skin than simpler synthetic alternatives, without the high test variability associated with biological models and does not require wetting.

## HDT Cell Membranes

Cat. No.	Description
7270	Pack of 100 PVDF Membranes 25 mm o.d.
7274A	Pack of 100 Supor Polyethersulfone Membranes 25mm o.d.
7275	Pack of 60 Strat-M Membranes 25 mm o.d.
7304	25 mm Punch For VDC Skin/Membrane



## VDC HDT 1

A simple test system for a single diffusion cell.

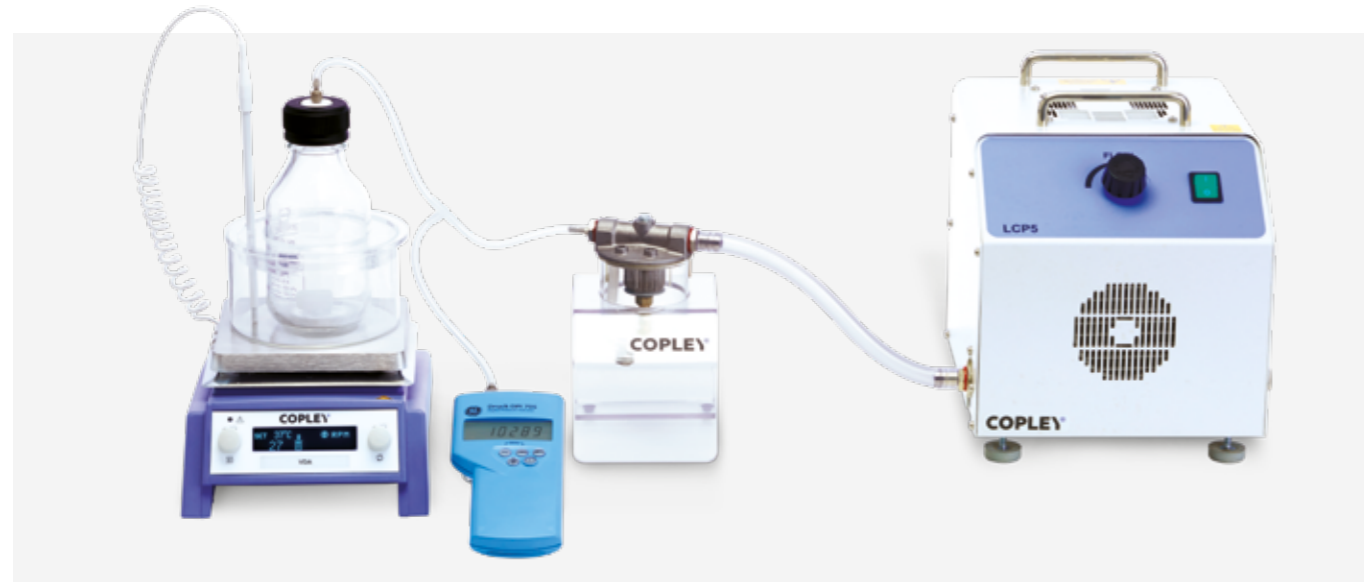
This is a smaller alternative to the main HDT 1000, ideal for entry-level semisolids testing.



## Degassing

The Vacuum Deaeration Apparatus Model (VDA) from Copley is an easy-to-use and inexpensive unit designed to degas receptor medium prior to its use, ensuring that diffusion is unimpeded by the collection of gas beneath the membrane. Once deaerated, the system can be used to maintain the temperature of the degassed dissolution medium to the required temperature for testing.

Used in combination with a vacuum pump, pressure meter and dissolved oxygen meter, the VDA system guarantees oxygen levels below 4 ppm, exceeding the recommendations set out in the pharmacopoeias (USP suggests an oxygen concentration <6 ppm is an adequate level of dissolution media deaeration).



### The VDA system comprises of:

- 500 mL pressure bottle containing receptor medium
- Water bath to heat the contents of the bottle to 45°C
- A magnetic stirrer/heater to stir the content of the bottle whilst heating it and the surrounding water bath
- A condensate filter to prevent condensate from damaging the vacuum pump

The following items are required in addition to provide a full system:

- A vacuum pump
- A differential pressure meter to display pressure and test for leaks
- A dissolved oxygen meter to measure and display dissolved oxygen levels in the media

### VDA

Cat. No.	Description
7291	Vacuum Deaeration Apparatus Model VDA
7300	IQ/OQ/PQ Documentation Pack for VDA
7903	Low Capacity Vacuum Pump Model LCP5
7293	Digital Differential Pressure Meter
7294	Dissolved Oxygen Meter

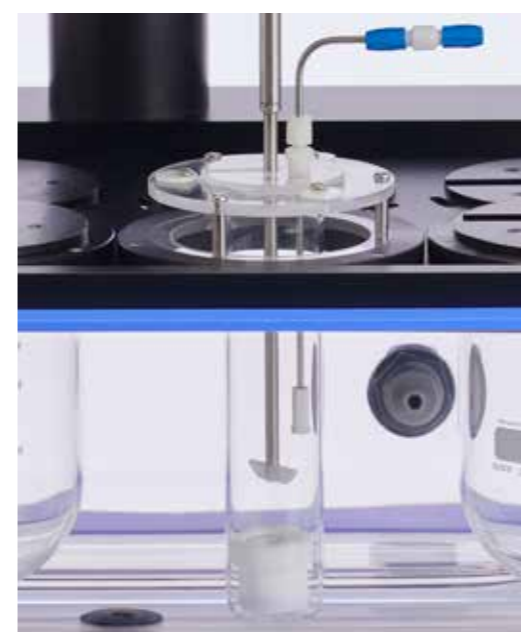
## Immersion Cell

An alternative to the Vertical Diffusion or Franz Cell for testing semisolids, the Immersion Cell (USP Model A) is described with the conventional USP Apparatus 2 for Dissolution testing on Page 75.

Accommodating a 25 mm diameter membrane, the Immersion Cell is comprised of 4 main parts:

1. A retaining ring to secure the membrane to the cell body
2. A washer to hold the membrane in contact with the sample
3. The membrane or skin
4. The cell body which contains the compartment in which the sample to be tested is placed

The immersion cell is used with a special flat-bottomed version of the 200 mL Small Volume Conversion Kit (see Page 38) to eradicate the issue of dead space under the cell that would occur with a round bottomed vessel.



Immersion Cell with 200 mL Small Volume Conversion Kit

### Immersion Cell & Accessories

Cat. No.	Description
7280	Immersion Cell
7281	200 mL Small Volume Conversion Kit for Immersion Cell
7270	Pack of 100 PVDF Membranes 25 mm o.d.
7274A	Pack of 100 Supor Polyethersulfone Membranes 25mm o.d.
7275	Pack of 60 Strat-M Membranes 25 mm o.d.



Immersion Cell

# Suppositories

## Background: Suppository Testing

Suppositories, which advantageously avoid the risk of digestion of the active drug in the gastrointestinal tract, are classified as either:

**Hydrophilic:** made from a water-soluble base such as polyethylene glycol, which dissolves in rectal or vaginal fluids.

**Lipophilic:** made from a greasy base such as cocoa butter, which melts at body temperature.

There is no single method of drug release testing suitable for all types of suppository formulations.

## Suppository Testing

### Test Apparatus & Method

The suppository is a more common and accepted dosage form in Europe than in the USA which may explain why references to specific test methods relating to suppositories and associated dosage forms are mainly confined to the European Pharmacopoeia.

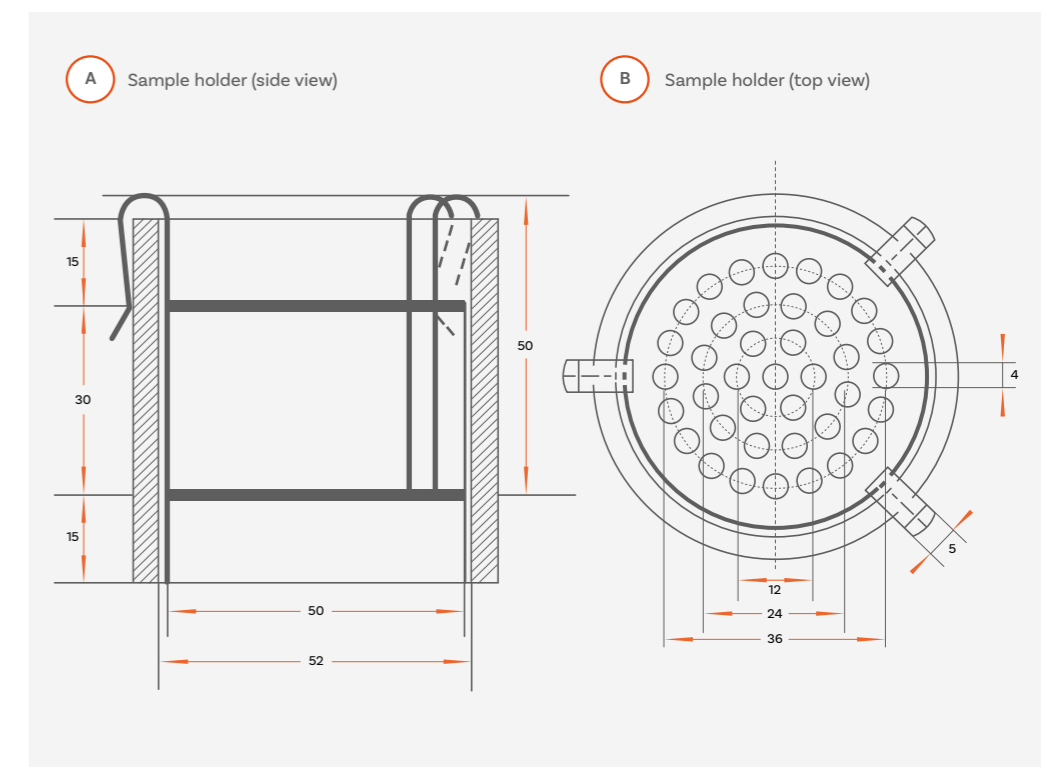
The rate of drug release (dissolution) for hydrophilic suppositories can be measured using the standard basket, paddle or flow through methods described in USP Chapter <711> and Ph. Eur. 2.9.3 (see Page 24-25). Methods for lipophilic suppositories include:

- a modified basket method (see Page 39)
- a paddle method (see Page 24)
- a modified flow method (see Ph. Eur. 2.9.42)

In addition to this, the European Pharmacopoeia references two other technical procedures relating to **disintegration** and **softening** time of suppositories:

**2.9.2** Disintegration of suppositories and pessaries

**2.9.22** Softening time determination of lipophilic suppositories



# Suppository Tester: SDT 1000

## Straightforward suppository testing

Designed in accordance with the specifications laid down in Ph. Eur. 2.9.2, the SDT 1000 is a single unit tester optimised for assessing the disintegration properties of suppositories and pessaries and with the appropriate attachment, for measuring the softening time of lipophilic suppositories (as per Ph. Eur. 2.9.22.-2).

The SDT 1000 has a simple design, which uses manual inversion controlled via a water-resistant pulley system. Test parameters including water bath temperature and stirrer speed are easily set using the touch key interfaces.



Ph. Eur. compliant



Easy-remove components for straightforward cleaning



Single unit assesses both disintegration and softening time (with necessary attachments)



## SDT 1000: Key Features



Integrated PT100 probe for precision temperature control and measurement



Manual sample inversion offers users ultimate control and flexibility



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



Powerful magnetic stirrer ensures consistent mixing during testing



Small unit footprint saves previous benchtop space

## Softening Time Attachment

A special attachment is used in place of the disintegration test station, in combination with a 4-litre beaker containing three glass rods (C1) for measuring the softening time of lipophilic suppositories, in accordance with Ph. Eur. 2.9.22.-2.



Softening Time Attachment



### SDT 1000

Cat. No.	Description
1704	Suppository Disintegration Tester SDT 1000
1705	Electro-Magnetic Stirrer for SDT 1000
1706	Softening Time Attachment (Ph. Eur. 2.9.22.-2)

### SDT 1000: Technical Specifications

<b>Pharmacopoeial Compliance</b>	Ph. Eur. Test 2.9.2 Ph. Eur 2.9.22.-2 (with suitable attachments)
<b>User Interface</b>	Touchpad buttons, LED display
<b>Test Stations</b>	Disintegration: 1 Softening Time: Up to 3
<b>Temperature Range</b>	Ambient - 50 °C
<b>Sample Inversion</b>	Manual
<b>Stirrer Speed</b>	80 - 2000 rpm (in 10 rpm intervals)
<b>Unit Dimensions (w x d x h)</b>	510 x 280 x 500 mm



### SDT 1000 Accessories

Cat. No.	Description
1707	Qualification Tools
1712	Re-calibration of Qualification Tools
1708	IQ/OQ/PQ Documentation
1710	Digital Timer with Audible Alarm (including calibration)



## Vaginal Tablet Tester (VTT)

Using the same sample holder as the SDT 1000 together with a low form beaker and heater/stirrer, Copley's VTT is a reliable, easy-to-use and compliant (Ph. Eur. 2.9.2) solution for assessing the disintegration properties of vaginal tablets.

### Vaginal Tablet Tester

Cat. No.	Description
1800	Vaginal Tablet Tester (VTT)
1709	Glass Plate for use with Vaginal Tablets



# Thickness

## Background: Thickness Testing

The thickness of a tablet is critical to its therapeutic efficacy since thickness impacts on disintegration and dissolution behaviour.

In addition, thickness can be a useful indicator of the consistency, or otherwise, of tablet weight which is controlled to ensure dose uniformity.

The weight of a compressed tablet is dependent on three factors:



Density



Diameter



Thickness

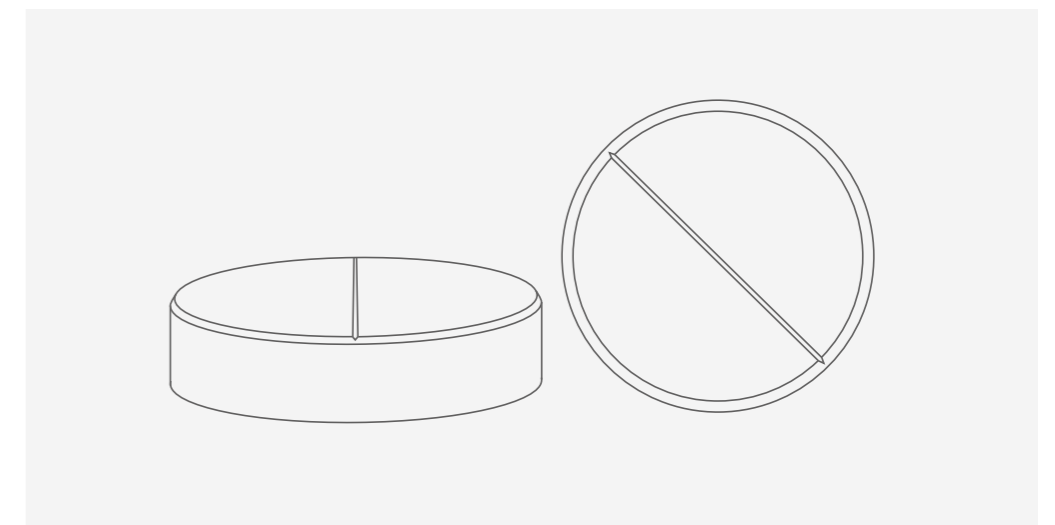
## Thickness

### Test Apparatus & Method

Though a modern tablet press should provide a good level of uniformity, there are several potential sources of variation, the most important of which is powder flow which can affect the uniformity with which the die is filled before compaction.

Mechanical wear and imperfections in the pressing or tooling may also introduce variability, as can the build-up of material on the punch face or die wall during a run. Any of these factors may impact tablet weight and the physical consistency of manufactured tablets.

Monitoring tablet thickness at regular intervals allows potential problems relating to tablet weight and hence content uniformity to be detected and efficiently diagnosed at an early stage.



# Calipers & Thickness Testers

## Easy-to-operate and portable tablet thickness testers for busy production environments

Copley's range of calipers and thickness testers are simple and easy-to-use instruments, designed for use by the press operator on the compression floor.



### Digital Caliper Model 500

Accepting tablets and similar samples up to a maximum size of 150mm, the inexpensive Digital Caliper 500 is a convenient, hand-held electronic caliper, for quick, simple and convenient tablet thickness testing.

Supplied in a handy plastic storage case, the Digital Caliper 500 can be readily connected to data processor units for statistical process control.

### Tablet Thickness Tester 700

A dedicated pocket-sized unit for simple, one-handed operation. Just switch the device on, zero the gauge, select the units, insert the sample, release the jaw and read off the measurement on the clear LCD display.

### Tablet Thickness Tester 547

A more sophisticated unit than the Tablet Thickness Tester 700, this gauge enjoys many of the same features but can be used in two different modes:

1. 'Direct measurement' mode which provides actual thickness
2. 'Comparator measurement' mode whereby a +/- variance from a pre-set norm is indicated on the display. This is extremely useful for rapid checks in the production environment.




### The Digimatic Mini Processor Model 264

A powerful compact data processor which provides a wide variety of calculations for generating X-R control charts, histograms and data displacement charts.

#### Calipers & Thickness Testers

Cat. No.	Description
4901	Digital Caliper 500
4902	Mini Processor SPC 264
4903	Tablet Thickness Tester 700
4904	Tablet Thickness Tester 547

# Choose your Thickness Tester

		
<b>Digital Caliper Tester 500</b>	<b>Tablet Thickness Tester 700</b>	<b>Tablet Thickness Tester 547</b>
<b>Cat. Number</b> 4901	<b>Cat. Number</b> 4903	<b>Cat. Number</b> 4904
<b>UKAS Calibration Cat. No.</b> 4901A	<b>UKAS Calibration Cat. No.</b> 4903A	<b>UKAS Calibration Cat. No.</b> 4904A
<b>Max. Tablet Size</b> 150 mm	<b>Max. Tablet Size</b> 12 mm	<b>Max. Tablet Size</b> 10 mm
<b>Accuracy</b> 0.01 mm	<b>Accuracy</b> 0.01 mm	<b>Accuracy</b> 0.01 mm
<b>Measurement Unit</b> mm   inches	<b>Measurement Unit</b> mm   inches	<b>Measurement Unit</b> mm   inches
<b>Measurement Modes</b> Direct: Outside, Inside, Depth, Step	<b>Measurement Modes</b> Direct: Actual Thickness Comparator: +/- Deviation from norm	<b>Measurement Modes</b> Direct: Actual Thickness Comparator: +/- Deviation from norm
<b>Data Output</b> Analogue Display	<b>Data Output</b> Analogue Display	<b>Data Output</b> Analogue display. Digimatic Mini Processor Model 264 (optional)

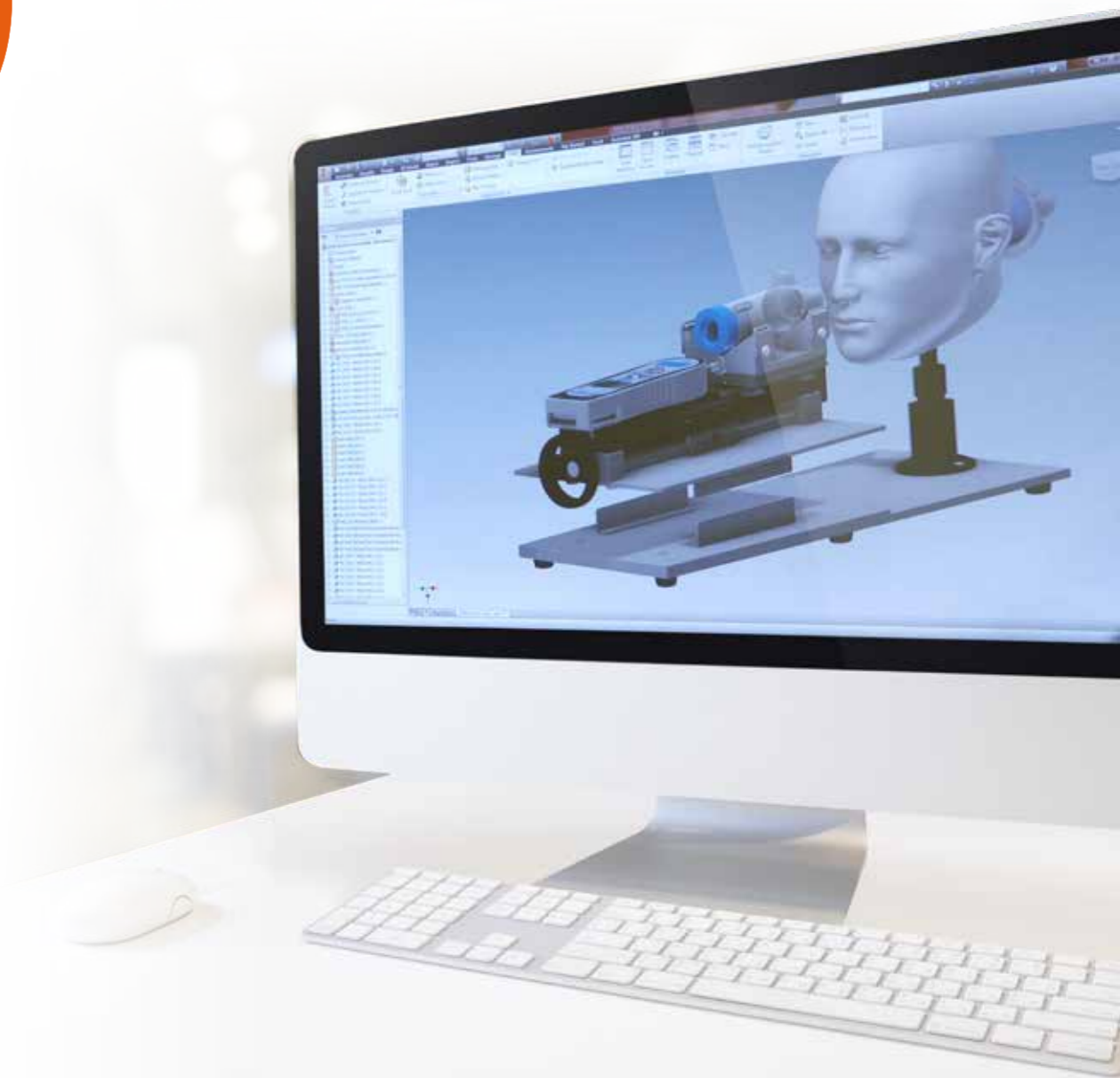
# Services

Copley offers a comprehensive range of services from bespoke product design to installation, expert training and technical support, optimising all aspects of pharmaceutical testing from start to finish.

## Design

Our design and development teams have many years' experience working closely with the pharmaceutical industry in helping to develop their ideas for solving problems.

Whether you have a longstanding problem, one that has been created by the introduction of a new process, or an idea for a new product, or even a bespoke design that you need manufacturing, we would be delighted to hear from you.





## Servicing

We understand how important it is that your equipment operates consistently throughout every test run, every day of the week. With the Copley range of pharmaceutical testing equipment you're opting not only for exemplary performance, but also quality, reliability and compliance. To keep your instruments operating in peak condition and to ensure they are properly calibrated, Copley offers a range of

comprehensive servicing options giving owners peace of mind.

We offer a broad range of both in-house and on-site service packages tailored to customers' specific needs. All our servicing packages follow well documented maintenance and calibration procedures.

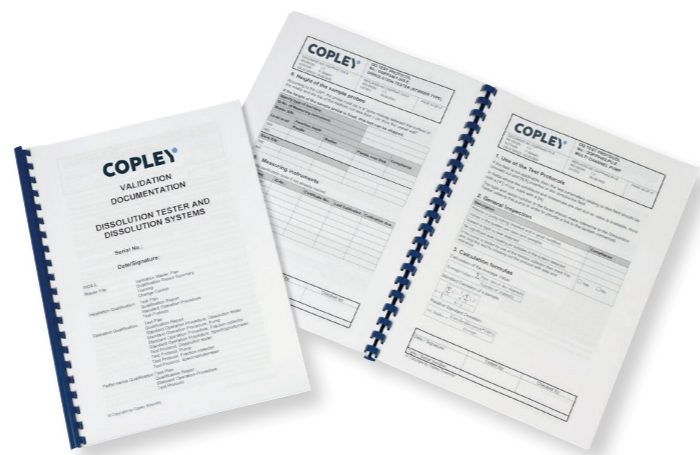


## IQ/OQ/PQ

We recognise the regulatory importance of proper Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). For this reason, full supporting IQ/OQ/PQ documentation is available for a wide selection of our products, to guide users through the qualification process.

Our team of highly skilled engineers and technicians are fully trained to deliver calibration and qualification (IQ/OQ) services for the complete range of Copley products, in compliance with GxP procedures.

Please contact us to find out more about our range of servicing options.



## Training

Copley training courses are interactive, lecture and exercise-based courses provided by experts in the field who can share their in-depth knowledge of evolving technologies and regulatory landscapes.

Our range of courses can be tailored to the needs of the user, from novice to experienced analyst, covering a narrow or broad range of subjects and can be conducted on-site or at our purpose-built training facility in Nottingham, UK. Training certificates are also supplied for users' training records.

Specially qualified trainers are able to put together bespoke packages for small or large groups, with typical training programs on topics including:

- Dosage technology, test equipment, regulatory requirements, monographs and methodology, new industry developments, etc.
- Audit of current system set-up and procedures (on-site training only)
- Training of users in operation of the equipment supplied
- Troubleshooting, questions and answers

- ✓ Highly experienced trainers
- ✓ Bespoke training programs
- ✓ On-site training available
- ✓ Certification provided



**Please contact us to find out more about our range of training packages.**

Contact us at: [sales@copleyscientific.co.uk](mailto:sales@copleyscientific.co.uk)

or call: +44 (0)115 961 6229

## Support

Buy with confidence from Copley. When you purchase equipment from us, you not only get outstanding instrumentation but also a complete customer care package which extends from the start of the sales process through to installation, training,

after-sales support and beyond. With a global network of experienced and knowledgeable distributors you can rest assured that, wherever you may be, there is support every step of the way.

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