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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Standard	<b>Test</b>	<b>Specificat</b>	ions
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Title: Sodium Benzoate EP Page No.: 1 of 3

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

 ACPL/FP/SP/042
 00
 26/08/2021
 25/08/2024

Change Control No. NA

Prepared By: \_\_\_\_\_ Date: 23/08/2021

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(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: <u>24/08/2021</u>

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(Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: <u>25/08/2021</u>

Name : Naresh Solanki\_\_\_\_\_

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):



26/08/2021

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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: Sodium Benzoate EP Page No.: 2 of 3

 Specification No.:
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### 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:** 532-32-1

**6.0 MOLECULAR FORMULA**: C<sub>6</sub>H<sub>5</sub>COONa.

**7.0 MOLECULAR WEIGHT**: 144.1 gm/mol.

8.0 CATEGORY: Excipient

9.0 STORAGE: Preserve in well-closed containers.

#### 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.

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**Quality Control** 

**Standard Test Specifications** 

**Page No.:** 3 of 3 **Title: Sodium Benzoate EP** 

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

Sr. No.	TEST PARAMETER	SPECIFICATION		
1.	Appearance	White or almost white, crystalline or granular powder or flakes, slightly hygroscopic.		
2.	Solubility	Freely soluble in water, sparingly soluble in ethanol (90 %).		
	Identification A	To Pass test		
3.	It gives reactions (b) and (c) of benzoates  Identification B  It gives reaction (a) of sodium	To Pass test		
4.	Appearance of Solution	Solution S is clear and not more intensely colored than reference solution Y6.		
5.	Acidity or alkalinity	Not more than 0.2 mL of 0.1 M sodium hydroxide or 0.1 M hydrochloric acid is required to change the colour of the indicator.		
6.	Halogenated compounds	Max. 200 ppm for ionized chlorine and Max. 300 ppm for total chlorine		
7.	Loss On Drying	Max. 2.0 %		
8.	Assay( Dried basis)	99.0 % – 100.5 %		

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	26/08/2021	First Issuance	N A

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