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

Ta- Savli, Dist. Vadodara, Gujarat, India

ra- Savii, Dist. Vadodara, Gujarat, India						
Quality Control						
Standard Test Specifications						
Title: Calcium Sulphate Anhydrous USP			Page No.: 1 of 3			
Specification No.:	Revision No.:	Effective Date	Review Date			
ACPL/FP/SP/021	00	15/07/2021	14/07/2024			
Change Control No.	NA					
_						

Prepared By: ______ Date: 12/07/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>13/07/2021</u>

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

Approved By: _____ Date: 14/07/2021

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):

Ri

15/07/2021

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Quality Control Standard Test Specifications						
Specification No.:	Revision No.:	Effective Date	Review Date			
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Change Control No.	NA	•	•			

1.0 SAMPLINGLEVEL:

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: 7778-18-9

6.0 MOLECULAR FORMULA: CaSO₄.

7.0 MOLECULAR WEIGHT: 136.14 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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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Calcium Sulphate Anhydrous USP Page No.: 3 of 3

 Specification No.:
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 00
 15/07/2021
 14/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, crystalline powder, hygroscopic	
2.	Solubility	Soluble in 3N hydrochloric acid	
3.	Identification A Test for Calcium Identification B Test for Sulphate	To pass test To pass test	
4.	Assay(Dried basis)	98.0 % to 101.0 %	
5.	Iron	Max. 100 ppm	
6.	Loss on Drying	Max. 1.5%	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	15/07/2021	First Issuance	N A

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