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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: Ferrous Gluconate USP


Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/056	00	31/07/2021	30/07/2024
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: 299-29-6**6.0 MOLECULAR FORMULA:** $C_{12}H_{22}FeO_{14}.2H_2O$.**7.0 MOLECULAR WEIGHT:** 482.17 gm/mol.**8.0 CATEGORY:** Excipient.**9.0 STORAGE:** Preserve in tight 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	Greenish-yellow or grey powder or granules.
2.	Solubility	Freely but slowly soluble in water giving a greenish-brown solution, more readily soluble in hot water, practically insoluble in ethanol (96 %)
3.	Identification A Thin-layer chromatography Identification B Ferrous Ion	To Pass test To Pass test
4.	Assay % (Dried Basis)	99.0 % to 101.0 %
5.	Chloride	Max. 700 ppm
6.	Sulfate	Max. 0.1 %
7.	Mercury	Max. 3 ppm
8.	Arsenic (AS)	Max. 3 ppm
9.	Limit of Lead	Max. 10 ppm
10.	Limit of Ferric Iron	Max. 2.0 %
11.	Oxalic Acid	No turbidity is produced within 5 min
12.	Reducing Sugars	No red precipitate is formed within 1 min.
13.	Loss on drying (at 105 °C)	6.5 % to 10.0 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	31/07/2021	First Issuance	N A

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