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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 Anhydrous EP

Page No.: 1 of 4

Specification No.:
ACPL/FP/SP/023

Revision No.:
00

Effective Date
17/07/2021

Review Date
16/07/2024

Change Control No.

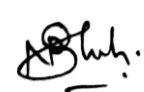
NA

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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: 77-92-9**6.0 MOLECULAR FORMULA:** C₆H₈O₇.**7.0 MOLECULAR WEIGHT:** 192.1 gm/mol.**8.0 CATEGORY:** Pharmaceutical aid.**9.0 STORAGE:** Containers - 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**

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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Description	White or almost white, crystalline powder, colorless crystals or granules.
2.	Solubility	Very soluble in water, freely soluble in ethanol (96 %).
3.	Melting Point (With decomposition)	About 153°C
4.	Identification A The solution is strongly acidic Identification B Comparison Identification C A red color develops Identification D A white precipitate is formed Identification E Water (See)	To pass test To pass test To pass test To pass test To pass test
5.	Appearance of Solution	The solution is clear and colorless or not more intensely colored than reference solution Y ₇ , BY ₇ or GY ₇
6.	Readily carbonisable substances	To pass test
7.	Oxalic acid	Max. 360 ppm
8.	Sulfate (SO ₄)	Max. 150 ppm
9.	Aluminum	Max. 0.2 ppm

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10.	Water	Max. 1.0 %
11.	Sulfated Ash	Max. 0.1 %
12.	Bacterial endotoxins	Less than 0.5 IU/mg
13.	Assay (dried basis)	99.5% - 100.5%

REVISION HISTORY:

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

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