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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Calcium Hydroxide USP Page No.: 1 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/002
 00
 14/07/2021
 13/07/2024

Change Control No. NA

Prepared By: _____ Date: <u>10/07/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>12/07/2021</u>

Name : Nilesh Shah (Unit Head / Designee)

Approved By: ______ Date: 13/07/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

1

14/07/2021

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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: Calcium Hydroxide USP Page No.: 2 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/002
 00
 14/07/2021
 13/07/2024

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: 1305-62-0

6.0 MOLECULAR FORMULA:Ca(OH)₂

7.0 MOLECULAR WEIGHT: 74.09 gm/mol.

8.0 CATEGORY: Excipient.

9.0 STORAGE: Preserve in tight 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: Calcium Hydroxide USP Page No.: 3 of 3

 Specification No.:
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Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, fine powder	
2.	Solubility	Practically insoluble in water	
	Identification A	To pass test	
3.	The clear supernatant from the magma is		
	alkaline to litmus		
	Identification B	To pass test	
	Test For Calcium		
4.	Assay %	95.0% - 100.5%	
5.	Limit of Magnesium And Alkali Salts	Max. 4.8 %	
6.	Limit of Acid-Insoluble Substances	Max. 0.5 %	
7.	Carbonates	The Analysis does not cause more than a slight effervescence	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	14/07/2021	First Issuance	N A

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Certified By (Sign/Date):



14/07/2021