MASTER COP	Y		A	INEXE				
Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,								
Ta- Savli, Dist. Vadodara, Gujarat, India Quality Control								
Standard Test Specifications								
Title: Citric Acid Monohydı	rate EP		Page No	5.: 1 of 3				
Specification No.: ACPL/FP/SP/003	Revision No.: 00	Effective Da 19/07/2021		eview Date 18/072024				
Change Control No.	NA							
	kaj Patel COfficer / Designee)	Date:	<u>15/07/2021</u>					
	lesh Shah hit Head / Designee)	Date:	<u>16/07/2021</u>					
	<u>resh Solanki</u> A/QC In Charge / Designee)	Date:	<u>17/07/202</u>	<u>1</u>				
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Format No. QC/017/F/01-00		Certified By (Sig	gn/Date) :	19/07/2021				

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 EP **Page No.:** 2 of 3 **Revision No.: Specification No.: Effective Date Review Date** ACPL/FP/SP/003 19/07/2021 18/072024 00 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: 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**: In an airtight container. 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. **UNCONTROLLED COPY** Format No. QC/017/F/01-00

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19/07/2021

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ic Acid Monohyd	lrate EP			Page No.: 3 of 3	
Specification No.:RevisACPL/FP/SP/003				Review Date 18/072024	
e Control No.	NA				
	TEST PARAMETE			y 9	
TEST P	ARAMETER	SPECIFICATION			
Appearance		White or almost white, crystalline powder, colorless crystals or granules, efflorescent.			
Solubility		Very soluble in water, freely soluble in ethanol (96 %).			
The solution is s Identification H	strongly acidic	To pass test			
Identification (
Identification I)	To pass test			
Appearance of Solution		The solution is clear and colorless or not more intensely colored than reference solution Y_7 , BY_7 or GY_7			
Readily carboni	sable substances	To pass test			
Oxalic acid		Max. 360 ppm			
Sulfate (SO ₄)		Max. 150 ppm			
		<u> </u>			
	515)	99.5% - 1	.00.5%		
	Effective Date	Revi	ision Description	Change Control No.	
00	19/07/2021]	First Issuance	N A	
	TINIC		LEDCORV		
	/FP/SP/003 Control No. TEST P Appearance Solubility Identification A The solution is s Identification I Comparison Identification I Comparison Identification I A red colour dev Identification I A white precipit Appearance of S Readily carbonic Oxalic acid Sulfate (SO4) Aluminium Water Sulfated Ash Bacterial endoto Assay (dried bass ON HISTORY: evision No.	/FP/SP/003 00 e Control No. NA TEST PARAMETER Appearance Solubility Identification A The solution is strongly acidic Identification B Comparison Comparison Identification C A red colour develops A Appearance of Solution A white precipitate is formed Appearance of Solution Readily carbonisable substances Oxalic acid Sulfate (SO4) Aluminium Water Sulfated Ash Bacterial endotoxins Assay (dried basis) ON HISTORY: evision No. Effective Date 00 19/07/2021	/FP/SP/003 00 Control No. NA TEST PARAMETERS AND S REF: EI TEST PARAMETER Mhite or crystals or Appearance White or crystals or Solubility Very solution Identification A The solution is strongly acidic To pass to Identification B Comparison To pass to Identification C A red colour develops To pass to Identification D A white precipitate is formed To pass to Appearance of Solution The solution intensely GY7 Readily carbonisable substances To pass to Oxalic acid Max. 360 Sulfate (SO4) Max. 150 Aluminium Max. 0.1 Bacterial endotoxins Less than Assay (dried basis) 99.5% - 1 ON HISTORY: To evision No. Effective Date Revi 00 19/07/2021 1	/FP/SP/003 00 19/07/2021 Control No. NA TEST PARAMETERS AND SPECIFICATIONS REF: EP TEST PARAMETER SPECIFIC Appearance White or almost white, cry crystals or granules, effloresc Solubility Very soluble in water, freely Identification A To pass test Identification B To pass test Identification D To pass test Identification B To pass test Identification M To pass test Identification D To pass test A white precipitate is formed To pass test Appearance of Solution The solution is clear and intensely colored than refere GY7 Readily carbonisable substances To pass test Oxalic acid Max. 360 ppm Sulfate (SO4) Max. 0.2 ppm Aluminium Max. 0.1 % Bacterial endotoxins Less than 0.5 IU/mg Assay (dried basis) 99.5% - 100.5% ON HISTORY: Revision Description </td	

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