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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 USP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/072


Revision No.:
00

Effective Date
18/09/2021

Review Date
17/09/2024

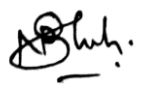
Change Control No.

NA

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Date: 15/09/2021

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Date: 16/09/2021

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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:** 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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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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 Zinc Identification B Thin-layer chromatography	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.	Assay % (Dried basis)	97.0 % – 102.0 %
6.	Chloride	Max. 500 ppm
7.	Sulfates (SO ₄)	Max. 500 ppm
8.	Arsenic	Max. 3 ppm
9.	Limit of Lead	Max. 10 ppm
10.	Limit of Cadmium	Max. 5 ppm
11.	Reducing Substances	Max. 1.0 %
12.	pH	5.5 – 7.5
13.	Water Determination	Max. 11.6 %

REVISION HISTORY:

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

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