

Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard '	Test Specification	S
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Title: Citric Acid Anhydrous BP Page No.: 1 of 4

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/023
 00
 16/07/2021
 15/07/2024

Change Control No. NA

Prepared By: _____ Date: 13/07/2021

Name : Pankaj Patel

(QC Officer / Designee)

Reviewed By: ______ Date: 14/07/2021

Name : Nilesh Shah (Unit Head / Designee)

Approved By: _____ Date: 15/07/2021

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):

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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: Preserve in well-closed containers.

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.

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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.	
2.	Solubility	Very soluble in water, freely soluble in ethanol (96 %).	
3.	Melting Point (With decomposition)	About 153°C	
	Identification A	To pass test	
	The solution is strongly acidic		
	Identification B	To pass test	
	Comparison		
	Identification C	To pass test	
4.	A red colour develops		
	Identification D	To pass test	
	A white precipitate is formed		
	Identification E	To pass test	
	Water (See)		
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.	Aluminium	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	16/07/2021	First Issuance	N A

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