# **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Title: Anhydrous Sodium Sulphate BP Page No.: 1 of 3

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

 ACPL/FP/SP/045
 00
 11/09/2021
 10/09/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_ Date: <u>08/09/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: 09/09/2021

Name : <u>Nilesh Shah</u>

(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):

Pai

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 BP **Page No.:** 2 of 3

**Revision No.: Specification No.: Effective Date Review Date** ACPL/FP/SP/045 11/09/2021 10/09/2024 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:** 7757-82-6

**6.0 MOLECULAR FORMULA**: Na<sub>2</sub>SO<sub>4</sub>

**7.0 MOLECULAR WEIGHT**: 142.04 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 BP **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/045 11/09/2021 10/09/2024 00

**Change Control No.** NA

## TEST PARAMETERS AND SPECIFICATIONS **REF: BP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white powder, hygroscopic.	
2.	Solubility	Freely soluble in water.	
	Identification A	To pass test	
	It gives reaction of sulfates		
3.	Identification B	To pass test	
	It gives reaction of sodium		
	<b>Identification</b> C	To Pass test	
	Loss on drying (See 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