



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

Title: Sodium Hydroxide 1.0 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 1.0 M Sodium Hydroxide.

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 hydroxide, Potassium hydrogen phthalate, conical flask, record book etc.

6.2 Preparation:

6.2.1 Dissolve 42.0 g of sodium hydroxide in sufficient carbon dioxide-free water to Produce 1000 ml.

6.3 Standardisation:

6.3.1 Weigh accurately about 0.150 g of potassium hydrogen phthalate, previously powdered and dried at 110° for 1 hours, and dissolve in 50 ml of carbon dioxide-free



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

Title: Sodium Hydroxide 1.0 M

SOP No.:		Department:	QC
Effective Date:		Review Date:	
Revision No.:	00	Page No.:	2 of 3
Supersede SOP No.:	Nil		

water. Add 0.1 ml of phenolphthalein solution and titrate with the sodium hydroxide solution until a permanent pink colour is produced.

Each ml of 1.0 M Sodium Hydroxide is equivalent to 0.2042 g of $C_8H_5KO_4$.

6.4 Calculation:

$$\text{Molarity (M)} = \frac{\text{Weight of primary std in gm} \times 1.0 \text{ M} \times \text{Potency of Primary std.}}{\text{Consume vol.} \times 0.2042 \text{ gm} \times 100}$$

7.0 Annexures:

7.1 Annexure-I: Molarity Calculation format of Volumetric Solution 1.0 M sodium Hydroxide.

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



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

Title: Sodium Hydroxide 1.0 M

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

ANNEXURE-I

Molarity Calculation format of Volumetric Solution 1.0 M Sodium Hydroxide

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):