MASTER COPY	1		<b>A</b>	nexe					
Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India									
Quality Control									
Standard Test Specifications       Title: Sodium Citrate Dihydrate IP     Page No.: 1 of 3									
Specification No.:	Revision No.:	Effective D	ate R	eview Date					
ACPL/FP/SP/011	00 NA	31/08/202	21 3	30/08/2024					
Change Control 140.	NA								
	aj Patel Officer / Designee)	Date	: <u>27/08/2021</u>						
	esh Shah Head / Designee)	Date	: <u>28/08/2021</u>						
	esh Solanki /QC In Charge / Designed		: <u>30/08/2021</u>						
	UNCON	FROLLED COPY	]						
Format No. QC/017/F/01-00		Certified By (Si	gn/Date) : Rei	31/08/2021					

## MASTER COPY Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India **Quality Control Standard Test Specifications** Title: Sodium Citrate Dihydrate IP Page No.: 2 of 3 **Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/011 31/08/2021 30/08/2024 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: 6132-04-3 6.0 MOLECULAR FORMULA: C<sub>6</sub>H<sub>5</sub>Na<sub>3</sub>O<sub>7</sub>.2H<sub>2</sub>O. 7.0 MOLECULAR WEIGHT: 294.1gm/mol. 8.0 CATEGORY: Systemic alkalinising substance.. 9.0 STORAGE: Store protected from light. 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

Certified By (Sign/Date) :

31/08/2021

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Plot no. 1116/P, Lamadapura Road,								
Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India								
Quality Control								
Standard Test Specifications								
<b>Citrate Dihydrate IPPage No.:</b> 3 of 3								
Specification No.: ACPL/FP/SP/011		<b>Revision No.:</b> 00			<b>Review Date</b> 30/08/2024			
	Change Control No. NA			31/08/2021				
TEST PARAMETERS AND SPECIFICATIONS REF: IP								
Sr. No.	TEST PARAMETER SP			SPECIFICATION				
1.	Appearance			White, granular crystals or a White Crystalline; odorless, slightly deliquescent in moist air.				
	Identification	Α	Тор	To pass test				
2.	Gives the reactive reactions citrate							
3.	Appearance of Solution (10 % Soln.)			Solution is clear & colorless				
4.	Acidity or alkalinity			To Pass Test				
5.	Arsenic(As)			Max. 2.0 ppm				
6.	Heavy metals			Max. 10 ppm				
7.	Chlorides (Cl)			Max. 100 ppm				
8.	Oxalate(as anhydrous oxalic acid)			Max. 300 ppm				
9.	Sulfates (SO <sub>4</sub> )			Max. 150 ppm				
10.	Tartrate		Тор	To pass test				
11.	Readily carbonisable substances			The solution is not more intensely colored than reference solution $YS_2$ or $GYS_2$ .				
12.	Water		11.0	11.0 % to 13.0 %				
13.	Assay %(Dried Basis)			99.0 % to 101.0 %				
	ON HISTORY:							
Revi	ision No.	Effective Date	Rev	vision Description	Change Control No.			
	00	31/08/2021		First Issuance	N A			
		UNCO	<b>NTR(</b>	OLLED COPY				
Format No.	QC/017/F/01-00			Certified By (Sign/Da	ate): 1/08/2021			