



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation, Cleaning and Calibration of Polarimeter	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for Operation, cleaning and calibration of Digital Polarimeter (MAKE: Rudolph Research Analytical MODEL: Autopol V) installed in Quality Control Department.

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

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 Operation and Calibration Procedure of Digital Polarimeter

5.1.1 Clean the instrument with clean and dry cotton cloth.

5.1.2 Switch 'ON' the mains.

5.1.3 Wait for few minutes, message will appear.

5.1.4 Using the touch screen select parameter like optical rotation, Specific rotation, concentration as per the requirement.

5.1.5 The cell length can be selected by pressing one soft key, 50 mm, 100 mm, and 200 mm.

5.1.6 By pressing TEMP Control key, allow entry of temperature control set point for the temptrol temperature control system.

5.1.7 Temperature correction- Select temperature correction by pressing TEMP Control key (if required).

5.1.8 To set response time, press the RESPONSE TIME soft key on the main menu.

5.1.9 For statistical calculation of measurements is selected by pressing STATS key.

5.1.10 Press the SAMPLES key to select the desired sample.

5.1.11 Now the instrument is ready for reading.

5.1.12 Clean and rinse the cell and fill the solution in it.

5.1.13 In case of temperature control condition, use temptrol sample cell for taking reading. Fill this cell with sample and insert the built in sample temperature probe in to the temptrol sample cell.

5.1.14 For measurement press START/STOP key on display.



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5.1.15 In case of room temperature, use the glass sample cell and take the reading in similar way but with out using temperature probe.

5.1.16 Press the print key to take out the print.

5.1.17 Switch 'OFF' the POWER.

5.1.18 Switch 'OFF' the mains.

5.2 CALIBRATION PROCEDURE

Frequency: Once in three months.

5.2.1 By using Sucrose solution:

5.2.1.1 Operate the instrument as per operational procedure given above.

5.2.1.2 Prepare 10%, 20%, 30%, 40% and 50% w/v aqueous solution of AR grade sucrose (previously dried) in purified water.

5.2.1.3 Note down the temperature of the solution and determine the optical rotation three times by changing the sucrose solution in tube and record the mean. Take an equal number of readings in the same tube with the solvent in place of the test solution.

5.2.1.4 Record the measured Optical Rotation readings in Annexure-I and calculate the correlation coefficient by plotting the graph between concentration against mean value of Optical Rotation and take the print out.

5.2.2 By using Quartz Control Plate (QCP):

5.2.2.1 Operate the instrument as per operational procedure.

5.2.2.2 Insert the QCP tube in instrument and insert temperature probe well in centre of QCP.

5.2.2.3 Set the temperature and determine the optical rotation five times at different wavelengths (633, 589, 546, 436, 405, & 365 nm) and record the mean.

5.2.2.4 Record the measurement in Annexure-I.

5.3 Procedure for Cleaning of Polarimeter

Frequency: Daily or After each use.

5.3.1 After completion of the testing, remove the Polarimeter tube from the instrument.

5.3.2 Switch "OFF" the instrument.



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- 5.3.3 Switch "OFF" the mains.
- 5.3.4 Remove the solution /sample from the Polarimeter tube.
- 5.3.5 Clean it with respective solvent in which solution of sample is prepared.
- 5.3.6 Clean it thoroughly with distilled water.
- 5.3.7 Wipe it with tissue paper.
- 5.3.8 Wipe the temperature probe with tissue paper.
- 5.3.9 Clean the instrument with clean and dry cotton cloth.

6.0 SAFETY & PRECAUTIONS:

Not Applicable.

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



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10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

Conc. : Concentration

α : Optical rotation

% : Percentage

w/v : weight by volume

$^{\circ}\text{C}$: Degree centigrade

Annexure-I : Calibration Record Of Polarimeter



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ANNEXURE-I

CALIBRATION RECORD OF POLARIMETER

CALIBRATION DATE	LAST CALIBRATION DONE ON	NEXT DUE FOR CALIBRATION

INSTRUMENT DETAILS

INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT IDENTIFICATION No.

OBSERVATION

1) **By using Sucrose solution:**

Sr. No.	Concentration (g/100ml)	Observed Optical rotation		Angle of rotation at 25°C (1-dm tube) & Acceptance Criteria
		Individual reading	Mean	
1.	10			6.665° (6.63° to 6.70°)
2.	20			13.305° (13.24° to 13.37°)
3.	30			19.930° (19.83° to 20.03°)
4.	40			26.530° (26.395° to 26.665°)
5.	50			33.115° (32.95° to 33.28°)

Correlation Coefficient (r): _____

Acceptance Criteria: NLT: 0.999



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2) By using quartz Control Plate (QCP):

S.No.	Wavelength(nm)	Mean Reading	Acceptance Criteria Rotation (deg.)
1.	633		$9.882 \pm 0.002^\circ$
2.	589		$11.486 \pm 0.002^\circ$
3.	546		$13.501 \pm 0.002^\circ$
4.	436		$21.961 \pm 0.2 \%$
5.	405		$25.746 \pm 0.2 \%$
6.	365		$32.646 \pm 0.2 \%$

CONCLUSION

INSTRUMENT WORKING SATISFACTORY	INSTRUMENT NOT WORKING SATISFACTORY
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PERFORMED BY			CHECKED BY		
NAME	SIGN	DATE	NAME	SIGN	DATE