



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### GENERAL TESTING PROCEDURE

**Title:** Benzethonium Chloride 0.004 M

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

#### 1.0 OBJECTIVE:

- 1.1 To lay down a procedure for the preparation and standardisation of 0.004 M Benzethonium Chloride.

#### 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, Benzethonium Chloride, Anhydrous Acetic acid, Acetic Anhydride, Crystal violet solution, conical flask, record book etc.

##### 6.2 Preparation:

- 6.2.1 Dissolved 12.7 g of Iodine and 20 g of Potassium Iodide in water and dilute to 1000 ml with the same solvent.

##### 6.3 Standardisation:

- 6.3.1 Dissolve 0.350 g of the dried substance in 35 mL of a mixture of 30 volumes of anhydrous acetic acid and 70 volumes of acetic anhydride. Titrate with 0.1 M



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<b>Revision No.:</b>	00	<b>Page No.:</b>	2 of 3
<b>Supersede SOP No.:</b>	Nil		

perchloric acid, using 0.05 mL of crystal violet solution as indicator. Carry out a blank titration.

1 mL of 0.1M perchloric acid is equivalent to 44.81 mg of  $C_{27}H_{42}ClNO_2$ .

#### 6.4 Calculation:

##### 6.4.1 Potency of Benzethonium chloride:

$$= \frac{\text{Volume of Perchloric Acid} \times \text{Mol. of Perchloric Acid Sol.} \times 0.04481 \text{ gm} \times 100}{\text{Wt. of Sample in gm} \times 0.1M}$$

##### 6.4.2 Molarity of Benzethonium Chloride:

$$= \frac{\text{Actual weight of Benzethonium chloride in gm} \times 0.004 \text{ Potency}}{1.792 \text{ gm} \times 100}$$

#### 7.0 Annexures:

7.1 Annexure-I: Molarity Calculation format of Volumetric Solution 0.004 M Benzethonium Chloride.

#### 8.0 Distribution:

8.1 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
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<b>Revision No.:</b>	00	<b>Page No.:</b>	3 of 3
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### ANNEXURE-I

#### Molarity Calculation format of Volumetric Solution 0.004 M Benzethonium Chloride

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):