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Date: <u>30/07/2021</u>

Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Ferrous Sulphate Heptahydrate EP Page No.: 1 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/030
 00
 03/08/2021
 02/08/2024

Change Control No. NA

Prepared By:

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: 31/07/02021

Name : <u>Nilesh Shah</u> (Unit Head / Designee)

Approved By: _____ Date: <u>02/08/2021</u>

Name : <u>Naresh Solanki</u>

(QA/QC In Charge / Designee)

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Format No. QC/017/F/01-00

Certified By (Sign/Date):

Ri

03/08/2021

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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 Sulphate Heptahydrate EP Page No.: 2 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/030	00	03/08/2021	02/08/2024

Change Control No. NA

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: 7782-63-0

6.0 MOLECULAR FORMULA: FeSO₄.7H₂O

7.0 MOLECULAR WEIGHT: 278.0 gm/mol.

8.0 CATEGORY: Haematinic.

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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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Ferrous Sulphate Heptahydrate EP Page No.: 3 of 3

 Specification No.:
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 03/08/2021
 02/08/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: EP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	Light green, crystalline powder or bluish-green crystals, efflorescent in air.	
2.	Solubility	Freely soluble in water, very soluble in boiling water, practically insoluble in ethanol (96 %).	
3.	Identification A It gives the reactions of sulfates Identification B It gives reaction (a) of iron	To Pass test To Pass test	
	Identification C It complies with the limits of the assay	To Pass test	
4.	pН	3.0 to 4.0	
5.	Chlorides (Cl)	Max. 200 ppm	
6.	Chromium	Max. 50 ppm	
7.	Copper	Max. 50 ppm	
8.	Ferric ions	Max. 0.3 %	
9.	Manganese	Max. 0.1 %	
10.	Nickel	Max. 50 ppm	
11.	Zinc	Max. 50 ppm	
12.	Assay % (Dried Basis)	99.0 % to 101.0 %	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	03/08/2021	First Issuance	N A

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Format No. QC/017/F/01-00

Certified By (Sign/Date):



03/08/2021