PHARMA DEVILS



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDUREDepartment: ProductionSOP No.:Title: Cleaning and Operation of Tablet Hardness TesterEffective Date:Supersedes: NilReview Date:Issue Date:Page No.:

1.0 OBJECTIVE:

To lay down the procedure for the Cleaning and Operation of Tablet Hardness Tester.

2.0 SCOPE:

This SOP is applicable to the Cleaning and Operation of Tablet Hardness Testers in Production department.

3.0 RESPONSIBILITY:

Operator, Officer and Executive – Production Department Manager – Production Department QA Officer – In process

4.0 **DEFINITION(S):**

NA

5.0 **PROCEDURE**:

5.1 Cleaning:

5.1.1 Clean the hardness tester by wiping with a clean dry lint free cloth followed by wiping with a lint free clean cloth dipped in 70 % IPA. Dry the surface by wiping with clean dry lint free cloth.

5.2 Operation:

- 5.2.1 Check and ensure the hardness tester is clean.
- 5.2.2 Turn the screw knob in anticlockwise direction such that tablet can be hold perpendicular in between the jaws.
- 5.2.3 Hold the tablet between the fixed and moving jaw in edgewise position. Tablet shall be in approximately perpendicular position.
- 5.2.4 Align the pointer and zero Kg/cm^2 on scale.
- 5.2.5 Turn the screw knob in clockwise direction slowly until the tablet breaks.
- 5.2.6 Note down the reading on the scale corresponding to the pointer.
- 5.2.7 Record the result of hardness in the Kg/cm².
- 5.2.8 Release the screw knob in anti clockwise direction.
- 5.2.9 Ensure that holding jaw is free of tablet powder before placing next tablet for testing.

Note: Calibration of the equipment will be done by outside party yearly or whenever is required.

6.0 ABBREVIATION(S):

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IPA : Iso Propyl Alcohol

Kg/cm² : Kilograms Per Centimeter Square

7.0 **REFERENCE(S)**:

NA

8.0 ANNEXURE(S):

Nil

9.0 **DISTRIBUTION:**

Master Copy : Quality Assurance

Controlled Copy (S): Production department, Quality Assurance

Reference Copy (S) : Production department