



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### GENERAL TESTING PROCEDURE

**Title:** Sodium Editeate 0.1 M

<b>SOP No.:</b>		<b>Department:</b>	QC
<b>Effective Date:</b>		<b>Review Date:</b>	
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<b>Supersede SOP No.:</b>	Nil		

#### 1.0 OBJECTIVE:

1.1 To lay down a procedure for the preparation and standardisation of 0.1 M Sodium Editeate.

#### 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, Silver Nitrate, Sodium chloride, conical flask, record book etc.

##### 6.2 Preparation:

6.2.1 Dissolve 37.5 g of sodium edetate in 500 mL of water, add 100 ml of I M sodium hydroxide and dilute to 1000.0 mL with water. (Storage in a Polyethylene Container).

##### 6.3 Standardisation:

6.3.1 Dissolve 0.120 g of zinc RV 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. Introduce the prescribed solution into a 500 mL conical flask and



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dilute to 200mL with water. Add about 50 mg of Xylenol orange triturate and hexamethylenetetramine until the solution becomes violet-pink. Add 2.g of hexamethylenetetramine in excess. Titrate with 0.1 M sodium edetate until the violet-pink colour changes to yellow.

1 mL of 0.1 M sodium edetate is equivalent to 0.00654 mg of Zn.

#### Calculation:

$$\text{Molarity (M)} = \frac{\text{Weight of primary std in gm} \times 0.1 \text{ M} \times \text{Potency of Primary std.}}{\text{Consume vol.} \times 0.00654 \text{ gm} \times 100}$$

#### 7.0 Annexures:

Annexure-I: Molarity Calculation format of Volumetric Solution 0.1 M sodium editate.

#### 8.0 Distribution:

Display copy 1 : Instrument Lab

#### 9.0 Abbreviation:

GTP : General Test Procedure  
QC : Quality Control laboratories

#### 10.0 Revision History:

##### 10.1 Revision history table:

Document Number	CC Number/Date	Brief Description of Change
		NEW SOP



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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):