MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications				
Title: Citric Acid Monohydrate LR			Page No.: 1 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			

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 : <u>Nilesh Shah</u>

(Unit Head / Designee)

Approved By: _____ Date: 16/07/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

UNCONTROLLED COPY

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

Certified By (Sign/Date):

17/07/2021

MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

C4 1 1	4	α .	U.	4 •
Standard	I OCT	Short	tien	tianc
Standard	1031	BUCU	пса	uons

Title: Citric Acid Monohydrate LR			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: Excipient.

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.

UNCONTROLLED COPY

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

Certified By (Sign/Date):

17/07/2021

MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

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

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0030017/07/202116/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: LR

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.	Chloride as Cl	Max. 10 ppm
4.	Residue after ignition	Max. 200 ppm
5.	Chloride as Cl	Max. 10 ppm
6.	Sulphate as SO ₄	Max. 20 ppm
7.	Oxalate as C ₂ O ₄	Max. 500 ppm
8.	Arsenic as As	Max. 1 ppm
9.	Barium as Ba	Max. 20 ppm
10.	Calcium as Ca	Max. 200 ppm
11.	Copper as Cu	Max. 10 ppm
12.	Iron as Fe	Max. 5 ppm
13.	Heavy Metal as Pb	Max. 10 ppm
14.	Zinc as Zn	Max. 10 ppm
15.	Sulphated ash	Max. 500 ppm
16.	Water by KF	7.5 % – 9.0%
17.	Assay (By acid – base titrimetry)	Min. 99.5% to Max. 101.5%

REVISION HISTORY:

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

UNCONTROLLED COPY

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

Certified By (Sign/Date):

