



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation, Cleaning 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, cleaning and calibration of Auto-titrator

2.0 SCOPE:

This SOP is applicable for Auto-titrator Apparatus, (MAKE : Metrohm Model: 702 SM Titrino) installed in Quality Control Department 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 Switch on the Titrino using **On/Off** switch at front panel of Titrino..

5.1.5 Select appropriate Exchange Unit and fit it on the top of the instrument

5.1.6 Exchange Unit is activated by the movement of cock changeover switch., which is present on front side of the exchange unit.

5.1.7 Connect the suitable electrode at the rear panel of the instrument using appropriate electrode cable. Also Verify it through s/w of Titrino.

5.1.8 Recalling a method:

Press <**user method**> keys repeatedly, till the option Recall Method comes on screen, press <**enter**>. Select the required method using <**select**> key on keyboard and then press <**enter**>.

5.1.9 The method name is displayed on the extreme right side of the first line of the screen.

5.1.10 Take the sample along with suitable solvent and place it on the stirrer.

5.1.11 Switch on the stirrer.

5.1.12 Clean the electrode with water and then rinse it with the solvent solution

5.1.13 Dip the electrode assembly along with dispensing tube of Exchange unit in the sample vessel just above the stirring bar.

5.1.14 Press <**start**> key either on front panel of instrument or on keyboard.



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5.1.15 After completion of the analysis, result will be shown on display.

5.1.16 For print out press <print> <Select> < Full Enter>

5.2 For Measurement:

5.2.1 Select the **MEAS** mode by pressing <mode> key repeatedly, until **MEAS** is displayed on second line of the screen and then press <enter> to confirm the selection.

5.2.2 Select the measuring quantity i.e. pH or milli volt by means of <select> key on keyboard, and then press <enter> to confirm the selection.

5.2.3 Connect the suitable electrode in appropriate input at the rear panel of Titrimo.

5.2.4 Press <start> key either on front panel of instrument or on keyboard.

5.2.5 Measured quantity will be displayed on the screen

5.3 CALIBRATION PROCEDURE

Frequency: Once in 3 months.

5.3.1 Operate the instrument as per operational procedure described above.

5.3.2 Take Potassium Hydrogen Phthalate previously dried at 105⁰C for 2hrs as the primary standard for titration.

5.3.3 Set the instrument parameter in MET mode.

5.3.4 Take 5 different accurate weights of primary standard varying from 0.1 to 0.3g.

5.3.5 Perform titration using standard 0.1M Perchloric acid & repeat the same procedure with 0.1M Sodium Hydroxide.

5.3.6 Refill the burette after each titration.

5.3.7 Report the results as per Annexure-I.

5.3.8 Calculate the linearity and correlation coefficient.

5.3.9 Linearity should not be less than 99.0%

5.3.10 Correlation coefficient should not be less than 0.990.

5.3.11 The performance of the instrument is satisfactory, if the obtained Linearity and Correlation



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9.0 REFERENCES:

SOP for “Action level procedure for out of calibration instruments”.

10.0 ABBREVIATIONS & ANNEXURES

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

% : Percentage

°C : Degree centigrade

g : Gram

ml : Millilitre

M : Molar

Annexure I: Calibration Of Autotitrator

Annexure II: Cleaning record for Autotitrator



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ANNEXURE-I CALIBRATION OF AUTOTITRATOR

	REF. No. : _____ ISSUED BY : _____ ISSUE DATE: _____	Page 1 of 3
CALIBRATION DATE	DATE OF LAST CALIBRATION	NEXT DUE FOR CALIBRATION

INSTRUMENT DETAILS		
INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT ID No.

OBSERVATION

Titrator Calibration:

Balance Id No. : _____

Ref. No. of Potassium Hydrogen Phthalate : _____

Actual Normality of 0.1M Perchloric acid : _____

Actual Normality of 0.1M NaOH : _____

S.No.	For 0.1M Perchloric acid		For 0.1M Sodium Hydroxide	
	Wt. of Potassium Hydrogen Phthalate (mg)	Burette reading at Ep1 (ml)	Wt. of Potassium Hydrogen Phthalate (mg)	Burette reading at Ep1 (ml)
1.				
2.				
3.				
4.				
5.				
Linearity :				



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Acceptance Criteria: **Linearity : NLT 99.0%** (Correlation coefficient: NLT 0.990)

Performed By:

Checked By:

REF. No. : _____	
ISSUED BY : _____	
ISSUE DATE: _____	

CONCLUSION

INSTRUMENT WORKING SATISFACTORY

INSTRUMENT NOT WORKING SATISFACTORY

PERFORMED BY			CHECKED BY		
NAME	SIGN.	DATE	NAME	SIGN.	DATE

