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

Ta- Savli, Dist. Vadodara, Gujarat, India

Qualit	y Control
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Title: Ferric Chloride Hexahydrate AR Page No.: 1 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0280031/07/202130/07/2024

Change Control No. NA

Prepared By: _____ Date: <u>28/07/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>29/07/2021</u>

Name : <u>Nilesh Shah</u>

(Unit Head / Designee)

Approved By: _____ Date: 30/07/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



31/07/2021

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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: Ferric Chloride Hexahydrate AR Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0280031/07/202130/07/2024

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

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

4.0 RETEST DATE: Three year

5.0 CAS No: 10025-77-1

6.0 MOLECULAR FORMULA: FeCl_{3.6}H₂O

7.0 MOLECULAR WEIGHT: 270.30 gm/mol.

8.0 CATEGORY: Excipients

9.0 STORAGE: In 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: Ferric Chloride Hexahydrate AR Page No.: 3 of 3

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

 ACPL/FP/SP/028
 00
 31/07/2021
 30/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: AR

Sr. No.	TEST PARAMETER	SPECIFICATION		
1.	Description	Crystalline mass or Orange-Yellow or Brownish-		
		Yellow Crystals, very hygroscopic		
2.	Solubility	Very soluble in water an in Ethanol (96%), Freely		
		soluble in Glycerol		
3.	Appearance of solution	Should comply the test		
4.	Appearance of solution (JPE)	Should comply the test		
5.	Acidity (HCl)	Should comply the test		
6.	Free Chlorine	Should comply the test		
7.	Nitrate as NO ₃	Should comply the test		
8.	Phosphate as PO ₄	Max. 20 ppm		
9.	Sulphate as SO ₄	Max. 50 ppm		
10.	Heavy Metals	Max. 50 ppm		
11.	Metal Impurities by IPC-MS			
12.	Arsenic	Max. 2 ppm		
13.	Copper	Max. 50 ppm		
14.	Ferrous (Fe ⁺²)	Max. 50 ppm		
15.	Manganese as Mn	Max. 500 ppm		
16.	Sodium as Na	Max. 500 ppm		
17.	Lead as Pb	Max. 50 ppm		
18.	Zinc	Max. 50 ppm		
19.	Assay by Titration (% W/w)	Min. 99.00 % to Max. 102.00 %		
20.	Substances not precipitated by ammonia solution (as Sulphate)	Max. 0.1 %		

REVISION HISTORY:

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

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

Certified By (Sign/Date):



31/07/2021