



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation, Cleaning and Calibration of Bursting Strength Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation, Cleaning and Calibration of Bursting strength Apparatus.

2.0 SCOPE:

This Procedure is applicable to Bursting Strength Apparatus (Make: Ubique ; Model – COMBI BS) installed in Packaging Material Section of Quality Control Laboratory.

3.0 RESPONSIBILITY – Execution - Executive QC.
Checking - Assistant Manager QC.

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 CLEANING & OPERATING PROCEDURE:

Cleaning Frequency: Daily: Before and after every use

5.1.1 Clean the instrument with a clean cotton cloth.

5.1.2 Switch 'ON' the mains.

5.1.3 Switch 'ON' the instrument.

5.1.4 Cut a piece of the sample of specified size (10 X 10 cm) using the standard templates.

5.1.5 Raise the upper clamping plate by pulling the blue knob of pneumatic pressure clamping system.

5.1.6 Place the sample piece on the lower clamping plate ensuring tight fitting of the sample between the clamping plates by pushing the blue knob.

5.1.7 Adjust the specified pressure from meter gauge as per requirement.

5.1.8 Press the START button to raise the rubber diaphragm for bursting the sample piece.

5.1.9 Press REVERSE button to release the pressure and wait for a few seconds till the rubber diaphragm regains its original position.

5.1.10 Pull the blue knob to raise upper clamping plate & remove the sample piece.

5.1.11 Note down the Peak Value for bursting strength from digital display screen of the instrument.

5.1.12 On completion switch "OFF" the instrument.

5.1.13 Switch 'OFF' the mains.

5.1.14 Record the details of operation in the 'Instrument Log Book'.

5.2 CALIBRATION PROCEDURE:



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Frequency: Once in 3 months

- 5.2.1 Clean the instrument with a clean cotton cloth.
- 5.2.2 Switch 'ON' the mains.
- 5.2.3 Switch 'ON' the instrument.
- 5.2.4 Raise the upper clamping plate by pulling the blue knob of pneumatic pressure clamping system.
- 5.2.5 Place the standard aluminium foil piece on the lower clamping plate ensuring tight fitting of the sample between the clamping plates by pushing the blue knob.
- 5.2.6 Adjust the specified pressure from meter gauge as per requirement.
- 5.2.7 Press the START button to raise the rubber diaphragm for bursting the sample piece.
- 5.2.8 Press REVERSE button to release the pressure and wait for a few seconds till the rubber diaphragm regains its original position.
- 5.2.9 Pull the blue knob to raise upper clamping plate & remove the sample piece.
- 5.2.10 Note down the Peak Value for bursting strength from digital display screen of the instrument.
Record the observations in Annexure-I.
- 5.2.11 The instrument is calibrated, when the reading meets with bursting strength value of the standard aluminium foil
- 5.2.12 On completion switch "OFF" the instrument.
- 5.2.13 Switch 'OFF' the mains.

6.0 SAFETY & PRECAUTIONS:
Not Applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date



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8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

Dept. : Department

cm : Centimetre

Annexure I : Calibration Check Report of Bursting Strength Tester



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ANNEXURE I

CALIBRATION CHECK REPORT OF BURSTING STRENGTH TESTER

	REF. No.: _____ ISSUE DATE: _____ ISSUED BY : _____	Page 1 of 2
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INSTRUMENT DETAILS

INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT IDENTIFICATION No.

CALIBRATION DETAILS

INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT IDENTIFICATION No.



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OBSERVATION

Certificate No. of Std. Foil used : (1) (2)

S.No.	Specified value Range of Std. Foil	Observed value
1.		
2.		

Acceptance Criteria: Observed value should be with in the specified range of standard foil value.

CONCLUSION	
INSTRUMENT WORKING SATISFACTORY	INSTRUMENT NOT WORKING SATISFACTORY

PERFORMED BY			CHECKED BY		
NAME	SIGN	DATE	NAME	SIGN	DATE