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 BP			**Page No.:** 1 of 4
Specification No.: ACPL/FP/SP/003	**Revision No.:** 00	**Effective Date** 19/07/2021	**Review Date** 18/07/2024
Change Control No.	NA		

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Title: Citric Acid Monohydrate BP			**Page No.:** 2 of 4
Specification No.: ACPL/FP/SP/003	**Revision No.:** 00	**Effective Date** 19/07/2021	**Review Date** 18/07/2024
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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:$C_6H_5O_7.H_2O$

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 TAKENWHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE:3 X 100gm.

Annexe CHEM PVT. LTD.
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TEST PARAMETERS AND SPECIFICATIONS
REF: BP

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.	**Identification A** The solution is strongly acidic **Identification B** Comparison **Identification C** A red colour develops **Identification D** 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_7, BY_7 or GY_7
5.	Readily carbonisable substances	To pass test
6.	Oxalic acid	Max. 360 ppm
7.	Sulfate (SO_4)	Max. 150 ppm
8.	Aluminum	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