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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test S	pecifications
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Standard Test opecinications						
Title: Calcium Hydroxide EP			Page No.: 1 of 3			
Specification No.: ACPL/FP/SP/002	Revision No.:	Effective Date 14/07/2021	Review Date 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: <u>13/07/2021</u>

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

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14/07/2021

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Quality Control

Standard Test Specifications

Title: Calcium Hydroxide EP Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0020014/07/202113/07/2024

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: 74.1 gm/mol.

8.0 CATEGORY: Excipient.

9.0 STORAGE: Preserve in well-closed 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 EP Page No.: 3 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0020014/07/202113/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: EP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, fine powder	
2.	Solubility	Practically insoluble in water	
	Identification A	To Pass test	
	The solution becomes colorless		
3.	Identification B	To Pass test	
	Give reaction (b) of Calcium		
4.	Matter insoluble in hydrochloric acid	Max. 0.5 %	
5.	Carbonates	Max. 5.0 % of CaCO ₃	
6.	Chloride	Max. 330 ppm	
7.	Sulfate (SO ₄)	Max. 0.4 %	
8.	Arsenic (As)	Max 4 ppm	
9.	Magnesium and Alkali metals as sulfates.	Max.4.0 %	
10.	Assay %	95.0% - 100.5%	

REVISION HISTORY:

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

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