



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

Title: Disodium Editate 0.1 M

SOP No.:		Department :	QC
Effective Date :		Review Date :	
Revision No.:	00	Page No.:	1 of 3
Supersede SOP No.:	Nil		

1.0 OBJECTIVE:

1.1 To lay down a procedure for the preparation and standardisation of 0.1 M Disodium Editate.

2.0 SCOPE:

2.1 It is applicable for the estimation of Raw material, bulk product, intermediate product and finish products.

3.0 RESPONSIBILITY:

3.1 Analyst / Officer / Executive follow the procedure.

3.2 Head-QC are responsible for effective implementation of this SOP.

4.0 REFERENCE:

4.1 BP

5.0 DEFINITION:

5.1 Molarity is the number of mole of substance that are present in the given Volume of the solution.

6.0 PROCEDURE:

6.1 Material and Equipment:

6.1.1 Volumetric flask 1000 ml, Sodium editate, Sodium hydroxide, Zinc, conical flask, record book etc.

6.2 Preparation:

6.2.1 Dissolve 37.5 g of Sodium editate in 500 ml water add 100 ml 1 M sodium hydroxide and dilute to 1000.0 mL with water.

6.3 Standardisation:

1.1.1 Dissolve 0.120 g of zinc in 4 mL of hydrochloric acid. Add dilute sodium hydroxide solution until the solution is weakly acid and carry out the assay of zinc by complexometry (2.5.11).



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Introduce the prescribed solution into a 500mL conical flask and dilute to 200mL with water. Add about 50 mg of xylene orange triturate and hexamethylenetetramine until the solution become violet-pink. Add 2.g of hexamethylenetetramine in excess. Titrate with 0.1M sodium edetate until the violet-pink colour changes to yellow. 1 ml of 0.1M sodium edetate is equivalent to 0.06538 mg of Zn.

Calculation:

$$\text{Molarity (M)} = \frac{\text{Weight of primary std in gm} \times 0.1 \text{ M} \times 20}{\text{Consume vol.} \times 0.6538 \text{ gm} \times 200}$$

7.0 Annexures:

1.1 Annexure-I: Molarity Calculation format of Volumetric Solution 0.1 M Sodium Editate.

8.0 Distribution:

1.2 Display copy 1 : Instrument Lab

9.0 Abbreviation:

GTP : General Test Procedure
QC : Quality Control laboratories

10.0 Revision History:

Revision history table:

Document Number	C C Number/Date	Brief Description of Change



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ANNEXURE-I

Molarity Calculation format of Volumetric Solution 0.1 M Sodium Editate

S. No.	Date	Qty. Prep.	Batch no.	Primary Std. ID. No.	Primary Std. Weight	Calculation	RSD NMT 0.2%	Mean Molarity	Date of Standardization.
1.									
2.									
3.									

Prepared By (Sign/Date):

Checked By (Sign/Date):