



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for operation, and calibration of disintegration test apparatus.

2.0 SCOPE:

This SOP is applicable to operation, and calibration of disintegration test apparatus used in QC department, Make: Electro lab, Model: ED-2L& ED 2AL

The Scope of this SOP covers the operation and calibration of disintegration test apparatus as per the current Pharmacopoeias (IP/BP/USP/Ph. Eur.) & In-House requirements.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control.

Head– Quality Control.

4.0 PROCEDURE:

4.1 Preliminary check:

4.1.1 Ensure that the instrument is clean and free from dust, if not then clean with dry cloth.

4.1.2 Ensure the water level in the water bath (Filling tank).

4.1.3 Ensure calibration status of the Instrument.

4.1.4 Clean the basket rack assembly and discs (if applicable) and beakers with purified water before start of the operation.

4.1.5 Before start ensure the temperature of the beakers achieved as per requirements.

4.2 Operation:(ED-2L)

4.2.1 Ensure the cleanliness of the instrument.

4.2.2 Switch 'ON' mains Switch.

4.2.3 Put the power switch 'ON' at the rear panel.

4.2.4 Set the conditions:

(Be sure that water is filled upto the mark in the water tank)

4.2.4.1 Setting the temperature:

4.2.4.1.1 Press "SET" key the yellow LED starts glowing.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.2.4.1.2 Press 'TEMP' key, the right digit of the previously set temperature on the temperature screen starts blinking.

4.2.4.1.3 Set the required temperature with pressing ▲ (up) or ▼ (down) keys. After the required setting, press "DISP SEL" key to change the position of blinking digit. After complete setting press "ENTER" key to store the temperature set in Instrument's memory.

4.2.4.2 Setting the timer:

4.2.4.2.1 Press "SET" key the yellow LED on the right side starts glowing.

4.2.4.2.2 Press "TIMER" key, the right digit of the previously set time starts blinking.

4.2.4.2.3 Set the required time in minutes with pressing ▲ (up) or ▼ (down) keys. After the required setting, press "DISP SEL" key to change the position of the blinking digit. After complete settings press, "ENTER" key to store the time set in instrument's memory.

4.2.4.2.4 Press the "TEMP" key to start the temperature. The red "LED" starts glowing.

4.2.4.2.5 Take two 1000 ml beakers and fill them with purified water/specified media upto the $\frac{3}{4}$ th level. Place them in the instrument.

4.2.4.2.6 Take the temperature of the selected area by keeping the external probe in that area and press "PROBE SEL" key. The LED of "EXT." position starts glowing and the temperature of that area will be displayed.

4.2.4.2.7 After attaining in the set temperature, place the tablets in the basket (use discs, if required), fix them on the clamps and start the test by pressing "START/ STOP" key. The instrument will automatically stop after completing the set time.

4.2.4.2.8 To halt the test, press "TIMER" key. The green LED of "TIMER" key start flashing and the time stop increasing. To continue the test press "TIMER" key once more.

4.2.4.2.9 To stop the test whenever required press "START/STOP" key, the test will stop.

4.2.4.2.10 Clean the baskets, discs and beakers for next use.

4.2.4.2.11 Put "OFF" the instrument from the rear panel and switch "OFF" the mains.

4.2.4.2.12 Record the operational details in instrument log book.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.3 Use Apparatus A for tablets and capsules that are not greater than 18 mm long. For larger tablets or capsules use Apparatus B.

4.4 Operation:(ED-2AL)

4.4.1 Ensure the cleanliness of the instrument.

4.4.2 Switch 'ON' mains Switch.

4.4.3 Put the power switch 'ON' at the rear panel.

4.4.4 Set the conditions:

(Be sure that water is filled up to the mark in the water tank)

4.4.4.1 Setting the temperature:

4.4.4.1.1 Press "SET" key the green LED starts glowing.

4.4.4.1.2 Press 'TEMP' key, the right digit of the previously set temperature on the temperature screen starts blinking.

4.4.4.1.3 Set the required temperature with pressing ▲ (up) or ▼ (down) keys. After the required setting, press "DISP SEL" key to change the position of blinking digit. After complete setting press "ENTER" key to store the temperature set in Instrument's memory.

4.4.4.2 Setting the timer:

4.4.4.2.1 Press "SET" key the green LED on the right side starts glowing.

4.4.4.2.2 Press "TIMER1/TIMER 2" key, the right digit of the previously set time starts blinking.

4.4.4.2.3 Set the required time in minutes with pressing ▲ (up) or ▼ (down) keys. After the required setting, press "DISP SEL" key to change the position of the blinking digit. After complete settings press, "ENTER" key to store the time set in instrument's memory.

4.4.4.2.4 Press the "TEMP" key to start the temperature. The red "LED" starts glowing.

4.4.4.2.5 Take two 1000 ml beakers and fill them with purified water/specified media upto the $\frac{3}{4}$ th level. Place them in the instrument.

4.4.4.2.6 Take the temperature of the selected area by keeping the external probe in that area and press "PROBE SEL" key. The LED of "EXT." position starts glowing and the temperature of that area will be displayed.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.4.4.2.7 After attaining in the set temperature, place the tablets in the basket (use discs, if required), fix them on the clamps and start the test by pressing “START/ STOP” key. The instrument will automatically stop after completing the set time.

4.4.4.2.8 To halt the test, press “TIMER” key. The green LED of “TIMER” key start flashing and the time stop increasing. To continue the test press “TIMER” key once more.

4.4.4.2.9 To stop the test whenever required press “START/STOP” key, the test will stop.

4.4.4.2.10 Clean the baskets, discs and beakers for next use.

4.4.4.2.11 Put “OFF” the instrument from the rear panel and switch “OFF” the mains.

4.4.4.2.12 Record the operational details in instrument log book.

4.5 Calibration:

4.5.1 Operate the Instrument (ED-2L) as per the point No. 4.2 and operate the Instrument (ED-2AL) as per point no. 4.4 Calibrate the Apparatus A and Apparatus B separately as given in procedure below.

4.5.2 Start the machine and count the number of cycles per minute by using calibrated stopwatch and record the same in Annexure - I.
(Limit: 29-32 cycles/minute)

4.5.3 Check the distance travelled by the mechanical device in the following manner.

4.5.3.1 Take out the cells.

4.5.3.2 Put a scale horizontal on both the arms when the arms are on top most positions. Make a marking on top position sideways by marker.

4.5.3.3 Start the motor. Switch off the supply of the instrument when the arms are not at the top most position. The arms will dropdown to the lower position.

Just push the arm by hand further down to ensure that it is in the lower most

Position. Make a marking of the lower most position by using a scale.

Measuring the stroke length i.e. between the markings by using calibrated vernier caliper.

4.5.3.4 The observed distance should be 53 to 57 mm.

4.5.3.5 Record the distance measured in the format as per Annexure - I.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.5.4 Set the required temperature, start the heater of machine and keep the instrument to maintain a stable temperature.
- 4.5.5 Check the temperature of water bath and beaker with a calibrated thermometer and note it down in Annexure - I.
- 4.5.6 Set the timer for 30 minutes and start the machine and the calibrated stopwatch simultaneously. Note down the stopwatch reading immediately when the machine stops.
- 4.5.7 Aperture verifies the basket with help of vernier caliper.
- 4.5.8 Aperture “a” can be calculated as formula
- 4.5.9 $a = (L-5W)/6$
- 4.5.10 Take readings from all mesh of glass cylinder and record in Annexure - I.
- 4.5.11 Affix calibration status label duly filled and signed on the equipment after completion of calibration.
- 4.5.12 If the instrument is out of calibration, put an “OUT OF CALIBRATION” tag, and proceed as per SOP No. QAD/055.
- 4.5.13 Record the calibration details in instrument log book.

4.5.14 Frequency: Quarterly

4.6 Cleaning:

4.6.1 Cleaning of basket–rack assembly and disc:

- 4.6.1.1 Clean the basket–rack assembly and discs after every disintegration test.
- 4.6.1.2 Clean the basket–rack assembly and discs of the disintegration apparatus with running tap water then purified water.
- 4.6.1.3 If required basket basket–rack assembly shall be dipped in purified water and sonicate.

4.6.2 Cleaning of water bath (tank):

- 4.6.2.1 Before cleaning switch off the instrument.
- 4.6.2.2 Wipe main body of the instrument with a clean dry cloth.
- 4.6.2.3 Clean the water bath (tank) every week or water is shown hazy, drain the water from bath (Tank) and shall be cleaned with purified water.
- 4.6.2.4 Fill the purified water up to the level in a disintegration bath (Tank).

4.7 Precaution:



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.7.1 Do not start the temperature controller till the water in the bath is filled up to the marked level without beakers.
- 4.7.2 Do not try to remove the baskets till they are disengaged from the hook.
- 4.7.3 Do not clean the bath with any strong solvent. Use purified water for cleaning.
- 4.7.4 The external probe shall be handled carefully.

5.0 ANNEXURE (S):

Annexure – I : Calibration record of disintegration test apparatus

6.0 REFERENCE (S):

SOP: Out of calibration of instrument

SOP: Preparation, Approval, Distribution control, revision and destruction of Standard operating Procedure (SOP).

USP/BP/Ph. Eur./IP

7.0 ABBREVIATION (S)/DEFINITION (S):

Apparatus A: The apparatus consists of a six basket-rack assembly with discs (Disc diameter is 20.7 ± 0.15 mm and five holes).

Apparatus B: The apparatus consists of a three basket-rack assembly with discs (Disc diameter is 31.4 ± 0.13 mm and seven holes).

SOP: Standard Operating Procedure.

IP : Indian Pharmacopoeia

BP : British Pharmacopoeia

USP : United States Pharmacopoeia

Ph. Eur.: European Pharmacopoeia



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	----



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

CALIBRATION RECORD OF DISINTEGRATION TEST APPARATUS

CALIBRATION RECORD OF DISINTEGRATION TEST APPARATUS			
			Reference SOP
Location		Page No.	2 of 3
Manufactured By		Model No.	
Date of calibration		Instrument ID	
Next Calibration Due on		Frequency	

Thermometer ID No.: _____ Valid up to: _____

Stopwatch ID No. : _____ Valid up to: _____

Vernier Calipers ID. No.: _____ Valid up to: _____

S.No.	Parameters		Observation		Tolerance Limits
			Apparatus A	Apparatus B	
1.0	Cycles/Minute	Left			28 – 32 Cycles/Minute
		Right			
2.0	Stroke Length	Left			53 to 57 mm
		Right			
3.0	Timer(30minute)	Timer 1			± 1 Minute
		Timer 2			± 1 Minute
4.0	Temperature				37° to 38°C
	Set Temperature 37.5° C		Thermometer	Displayed on the screen	
		Beaker Left			
		Beaker Right			
Bath					



STANDARD OPERATING PROCEDURE

Department: Quality Control

SOP No.:

Title: Operation and Calibration of Disintegration Test Apparatus

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.0 Aperture Size

BASKET 1				
S.No.	Wire Diameter in mm(W)	Length for Opening in mm (L)	Aperture Opening(a)	Limit
1.				1.8 to 2.2
2.				1.8 to 2.2
3.				1.8 to 2.2
4.				1.8 to 2.2
5.				1.8 to 2.2
6.				1.8 to 2.2

BASKET 2

S.No.	Wire Diameter in mm(W)	Length for Opening in mm (L)	Aperture Opening(a)	Limit
1				1.8 to 2.2
2				1.8 to 2.2
3				1.8 to 2.2
4				1.8 to 2.2
5				1.8 to 2.2
6				1.8 to 2.2

$$a = (L-5W)/6$$

Where L= Length of N opening.

No. opening = 6

W = Wire Diameter.



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Remarks: The Instrument Calibration is **OK / Not OK** as per **IP/BP/USP/Ph. Eur./In-House** requirements.

Calibrated By :

Checked By :

Approved By :

Date:

Date:

Date: