



STANDARD OPERATING PROCEDURE

| | |
|--|------------------------|
| Department: Quality Control | SOP No.: |
| Title: Operation and calibration of Refractometer | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for Operation & Calibration of Refractometer.

2.0 SCOPE:

The Scope of this SOP covers the Operation and Calibration of Refractometer as per the current pharmacopoeias (IP/BP/USP) and In-House requirements in Quality Control department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department.

Head – Quality Control.

4.0 PROCEDURE:

4.1 Operation:

4.1.1 Ensure that the instrument is clean and free from dust.

4.1.2 Switch ON the mains.

4.1.3 Open the prism box for measurement of refractive index of the sample.

4.1.4 Equilibrate the sample temperature as per requirement.

4.1.5 Place 2-3 drops of sample on the ground surface of lower prism.

4.1.6 Close and fit the prism box.

4.1.7 Focus the cross wires of eyepiece by adjusting screw.

4.1.8 Adjust the mirror till good illumination is obtained.

4.1.9 Gently turn the prism box by means of milled head screw clockwise or anticlockwise till a coloured band appears in the field of view.

4.1.10 Turn the milled ring at the base of telescope clockwise or anticlockwise where coloured band is illuminated and a sharp dividing line is seen. Which divides a field of view in half illuminated and a half dark position.

4.1.11 By means of milled head screw, adjust the dividing line exactly at the intersection of the cross wire.

4.1.12 Read the refractive index on the divided arc by means of magnifier to the third decimal point and



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fourth decimal on the milled ring at the base of telescope.

- 4.1.13 Note down the reading, which is the refractive index of the sample.
- 4.1.14 Open the prism box Wipe off the sample with moistened tissue paper 2-3 times and dry the prism with dry tissue paper. Close the prism box and keep instrument in its cabinet securely.
- 4.1.15 Record the details in the instrument log book.

4.2 Calibration:

- 4.2.1 Operate the instrument as mentioned in the operation procedure.
- 4.2.2 Check the instrument by determining the Refractive Index of purified water at 25°C.
- 4.2.3 If the observed refractive index of purified water is below or above 1.3325, adjust the small square screw and at the back of telescope with the key provided with instrument. Bring the reading setting to 1.3325 and adjust the diving line exactly at the intersection of the cross wire by turning the key clockwise or anticlockwise, remove the key
- 4.2.4 The instrument shall be further checked by determining the refractive index of the reference liquids. (Toluene) & record in Annexure – I.
- 4.2.5 Refractive index of the reference liquids at respective temperature are as follows:
Toluene at 25°C 1.494
- 4.2.6 Calibration Frequency - Quarterly
- 4.2.7 Fill the calibration status on metallic calibration label of the instrument, record the calibration results in Annexure-I.
- 4.2.8 If the instrument is out of calibration, put an “OUT OF CALIBRATION” tag, and proceed as per SOP.

4.3 Precaution:

- 4.3.1 Handle the delicate optics of the machine, namely prism and mirror very carefully.
- 4.3.2 Clean and wipe and dry prism box after each reading.
- 4.3.3 Use water jacket provided for control of temperature, whenever required.

5.0 ANNEXURE (S) :

Annexure–I: Calibration Record of Refractometer.



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6.0 REFERENCE (S):

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

7.0 ABBREVIATION (S)/DEFINITION (S):

USP – United State Pharmacopoeia

BP - British Pharmacopoeia

Ph. Eur. – European Pharmacopoeia

IP - Indian Pharmacopoeia

REVISION CARD

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



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Instrument set at _____ (1.3325 at 25°C with purified water)

| S. No. | Reference liquid | Batch No. | Refractive index of reference liquid at 25°C | Temp. Coeff. | Refractive Index at 25°C | Observed refractive index | Limits |
|--------|------------------|-----------|--|--------------|--------------------------|---------------------------|----------------|
| 1. | Toluene | | 1.4969 | -0.00056 | 1.494 | | 1.492 to 1.496 |

Remarks: The instrument calibration is OK / Not OK.

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

Calibrated By:

Checked By :

Approved By :

Date :

Date :

Date :



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ANNEXURE I

| CALIBRATION RECORD OF REFRACTOMETER | | | |
|--|--|-------------------------|---------------|
| | | | Reference SOP |
| Location | | Page No. | 2 of 1 |
| Manufactured By | | Model No. | |
| Frequency | | Identification No. | |
| Date of Calibration | | Next Calibration Due on | |

Instrument set at _____ (1.3325 at 25°C with purified water)

| S. No. | Reference liquid | Batch No. | Refractive index of reference liquid at 25°C | Temp. Coeff. | Refractive Index at 25°C | Observed refractive index | Limits |
|--------|------------------|-----------|--|--------------|--------------------------|---------------------------|----------------|
| 1 | Toluene | | 1.4969 | -0.00056 | 1.494 | | 1.492 to 1.496 |

Remarks: The instrument calibration is OK / Not OK.

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

| | | |
|-----------------------|---------------------|----------------------|
| Calibrated By: | Checked By : | Approved By : |
| Date : | Date : | Date : |