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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: Zinc Gluconate EP


Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/072	00	18/09/2021	17/09/2024
Change Control No.	NA		

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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: 4468-02-4**6.0 MOLECULAR FORMULA:** $C_{12}H_{22}ZnO_{14}.xH_2O$ **7.0 MOLECULAR WEIGHT:** 455.7 gm/mol. (anhydrous substance)**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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, hygroscopic, crystalline powder.
2.	Solubility	Soluble in water, practically insoluble in anhydrous ethanol and in methylene chloride.
3.	Identification A Thin-layer chromatography Identification B A white precipitate is formed that does not dissolve upon the addition of 5 mL of hydrochloric acid.	To pass test To pass test
4.	Appearance of solution	Solution S is not more opalescent than reference suspension II and not more intensely colored than reference solution Y6.
5.	Sucrose and reducing sugars	To Pass test (No red precipitate is formed)
6.	Chloride	Max. 500 ppm
7.	Sulfates (SO ₄)	Max. 500 ppm
8.	Cadmium	Max. 2 ppm
9.	Water	Max. 12.0 %
10.	Microbial contamination	TAMC: acceptance criterion 10 ³ CFU/g. TYMC: acceptance criterion 10 ² CFU/g.
11.	Assay % (Dried basis)	98.0 % – 102.0 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	18/09/2021	First Issuance	N A

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