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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 EP**

**Page No.:** 1 of 3

**Specification No.:**  
ACPL/FP/SP/003

**Revision No.:**  
00

**Effective Date**  
19/07/2021

**Review Date**  
18/072024

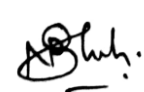
**Change Control No.**

NA

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Date: 15/07/2021

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Reviewed By: 

Date: 16/07/2021

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Date: 17/07/2021

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**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:**  $C_6H_8O_7 \cdot H_2O$ **7.0 MOLECULAR WEIGHT:** 210.1 gm/mol.**8.0 CATEGORY:** Pharmaceutical aid.**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 100gm.**UNCONTROLLED COPY****Format No. QC/017/F/01-00****Certified By (Sign/Date) :**  **19/07/2021**

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**TEST PARAMETERS AND SPECIFICATIONS****REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder, colorless crystals or granules, efflorescent.
2.	Solubility	Very soluble in water, freely soluble in ethanol (96 %).
3.	<b>Identification A</b> The solution is strongly acidic <b>Identification B</b> Comparison <b>Identification C</b> A red colour develops <b>Identification D</b> A white precipitate is formed	To pass test To pass test To pass test To pass test
4.	Appearance of Solution	The solution is clear and colorless or not more intensely colored than reference solution Y <sub>7</sub> , BY <sub>7</sub> or GY <sub>7</sub>
5.	Readily carbonisable substances	To pass test
6.	Oxalic acid	Max. 360 ppm
7.	Sulfate (SO <sub>4</sub> )	Max. 150 ppm
8.	Aluminium	Max. 0.2 ppm
9.	Water	7.5 % to 9.0 %
10.	Sulfated Ash	Max. 0.1 %
11.	Bacterial endotoxins	Less than 0.5 IU/mg
12.	Assay (dried basis)	99.5% - 100.5%

**REVISION HISTORY:**

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

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