



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning, Operation and Calibration of Disintegration Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Cleaning, Operation and Calibration of Disintegration Test Apparatus.

2.0 SCOPE:

This procedure is applicable to Cleaning, Operation and Calibration of Disintegration Test Apparatus used in Production Department.

3.0 RESPONSIBILITY:

Officer, Executive Production : Operation and Calibration
Head Production : SOP Compliance
IPQA : Operation and Calibration

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Cleaning:

5.1.1 Cleaning of basket and disc:

5.1.2 Clean the basket of the disintegration apparatus with 5-10 liters purified water use soft nylon brush if required.

5.1.3 Clean the body with a wet lint free duster.

5.1.4 Clean the basket and discs after every disintegration test.

5.1.5 **Frequency:** After every test or weekly which ever is earlier.

5.1.6 Cleaning of water bath:

5.1.6.1 Clean the water bath with 5-10 liters of purified water use soft nylon brush if required.

5.1.6.2 Clean the body with a wet lint free duster if not in use.

5.1.6.3 **Frequency:** Weekly

5.2 Operation:

5.2.1 Ensure the cleanliness of the instrument.

5.2.2 Switch 'ON' mains Switch.

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

5.2.4 **Set the conditions: (Be sure that water is filled upto the mark in the water bath).**

5.2.5 Setting the temperature:

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



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- 5.2.5.2 Press 'TEMP' key, the right digit of the previously set temperature on the temperature screen starts blinking.
- 5.2.5.3 Set the required temperature with pressing Up/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.
- 5.2.6 **Setting the timer:**
- 5.2.6.1 Press "SET" key the yellow LED on the right side starts glowing.
- 5.2.6.2 Press "TIMER" key, the right digit of the previously set time starts blinking.
- 5.2.6.3 Enter the required time in minutes with pressing up / 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.
- 5.2.6.4 Press the "TEMP" key to start the heating of water in water bath. The red "LED" starts glowing.
- 5.2.6.5 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.
- 5.2.6.6 Take the temperature of the water bath / beaker solution by keeping the external probe in that and press "PROBE SEL" key. The LED of "EXT." position starts glowing and the temperature of that area will be displayed.
- 5.2.6.7 After attaining the set temperature, place the tablets/capsules 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.
- 5.2.6.8 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.
- 5.2.6.9 To stop the test whenever required press "START/STOP" key, the test will stop.
- 5.2.6.10 Clean the baskets, discs and beakers for next use.
- 5.2.6.11 Put "OFF" the instrument from the rear panel and switch "OFF" the mains.
- 5.3 **Calibration:**
- 5.3.1 Operate the Instrument as per the step no. 5.2.
- 5.3.2 Start the machine and count the number of cycles per minute and record the same in Annexure- I.



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- 5.3.3 Check the distance traveled by the mechanical device holding the basket and the discs by using vernier calipers/ calibrated scale and record the same in Annexure- I. Ensure that the mechanical device holding the basket and discs should be moving smoothly through a distance of 50 to 60 mm at a constant frequency.
- 5.3.4 Note the number of cycles per minute by using a calibrated stop watch and record the same in Annexure-I.
- 5.3.5 Set the required temperature, start the heater of machine and keep the instrument to maintain a stable temperature.
- 5.3.6 Check the temperature of water bath with a calibrated thermometer and note it down in Annexure-I.
- 5.3.7 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.
- 5.3.8 Check integrity of sieve attached to the baskets visually and record the same in Annexure-I.
- 5.3.9 Affix calibration status label duly filled and signed on the equipment after completion of calibration.
- 5.3.10 In case of any discrepancies observed, inform the Head of the department and the engineering department for the corrective action. Put an 'UNDER MAINTENANCE' tag on the machine.
- 5.3.11 Recalibrate the machine after the rectification of the machine and enter the same in Annexure-I.
- 5.3.12 **Frequency:** Once in a month and after every maintenance.

5.4 Precaution

- 5.4.1 Do not start the temperature controller till the water in the bath is filled upto the marked level without beakers.
- 5.4.2 Do not try to remove the baskets till they are removed from the hook.
- 5.4.3 Do not clean the bath with any strong solvent. Use purified water for cleaning.
- 5.4.4 Handle the external probe carefully to avoid any damage.

6.0 ABBREVIATION(S):

QA : Quality Assurance
SOP : Standard Operating Procedure
mm : Milliliters

7.0 REFERENCE(S):

NA



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8.0 ANNEXURE(S):

ANNEXURE – I : Calibration Record of Disintegration Test Apparatus

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled Copy (s)** : Production Department, Quality Assurance

9.3 **Reference Copy (s)** : Production Department



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ANNEXURE I CALIBRATION OF DISINTEGRATION TEST APPARATUS INSTRUMENT: DISINTEGRATION TEST APPRATUS

Department		Make & Model	
Instrument ID.		Calibration Done On	
Calibration frequency	One in month	Calibration Due On	

Instruments	ID No.	Calibrated On	Calibration Due On
Calibrated thermometer			
Stop watch			
Vernier calipers/ss scale			

Parameters	Parameters set	Parameters observed		Tolerance limits
		Left	Right	
Cycles/Minute	----			29 – 32 Cycles/ Minute (Ref.– BP)
Distance traveled during raising & lowering of basket	-----			55 ± 2 mm
Temperature with Thermometer	Bath	37.0°c		35 to 39°C (Ref. – BP)
	Beaker			
Temperature displayed on the screen	Bath	37.0°c		
	Beaker			
Timer	30 minutes			29 to 31 minutes
Sieve Integrity	----			Should be intact

Remarks: The Instrument is Calibrated/Out of Calibration for use.

Done By:
Date:

Checked By:
Date: