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Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Toct C	pecifications
Standard	ICSUB	pecnications

Title: Sodium Hydroxide Pellets BP Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/013	00	07/09/2021	06/09/2024

Change Control No. NA

Prepared By: ______ Date: <u>03/09/2021</u>

Name : Pankaj Patel_____

(QC Officer / Designee)

Reviewed By: _____ Date: 04/09/2021

Name : <u>Nilesh Shah</u>
(Unit Head / Designee)

Approved By: _____ Date: 06/09/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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Format No. QC/017/F/01-00

Certified By (Sign/Date):



07/09/2021

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Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Sodium Hydroxide Pellets BP **Page No.:** 2 of 3

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/013 07/09/2021 06/09/2024 00

Change Control No. NA

1.0 SAMPLING LEVEL:

As mentioned in the "Sampling procedure" SOP.

2.0 SAMPLING METHOD TO BE FOLLOWED:

100% sampling to be done from each container.

3.0 TOTAL COMPOSITE SAMPLE TO BE COLLECTED:

100 gm

4.0 EXPIRY:

Five years from the Date of Manufacturing.

5.0 CAS No: 1310-73-2

6.0 MOLECULAR FORMULA: NaOH

7.0 MOLECULAR WEIGHT: 40.00gm/mol.

8.0 CATEGORY: Pharmaceutical aid (alkalising agent).

9.0 STORAGE: Store protected from moisture, in non-metallic containers.

10.0 SAFETY PRECAUTIONS TO BE TAKENWHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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Quality Control

Standard Test Specifications

Title: Sodium Hydroxide Pellets BP **Page No.:** 3 of 3

Specification No.: Revision No.: **Effective Date Review Date** ACPL/FP/SP/013 07/09/2021 06/09/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS **REF: BP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, crystalline masses, supplied as pellets, sticks or slabs, deliquescent, readily absorbing carbon dioxide.	
2.	Solubility	Very soluble in water, freely soluble in ethanol (96 per cent).	
	Identification A pH: Minimum 11.0.	To pass test	
3.	Identification B Solution S gives reaction (a) of Sodium	To pass test	
4.	Appearance of Solution	The solution is clear and colorless	
5.	Carbonates	Max. 2.0 %	
6.	Chlorides	Max. 200 ppm	
7.	Sulfates	Max. 200 ppm	
8.	Iron	Max. 10 ppm	
9.	Assay	97.0% - 100.5%	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	07/09/2021	First Issuance	N A

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Format No. QC/017/F/01-00

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07/09/2021