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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 EP**


**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:** Protected from light.**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	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.	<b>Identification A</b> Thin-layer chromatography <b>Identification B</b> 1 mL of solution S gives reaction (a) of iron	To pass test
		To pass test
4.	Appearance of Solution (20 % Soln.)	Solution is clear & colorless
5.	pH	4.0 to 5.5
6.	Sucrose and reducing sugars	No red precipitate is formed
7.	Chlorides (Cl)	Max. 600 ppm
8.	Oxalates	No precipitate is formed.
9.	Sulfates (SO <sub>4</sub> )	Max. 500 ppm
10.	Arsenic (AS)	Max. 2 ppm
11.	Barium	To Pass test
12.	Ferric ions	Not more than 9.0 mL of 0.1 M sodium thiosulfate is used
13.	Loss on drying (at 105 °C)	5.0 % to 10.5 %
14.	Microbial contamination	TAMC: acceptance criterion 10 <sup>3</sup> CFU/g TYMC: acceptance criterion 10 <sup>2</sup> CFU/g
15.	Assay % (Dried Basis)	99.0 % to 101.0 %

**REVISION HISTORY:**

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

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