

ELECTROLAB

Tablet Disintegration Tester

(ED - 2 SAPO)*



CE

(Patent pending)

Salient Features —

- Disintegration time registration of each tablet
- USP / EP / IP compliant
- Unique camless drive
- Dual station with individual drive and timer
- Magnetic coupling to the moving arm allows quick, easy and safe basket handling
- Moulded water bath with fliptop cover
- Built-in stirrer for precise temperature control in the water bath
- Specially designed temperature probes for continuous monitoring of temperature in both the beakers.
- Illumination of tablets for better visibility of the disintegration process.
- PC keyboard interface provided for ease of entering product data.
- Print report of tablet disintegration time and online validation of strokes/minute with temperature as per cGMP.

(*SAPO — Semi Automatic Park Out)

The increasingly sensitive and demanding needs made by the pharmaceutical industry for better and more sophisticated disintegration systems have resulted in a virtual re-invention of the process. **ELECTROLAB's** ED-2SAPO is the answer to the pharmaceutical sectors increasing needs for disintegration testing.

ELECTROLAB's microprocessor based ED-2 SAPO (Semi Automatic Park Out) is a cost effective instrument used for testing the disintegration time of tablets, capsules and other solid dosage forms. The instrument has a small footprint and complies with USP, EP and IP requirements.

The ED-2 SAPO is a dual station instrument with individual camless drives and timers. These unique linear drives produce a sinusoidal (jerk-free) motion to comply with USP requirements. The drive is vibration free in movement and silent in operation. Special curtains are provided to keep the drive dust free.

The bath is one piece moulded and is crevice free. A simple fliptop cover which can be locked in the top position ensures an easy removal of the bath. It is illuminated from the bottom with soothing, white LED's to aid better observation of the disintegration process.

Baskets — Attaching and Dismantling



The baskets are ergonomically designed for user friendly handling. Each basket has 6 color coded rings for easy visual identification during the registration of disintegration time. The baskets are magnetically coupled to the

arm using permanent magnets which ensure a strong swivel free and easy attachment with correct orientation on every engagement. The baskets can be completely dismantled for thorough cleaning using a simple knurl screw. A device has been provided to keep the glass tube safely in place whilst assembling or dismantling.



The advanced microcontroller along with the PT 100 sensor and a stirrer in the bath ensures uniform temperature and a control accuracy of within $\pm 0.2^{\circ}\text{C}$. The temperature can be set in the range of 30° to 40°C . No routine temperature calibrations are required since the system autocalibrates itself.

The thin mobile temperature probes are placed in the beaker to monitor and validate the beaker temperature

Validation and Test Results

Test results for each basket can be recorded separately. The instrument ensures that parameters like temperature of individual beakers, the bath and strokes per minute are validated online. A report of these parameters can be printed after the test as per cGMP guidelines. In Registration Mode the Validation and Test Results are printed whereas in the Timer Mode the Validation results are printed out.

ELECTROLAB DISINTEGRATION TESTER TEST REPORT

Model No : ED-2SAPO Sr. No. : 0502010 Start Date: 15/02/2005 Start Time: 12:07:16

USER NAME : Mr. Peter Bob
 SET PARAMETERS : Registration BASKET A
 MODE OF TEST : BASKET B TEMP. : 37.0

PRODUCT NAME	ASPIRIN Tablets	Carbamazole Tablets
BATCH No.	PT0001/FUR01A105	PT002/FUR01G236
LOT No.	IV	IV
MEDIA	0.1 NHCl	pH 6.8 buffer
BASKET TYPE	USP Apparatus A	USP Apparatus A
TEST DURATION	00:15:00	00:15:00

TEST SUMMARY	BASKET A	BASKET B
TEST STATUS	TEST COMPLETED	TEST COMPLETED
TEST ON DUR.	00:05:20	00:06:00
1.	00:05:40	00:06:30
2.	00:06:00	00:06:20
3.	00:06:10	00:06:40
4.	00:06:20	00:05:50
5.	00:06:40	00:05:40
6.	00:06:00	00:05:20
HALT DUR.		

COMMENT : Pass
 SIGNATURE : Peter Bob
 TEST No. : 000002
 PRINT No. : 000001

ELECTROLAB DISINTEGRATION TESTER TEST REPORT

Model No : ED-2SAPO Sr. No. : 0502010 Start Date: 15/02/2005 Start Time: 11:03:27

USER NAME : Mr. Joy Adamson
 SET PARAMETERS : Dual Timer BASKET A
 MODE OF TEST : BASKET B TEMP. : 30.0

PRODUCT NAME	ASPIRIN Tablets	Carbamazole Tablets
BATCH No.	PT0001/FUR01A105	PT002/FUR01G236
LOT No.	IV	IV
MEDIA	0.1 NHCl	pH 6.8 buffer
BASKET TYPE	USP Apparatus A	USP Apparatus A
TEST DURATION	00:15:00	00:15:00

TEST SUMMARY	BASKET A	BASKET B
TEST STATUS	TEST COMPLETED	TEST COMPLETED
TEST ON DUR.	00:15:00	00:15:00
HALT DUR.	00:00:00	00:00:00

COMMENT : Pass
 SIGNATURE : JAdamson
 TEST No. : 000001
 PRINT No. : 000001

Validation and Test Results

Two Modes of Operation for Baskets A and B

Timer Mode :

Individual test time can be programmed for each basket. The basket can be run for a set time and it parks out at the end of the test. In both modes of operation for better observation of the disintegrating tablet the baskets are parked out of the media, when the test is halted.



Registration Mode :

In this mode the disintegration process for each sample can be observed and on completion of this process the respective color coded key can be pressed to register the disintegration time of the corresponding sample. This registered time is displayed on the instrument panel and the result can be printed out. On completion of registration for all the 6 tablets the basket will park out of the beaker.

and start the test when the set temperature has been reached. The probes are designed to match the beaker profile and prevent interference with the basket movement.

APC keyboard interface is provided for ease of entering alphanumeric data like user name, product name, batch nos., lot nos., media and set parameters. All such data for upto 10 products can be stored and retained to save time.

The ED - 2 SAPO complies with cGMP guidelines.

Safety Features ▲

Special attention has been given to safety factors and status indicators which have been incorporated in the instrument —

- ▲ The test does not start till the temperature is reached.
- ▲ A thermal cutout is provided to cut off the power to the heater when the temperature exceeds a safety limit.
- ▲ The instrument is also provided with a power failure recovery feature.

- ▲ Positive engagement (coupling) of the baskets to the arm with permanent magnets to prevent them from coming out or loosening.
- ▲ The heater cuts off if the water level in the bath is below the minimum level or if the fliptop cover is in the “top” position.
- ▲ Error indications for various conditions are prompted on the display.

Standard Accessories— 2 magnetic baskets with 6 positions each (USP Apparatus A), 12 guided discs (6 x 2 stations), 1000 ml glass beakers(2 nos), External temperature

probes (2 nos.), moulded bath (1 no.)

Optional Accessories— PC keyboard, Basket with 20, 40 and other mesh sizes on request, Cover

for basket assembly, Bolus basket with 3 tubes and 3 guided discs (USP Apparatus B), Bolus basket with 1 tube and guided disc, A magnetic disc handling device can

be supplied with special guided disks to ensure easy trouble-free removal and insertion of the discs in the baskets, IQ / OQ documents.

Accessories for SAPO



1. Magnetic basket (SAPO)



2. Glass tubes



3. Basket cover



4. Clear guided discs



5. Glass beaker



6. Temperature probe



7. Disc handling device

Specifications for SAPO

Water bath	Clear acrylic moulded water bath	
Baskets	2 nos. each carrying 6-test position (10 mesh) USP	
Guided disk	Perforated cylinder disk 6 nos. in each basket (USP)	
Display	20 characters x 4 lines LCD	
Printer interface	Centronics Parallel Port	
Printer supported	80 col. dot matrix printers, HP deskjet, HP laserjet	
Motor	Stepper motor (2 nos)	
Heater	230 V AC, 400 - Watts, S S 304	
Illumination	White light (LED)	
Power supply	230 V AC, 50 / 60 Hz, 490 VA or 110 V AC, 50 / 60 Hz (on request)	
Stroke rate	30 ± 1 stroke / minute	
Stroke height	55 mm ± 2 mm	
Temperature	30.0° C to 40.0° C	Temperature Accuracy : ± 0.2° C
Timer setting	23 hrs:59 min:59 secs	
Dimension	570 (H) mm x 372 (W) mm x 360 (D) mm	
Weight	18 kg net / 30 kg gross	

Tablet Disintegration Tester ED-2L (USP)

Features

- Complies with USP, IP specifications
- Single drive dual station unit
- **Snap-Click™** loading and a swivel free basket movement
- Programmable Timer with alarm and Temperature controller
- External probe for beaker temperature validation
- Illuminated bath for better visibility



Accessories for ED 2L



1. Basket for ED-2L
2. Glass tubes
3. Clear guided discs

4. Basket Cover
5. Glass beaker
6. Bolus basket with 3 tubes

7. Bolus basket with 1 tube
8. Temperature probe
9. Disc handling device

The information contained in this document is believed to be correct, but ELECTROLAB accepts no liability for any errors it contains and reserves the right to alter specifications without notice.

ELECTROLAB

401, Tirupati Udyog, I. B. Patel Road, Off Western Express Highway, Goregaon (East), Mumbai 400 063 India

Tel: 91 - 22 - 2686 27 29 / 91 - 22 - 5570 40 80 / 91 - 22 - 5570 40 81 / 91 - 22 - 5570 40 82

Fax: 91 - 22 - 2686 2111 e-mail : sales@electrolabindia.com website : www.electrolabindia.com