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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 Gluconate USP


Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/069	00	04/09/2021	03/09/2024
Change Control No.	NA		

Prepared By: 


Date: 01/09/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 02/09/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 03/09/2021

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

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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: 527-07-1

6.0 MOLECULAR FORMULA: C₆H₁₁NaO₇

7.0 MOLECULAR WEIGHT: 218.14 gm/mol.

8.0 CATEGORY: Excipient.

9.0 STORAGE: 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.

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NA

TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, hygroscopic, crystalline powder.
2.	Solubility	Soluble in water.
3.	Identification A Test for Sodium Identification B Thin-layer chromatography	To pass test To pass test
4.	Assay % (Dried basis)	98.0 % – 102.0 %
5.	Chloride	Max. 700 ppm
6.	Sulfates (SO ₄)	Max. 500 ppm
7.	Lead	Max. 10 ppm
8.	Reducing Substances	Max. 0.5 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	04/09/2021	First Issuance	N A

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