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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Sodium Benzoate JP 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

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>24/08/2021</u>

Name : <u>Nilesh Shah</u>

(Unit Head / Designee)

Approved By: _____ Date: <u>25/08/2021</u>

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Di

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 JP Page No.: 2 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

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: C₆H₅COONa.

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

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

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/042 26/08/2021 25/08/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: JP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White, granules, crystals or crystalline powder. It is	
	Appearance	odorless, and has a sweet and saline taste	
2.	Solubility	It is freely soluble in water, slightly soluble in ethanol	
2.		(95), and practically insoluble in diethyl ether.	
	Identification	To Pass test	
3.	Responds to the Qualitative Tests for		
	benzoate and the Qualitative Tests		
	(1) and (2) for sodium salt.		
4.	Clarity and color of solution	The solution is clear and colorless	
5.	Acidity or alkalinity	A red color develops.	
6.	Sulfate	Max. 1200 ppm	
7.	Heavy metals	Max. 20 ppm	
8.	Arsenic	Max. 2 ppm	
9.	Chlorinated compounds	To Pass test	
10.	Phthalic acid	The solution is not more intense than that of the following control solution.	
11.	Loss on drying	Max. 1.5 %	
12.	Assay (Dried basis)	Min. 99.0 %	

REVISION HISTORY:

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

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

Certified By (Sign/Date):



26/08/2021