



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### STANDARD OPERATING PROCEDURE

**Department:** Quality Control

**SOP No.:**

**Title:** Operation, cleaning and calibration of Refractometer

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

#### 1.0 OBJECTIVE:

To lay down a procedure for Operation, cleaning and calibration of Refractometer.

#### 2.0 SCOPE:

This SOP is applicable for Refractometer (MAKE: Rudolf Research Analytical MODEL: J357 Automatic Refractometer) installed in Quality Control Department.

#### 3.0 RESPONSIBILITY – Execution - Executive QC.

Checking - Assistant Manager QC .

#### 4.0 ACCOUNTABILITY - Manager Quality Control

#### 5.0 PROCEDURE:

##### 5.1 Operation And Calibration Procedure of Refractometer.

5.1.1 Switch on the mains.

5.1.2 Switch on the instrument power. The main display will appear after one flash of the instrument information.

5.1.3 Clean the prism with a clean cotton cloth.

5.1.4 Select 'Set UP' key on the instrument.

5.1.5 Enter the password '123' & press ENTER key.

5.1.6 A menu will be displayed. Select 'Sample' to enter the details of sample to be analysed.

5.1.7 Select the SCALE on the touch screen.

5.1.8 Select REFRACTIVE INDEX.

5.1.9 Select TEMPERATURE.

5.1.10 Select TEMPERATURE CONTROL.

5.1.11 Select the desired temperature. Wait till temperature stabilizes.

5.1.12 Apply a thin layer of the sample on the prism.

5.1.13 Press the MEASURE key on the touch screen. RI value will be displayed on the screen. Take the printout and switch off the instrument.

##### 5.2 CALIBRATION PROCEDURE:

Frequency: Once in three months.

5.2.1 Operate the instrument as per operational procedure.



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- 5.2.2 Press the SET UP key on the instrument.
- 5.2.3 Enter the password '123' & press ENTER key.
- 5.2.4 Select USER CALIBRATION on the touch screen.
- 5.2.5 Select TWO POINT CALIBRATION on touch screen.
- 5.2.6 Then select REFRACTIVE INDEX.
- 5.2.7 Select TEMPERATURE.
- 5.2.8 Place the following calibration standards one by one on the prism:  
i) Water  
ii) Laser solution  
Cross checked by Toulene & Carbon tetrachloride
- 5.2.9 Press DONE and wait till the temperature get stabilizes.
- 5.2.10 Then enter the actual RI of the calibration standard.
- 5.2.11 Remove first calibrating standard and place the second calibrating standard.
- 5.2.12 Press DONE.
- 5.2.13 Enter actual refractive index of second calibrating standard.
- 5.2.14 The display will show whether the calibration is successful or not.
- 5.2.15 Then take the print out and switch off the mains.
- 5.2.16 The performance of the instrument is satisfactory, if the observed values are within the tolerance limit.
- 5.2.17 Maintain the record of calibration as per Annexure -I
- 5.3 Procedure For Cleaning Of Refractometer**  
Frequency: After each Analysis.
- 5.3.1 Clean the instrument after each use.
- 5.3.2 Clean the prism with Xylene and then wipe with tissue paper.
- 5.3.3 Clean the mirror with tissue paper.
- 5.3.4 Clean the instrument with dry and clean cotton cloth.



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5.3.5 Record the details of cleaning in the instrument log card .

#### 6.0 SAFETY & PRECAUTIONS:

6.1 Handle the instrument carefully.

6.2 Clean the instrument after every use.

6.3 Always switch off the main after completion of the analysis.

#### 7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

#### 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

**Annexure-I : Calibration Report of Refractometer**



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#### ANNEXURE-I

#### CALIBRATION REPORT OF REFRACTOMETER

	REF. No. _____ ISSUE DATE: _____ ISSUED BY : _____	Page 1 of 2
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<b>CALIBRATION DATE</b>	<b>LAST CALIBRATION DONE ON</b>	<b>NEXT DUE FOR CALIBRATION</b>

<b>INSTRUMENT DETAILS</b>		
<b>INSTRUMENT NAME</b>	<b>INSTRUMENT MAKE</b>	<b>INSTRUMENT IDENTIFICATION No.</b>

<b>OBSERVATION</b>
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Sr. No.	Liquid	Temperature	Observed Refractive index	Limit
1.	Distilled water	25°C		1.3325 ± 0.001
2.	Laser Liquid	20°C		1.57002 ± 0.001
3.	Carbon tetrachloride (AR grade)	20°C		1.4603 ± 0.002
4.	Toluene (AR grade)	20°C		1.4969 ± 0.002

<b>CONCLUSION</b>	
<b>INSTRUMENT WORKING SATISFACTORY</b>	<b>INSTRUMENT NOT WORKING SATISFACTORY</b>



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PERFORMED BY			CHECKED BY		
NAME	SIGN	DATE	NAME	SIGN	DATE