

PHARMA DEVILS QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

| Title: Hydrochloride A | .cid 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 Hydrochloric acid.

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, Hydrochloric acid, Trometamol, Methyl orange conical flask, record book etc.

6.2 Preparation:

6.2.1 Dilute 100.0 mL of 1 M hydrochloric acid to 1000.0 mL with carbon dioxide-free water.

6.3 Standardisation:

1.1.1 Dissolve 0.095 g of trometamol RV in 50 mL of water. Titrate with the hydrochloric acid solution, determining the end-point potentiometrically or using 0.1 mL of methyl orange solution as indicator until a yellowish-red colour is obtained.

1 mL of 0.1 M Hydrochloric acid is equivalent to 0.01211 g of C4H11N03.



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Calculation:

Weight of primary std in gm X 0.1 M X Potency of Primary std.

Molarity (M) = -----

Consume vol. X 0.01211gm X 100

7.0 Annexures:

1.1 Annexure-I: Molarity Calculation format of Volumetric Solution 0.1 M Hydrochloric acid.

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:

1.3 Revision history table:

| Document Number | CC Number/Date | Brief Description of Change | | |
|-----------------|----------------|-----------------------------|--|--|
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ANNEXURE-I

Molarity Calculation format of Volumetric Solution 0.1 M Hydrochloric acid

| 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):