



**STANDARD OPERATING PROCEDURE**

**Department:** Production

**SOP No.:**

**Title:** SOP for Cleaning, Operation and calibration of Disintegration test apparatus (Electrolab)

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

**1.0 OBJECTIVE :**

To lay down the procedure for cleaning, operation and calibration of disintegration test apparatus (Electrolab).

**2.0 SCOPE :**

This procedure is applicable to cleaning, operation and calibration of disintegration test apparatus (ElectrolabED-2L and Electrolab ED- 2AL) used in production department.

**3.0 RESPONSIBILITY :**

Production: Technical Associate/Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance

Head QA: To ensure the compliance

**4.0 PROCEDURE:**

**4.1 Cleaning:**

**4.1.1 Cleaning of basket and disc:**

4.1.1.1 Clean the basket of the disintegration apparatus with 5-10 liters of purified water.

4.1.1.2 Dry the body with a Dry lint free cloth.

4.1.1.3 Clean the basket and discs after every disintegration test.

**4.1.2 Cleaning of water bath:**

4.1.2.1 Clean the water bath with 5-10 liters of purified water.

4.1.2.2 Dry the body with a Dry lint free duster.

4.1.2.3 Clean the water bath after every week and whenever necessary.

**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.



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### 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.

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 temperature 37<sup>0</sup>C with pressing ▲ (up) or ▼ (down) keys. After the desired setting, press "DISP SEL" key to change the position of blinking digit. After complete setting press "ENTER" key to store the temperature setting 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 up to the ¾<sup>th</sup> 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 the temperature 37<sup>0</sup>C + 2<sup>0</sup>C, 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.



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

4.3 Use Apparatus A for tablets and capsules that are not greater than 18 mm long. For larger (more than 18 mm) 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 temperature 37°C with pressing ▲ (up) or ▼ (down) keys. After the desired setting, press "SET" 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 "SET" key to change the position of the blinking digit. After complete settings press, "ENTER" key to store the time set in instrument's memory.

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

4.4.4.4 Take two 1000 ml beakers and fill them with purified water/specified media upto the ¾<sup>th</sup> level. Place them in the instrument.

4.4.4.5 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.



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- 4.4.4.6 After attaining the temperature  $37^{\circ}\text{C} + 2^{\circ}\text{C}$ , place the tablets in the basket (use discs, if required), fix them on the clamps and start the test by pressing “START/ STOP” key followed by “TIMER 1 or TIMER 2 key” . The instrument will automatically stop after completing the set time.
- 4.4.4.7 To halt the test, press “TIMER 1 or TIMER 2 ” key. The green LED of “TIMER 1 or TIMER 2” key start flashing and the time stop increasing. To continue the test press “TIMER 1 or TIMER 2 ” key once more.
- 4.4.4.8 To stop the test whenever required press “START/STOP” key followed by TIMER 1 or TIMER 2 key, the test will stop.
- 4.4.4.9 Clean the baskets, discs and beakers for next use.
- 4.4.4.10 Put “OFF” the instrument from the rear panel and switch “OFF” the mains.

**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 traveled by the mechanical device in the following manner.
- 4.5.4 Take out the cells.
- 4.5.5 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.
- 4.5.6 Start the instrument then 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.
- 4.5.7 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.
- 4.5.8 Measuring the stroke length i.e. between the markings by using calibrated vernier caliper.



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- 4.5.9 The observed distance should be 53 to 57 mm.
- 4.5.10 Record the distance measured in the format as per Annexure - I.
- 4.5.11 Set the required temperature, start the heater of machine and keep the instrument to maintain a stable temperature.
- 4.5.12 Check the temperature of water bath and beaker with a calibrated thermometer and note it down in Annexure - I.
- 4.5.13 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.
- 4.5.14 Verify the Size of Sieve with the help of illuminated Magnifier Scale.
- 4.5.15 Place the illuminated Magnifier Scale above the Sieve for verification.
- 4.5.16 Press the Switch "ON" for glowing of Light of illuminated scale magnifier.
- 4.5.17 Check the distance between adjacent parallel wires by measuring in warp or weft directions.
- 4.5.18 Take readings from all mesh of glass cylinder and record in annexure I.
- 4.5.19 Visually check integrity of sieve attached to the baskets against light source and record the same in Annexure- I.
- 4.5.20 Record Sieve integrity of left and right side basket with "OK" (If all sieve passes test) or "Not OK".
- 4.5.21 In case of any discrepancies observed, inform the Head of the department and the engineering department for the corrective action.
- 4.5.22 Affix calibration status label duly filled and signed on the equipment after completion of calibration.
- 4.5.23 If the instrument is out of calibration, put an "OUT OF CALIBRATION" tag, and proceed as per SOP.
- 4.6 Frequency:**  
Quarterly + 7 days  
If any breakdown, after rectification calibration is to be done.
- 4.7 Precaution:**



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- 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 (Electrolab)

### 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  $20.7 \pm 0.15$  mm and five holes).

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

IP : Indian Pharmacopoeia

BP : British Pharmacopoeia

USP : United States Pharmacopoeia

Ph. Eur.: European Pharmacopoeia

### REVISION CARD

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