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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test	Specifications	5

Title: Citric Acid Monohyd	Page No.: 1 of 3		
Specification No.: ACPL/FP/SP/003	Revision No.:	Effective Date 17/07/2021	Review Date 16/07/2024
Change Control No.	NA		

Prepared By: _____ Date: <u>14/07/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>15/07/2021</u>

Name : Nilesh Shah_____

(Unit Head / Designee)

Approved By: ______ Date: <u>16/07/2021</u>

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Ri

17/07/2021

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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: Citric Acid Monohydrate ACS Page No.: 2 of 3

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

 ACPL/FP/SP/003
 00
 17/07/2021
 16/07/2024

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

4.0 EXPIRY:

Five years from the Date of Manufacturing.

5.0 CAS No: 5949-29-1

6.0 MOLECULAR FORMULA: C₆H₅O₇.H₂O

7.0 MOLECULAR WEIGHT: 210.1 gm/mol.

8.0 CATEGORY: Pharmaceutical aid.

9.0 STORAGE: Store protected from moisture.

10.0 SAFETY PRECAUTIONS TO BE TAKENWHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Citric Acid Monohydrate ACS Page No.: 3 of 3

 Specification No.:
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 ACPL/FP/SP/003
 00
 17/07/2021
 16/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: ACS

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Description	White or almost white, crystalline powder, colorless crystals or granules, efflorescent.	
2.	Solubility	Very soluble in water	
3.	Insoluble matter	Max. 50 ppm	
4.	Residue after ignition	Max. 200 ppm	
5.	Chloride as Cl	Max. 10 ppm	
6.	Oxalate as C ₂ O ₄	To Pass test	
7.	Phosphate as PO ₄	Max. 10 ppm	
8.	Sulphate as SO ₄	Max. 20 ppm	
9.	Iron as Fe	Max. 3 ppm	
10.	Lead as Pb	Max.2 ppm	
11.	Substances Carbonizable by hot sulfuric acid	To Pass test	
12.	Assay (By acid – base titrimetry)	Min. 99% and Max. 102%	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	17/07/2021	First Issuance	N A

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

Certified By (Sign/Date):



17/07/2021