

Date: <u>13/07/2021</u>

Date: 15/07/2021

Date: 15/07/2021

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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Standard	Test S	pecifica	tions
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Title: Citric Acid Anhydrous IP 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

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Certified By (Sign/Date):

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**Quality Control** 

**Standard Test Specifications** 

Title: Citric Acid Anhydrous IP Page No.: 2 of 4

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0230016/07/202115/07/2024

Change Control No. NA

#### 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**: C<sub>6</sub>H<sub>8</sub>O<sub>7</sub>.

7.0 MOLECULAR WEIGHT: 192.1 gm/mol.

8.0 CATEGORY: Pharmaceutical aid; anticoagulant for storage of whole blood (along with

sodium citrate).

**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.

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**Quality Control** 

**Standard Test Specifications** 

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#### TEST PARAMETERS AND SPECIFICATIONS **REF: IP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Description	Colorless crystals or a white powder; slightly hygroscopic in moist air.	
	Identification A	To pass test	
	Compare the spectrum with that		
	obtained with citric acid or with the	To pass test	
	reference spectrum of citric acid.		
2.	Identification B	To pass test	
	Itgivesreaction A of citrates		
	Identification C	To pass test	
	A 10percentw/v solution is		
	stronglyacidic.		
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 <sub>7</sub> , BYS <sub>7</sub> or GYS <sub>7</sub> .	
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 (Fe)	Max. 50 ppm	
9.	Chloride (Cl)	Max. 50 ppm	
10.	Sulfate (SO <sub>4</sub> )	Max. 150 ppm	

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**Quality Control** 

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11.	Oxalic acid	To Pass test
12.	Readily carbonisable substances	To pass test
13.	Sulfated Ash	Max. 0.1 %
14.	Water	Max. 1.0 %
15.	Assay (dried basis)	99.0% - 101.0 %

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	16/07/2021	First Issuance	N A

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