

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 USP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/003

Revision No.:
00

Effective Date
19/07/2021

Review Date
18/07/2024

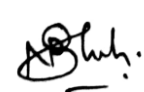
Change Control No.

NA

Prepared By: 


Date: 15/07/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 16/07/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 17/07/2021

Name : Naresh Solanki
(QA/QC In Charge / Designee)

UNCONTROLLED COPY

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

Certified By (Sign/Date) :  19/07/2021

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 USP****Page No.: 2 of 3****Specification No.:**
ACPL/FP/SP/003**Revision No.:**
00**Effective Date**
19/07/2021**Review Date**
18/07/2024**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:** $C_6H_5O_7 \cdot H_2O$ **7.0 MOLECULAR WEIGHT:** 210.1 gm/mol.**8.0 CATEGORY:** Pharmaceutical aid.**9.0 STORAGE:** Preserve in tight containers.**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 100gm.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  19/07/2021

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 USP****Page No.:** 3 of 3**Specification No.:**
ACPL/FP/SP/003**Revision No.:**
00**Effective Date**
19/07/2021**Review Date**
18/07/2024**Change Control No.**

NA

TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder, colorless crystals or granules, efflorescent.
2.	Identification Spectroscopic Identification Tests , Infrared Spectroscopy	To pass test
3.	Assay (dried basis)	99.5% - 100.5%
4.	Residue on ignition	Max. 0.1 %
5.	Sulfate (SO ₄)	Max. 150 ppm
6.	Limit of Aluminum	Max. 0.2 ppm
7.	Limit of Oxalic Acid	Max. 360 ppm
8.	Bacterial Endotoxins Test	To Pass test
9.	Clarity of Solution	The Sample solution shows the same clarity as that of water or its opalescence is not more pronounced than Standard suspension.
10.	Color of Solution	To Pass test
11.	Readily carbonisable substances	To Pass test
12.	Sterility Tests	To Pass test
13.	Water Determination	7.5%–9.0%

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	19/07/2021	First Issuance	NA

UNCONTROLLED COPY**Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  19/07/2021