

**MASTER COPY**



Plot no. 1116/P, Lamadapura Road,  
Manjusar – 391 775,  
Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control**

**Standard Test Specifications**

**Title: Anhydrous Sodium Sulphate EP**

**Page No.:** 1 of 3

**Specification No.:**  
ACPL/FP/SP/045

**Revision No.:**  
00

**Effective Date**  
11/09/2021

**Review Date**  
10/09/2024

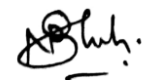
**Change Control No.**

NA

Prepared By: 

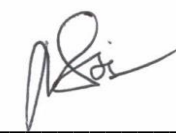
Date: 08/09/2021

Name : Pankaj Patel  
(QC Officer / Designee)

Reviewed By: 

Date: 09/09/2021

Name : Nilesh Shah  
(Unit Head / Designee)

Approved By: 

Date: 10/09/2021

Name : Naresh Solanki  
(QA/QC In Charge / Designee)

**UNCONTROLLED COPY**

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

Certified By (Sign/Date) :  11/09/2021

**MASTER COPY**

Plot no. 1116/P, Lamadapura Road,  
Manjusar – 391 775,  
Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control****Standard Test Specifications****Title: Anhydrous Sodium Sulphate EP****Page No.: 2 of 3****Specification No.:**  
ACPL/FP/SP/045**Revision No.:**  
00**Effective Date**  
11/09/2021**Review Date**  
10/09/2024**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:** 7757-82-6**6.0 MOLECULAR FORMULA:** Na<sub>2</sub>SO<sub>4</sub>**7.0 MOLECULAR WEIGHT:** 142.0 gm/mol.**8.0 CATEGORY:** Excipient**9.0 STORAGE:** Store in an airtight container.**10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING :**

Use hand gloves, goggles and apron during Handling.

**11.0 CONTROL SAMPLE:** 3 X 100 gm.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

11/09/2021

**MASTER COPY**

Plot no. 1116/P, Lamadapura Road,  
Manjusar – 391 775,  
Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control****Standard Test Specifications****Title: Anhydrous Sodium Sulphate EP****Page No.:** 3 of 3**Specification No.:**  
ACPL/FP/SP/045**Revision No.:**  
00**Effective Date**  
11/09/2021**Review Date**  
10/09/2024**Change Control No.**

NA

**TEST PARAMETERS AND SPECIFICATIONS****REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Description	White or almost white powder, hygroscopic.
2.	Solubility	Freely soluble in water.
3.	<b>Identification A</b> It gives reaction of sulfates <b>Identification B</b> It gives reaction of sodium <b>Identification C</b> Loss on drying (See test)	To pass test  To pass test  To Pass test
4.	Appearance of Solution	The solution is clear and colorless
5.	Acidity or alkalinity	Not more than 0.5 mL of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide is required to change the colour of the indicator.
6.	Chloride	Max. 450 ppm
7.	Calcium	Max. 450 ppm
8.	Iron	Max. 90 ppm
9.	Magnesium	Max. 200 ppm
10.	Loss on drying	Max. 0.5 %
11.	Assay %(Dried substance)	98.5 % - 101.0 %

**REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	11/09/2021	First Issuance	N A

**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

11/09/2021