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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test Specifications
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Title: Sodium Hydroxide Pellets EP 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: 03/09/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: 04/09/2021

Name : Nilesh Shah

(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):

Ri

07/09/2021

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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

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

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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 %).		
3.	Identification A pH: Minimum 11.0. Identification B Solution S gives reaction (a) of Sodium	To pass test 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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