



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Auto Titrator	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for operation & calibration of Auto Titrator.

2.0 SCOPE:

This SOP is applicable for Auto Titrator in the QC department.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control.

Head-Quality Control.

4.0 PROCEDURE :

4.1 Operation:

4.1.1 For Aqueous, Non aqueous titration :

4.1.1.1 Ensure that instrument is cleaned and free from dust.

4.1.1.2 Switch on the instrument.

4.1.1.3 Attached interchangeable Burette Assembly perform the steps mentioned in user Guide for Burette Attachment.

4.1.1.4 Select appropriate stirrer (magnetic stirrer or rod stirrer)

4.1.1.5 Connect the appropriate Electrode.

4.1.1.6 Selection of the electrode depends upon the method of analysis and the type of Titration so the appropriate selection of the electrode can be done by referring Indian Pharmacopeia or British Pharmacopeia.

4.1.1.5 Fill the Burette by going into Rinsing Mode present in Auxiliary Function .While in Rinsing mode, The Reservoir tube should be dipped into reservoir bottle filled with the appropriate solution required for the titration and the dosing capillary should be kept into the waste beaker.

4.1.2 Method Development :

4.1.2.1 Select appropriate mode and method .Press Mode key to switch from one method to other and then press enter Key to select The Required Mode.



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4.1.2.2 Press Method Key to switch from one method to other and then press Parameter Key followed by the Enter Key to select appropriate Parameters.

4.1.2.3 You can also select the desired method stored in the memory by pressing User Method Key and recalling that method by entering the Method Number.

4.1.3 Sample Analysis :

4.1.3.1 Before starting the analysis ensuring followings:

4.1.3.2 The instrument is clean, free from dust and calibrated.

4.1.3.3 All tubing is connected properly.

4.1.3.4 Required sensor/electrode is attached in proper condition.

4.1.3.5 Required volumetric solution/reagent filled in bottle.

4.1.3.6 Weight the sample in the Titration Flask. Dissolve it in the appropriate medium and attach it to the Titration Vessel Stand, and Start the stirrer .Ensure that the electrode and dosing tip is deep in the titration beaker.

4.1.3.7 Enter the data required for result calculation.

4.1.3.8 Start the titration by pressing Method Key followed by the GO key

4.1.3.9 Take the Report on the connected output device

4.1.3.10 Reprocess the Report if required types of Report by Pressing Report and then pressing The Enter Key.

4.1.3.11 Record the use of instrument in instrument log book.

4.2 Calibration:

4.2.1 Standardization with 4.01 , 6.86 , & 9.18 pH (For Glass Electrode)

4.2.1.1 Clean the electrode (Sensor) with purified water and start the system as operating procedure.

4.2.1.2 Open the Method for calibration of pH Electrode in New titrator method folder and prepare a sample series, serially enter pH in series data, save it and close.

4.2.1.3 Place buffer solution in stand. Run the sample in sample folder and give confirmation. After completion of time result will be displayed. Remove previous buffer solution and place the second buffer solution in the stand and give confirmation for analysis.

4.2.1.4 Follow the above same procedure for second and third buffer.



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4.2.1.5 After completion of all samples take print out of all results.

4.2.1.6 Slope of pH should not deviate from – 0.80 to 1.02

4.2.1.7 Tolerance (± 0.05)

4.2.1.8 Frequency: Quarterly

5.0 ANNEXURE (S):

Annexure – I: Calibration Record of Auto Titrator.

6.0 REFERENCE (S):

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

7.0 ABBREVIATION (S)/ DEFINITION (S):

SOP: Standard operating Procedure

REVISION CARD

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



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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ANNEXURE I
CALIBRATION RECORD OF AUTO TITRATOR

CALIBRATION RECORD OF AUTO TITRATOR.

Reference SOP No.

Location		Page No.	4 of 1
Manufactured By		Model No.	
Frequency		Identification No.	
Date of Calibration		Next Due Date of Calibration	

pH Buffer	B. No. of Buffer solution	Observed pH	Slope	Limit	Remark
4.01				0.80 to 1.02	
6.86					
9.18					

Tolerance (pH): ± 0.05

Remarks: The Instrument Calibration is Ok / Not Ok.

Calibrated By:	Checked By :	Approved By :
Date	Date	Date