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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 IP


Page No.: 1 of 4

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/003	00	19/07/2021	18/07/2024
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: 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 TAKEN WHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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TEST PARAMETERS AND SPECIFICATIONS**REF: IP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Description	Colorless crystals or white, crystalline powder; slightly efflorescent in warm, dry air.
2.	Identification A Compare the spectrum with that obtained with citric acid or with the reference spectrum of citric acid. Identification B It gives reaction A of citrates Identification C A 10 percent w/v solution is strongly acidic.	To pass test To pass test To pass test To pass test
3.	Appearance of Solution	Dissolve 2.0g insufficient water to produce 10 ml. The solution is Clear, and not more intensely colored than reference solution YS ₇ , BYS ₇ or GYS ₇ .
4.	Arsenic (As)	Max. 1 ppm
5.	Barium (Ba)	To Pass test
6.	Calcium (Ca)	Max. 200 ppm
7.	Heavy Metals	Max. 10 ppm
8.	Iron	Max. 50 ppm

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9.	Chloride	Max. 50 ppm
10.	Sulfate (SO ₄)	Max. 150 ppm
11.	Oxalic acid	To Pass test
12.	Readily carbonisable substances	To pass test
13.	Sulfated Ash	Max. 0.1 %
14.	Water	7.5 % to 9.0 %
15.	Assay (dried basis)	99.0 % - 101.0 %

REVISION HISTORY:

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

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