MASTER COPY			Annexe							
Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India										
Quality Control Standard Test Specifications										
Standard Test SpecificationsTitle: Potassium Citrate Monohydrate BPPage No.: 1 of 3										
			_							
Specification No.: ACPL/FP/SP/036	Revision No.: 00	Effective Date 17/08/2021	Review Date 16/08/2024							
Change Control No. NA	Α									
Prepared By: Name : <u>Pankaj</u> (QC Of	Patel ficer / Designee)	Date: <u>1</u> ;	<u>3/08/02021</u>							
Reviewed By: Name : <u>Nilesh</u> (Unit F	Shah Head / Designee)	Date: <u>1</u> 4	<u>4/08/2021</u>							
	<u>n Solanki</u> C In Charge / Designee		<u>6/08/2021</u>							
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Format No. QC/017/F/01-00		Certified By (Sign/	Date): 17/08/2021							

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Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India											
Quality Control											
Standard Test Specifications Title: Potassium Citrate Monohydrate BP Page No.: 2 of 3											
Specification No.: ACPL/FP/SP/036	Revision No.: 00		ve Date 8/2021	Review Date 16/08/2024							
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: 6100-05	5.0 CAS No: 6100-05-6										
6.0 MOLECULAR I	6.0 MOLECULAR FORMULA: C ₆ H ₅ K ₃ 0 ₇ .H ₂ O										
7.0 MOLECULAR	7.0 MOLECULAR WEIGHT: 324.4 gm/mol.										
8.0 CATEGORY: Sy	stemic alkaliser.										
9.0 STORAGE: In an	9.0 STORAGE: In an airtight container.										
10.0 SAFETY PREC	CAUTIONS TO BE	TAKEN WHILE	SAMPLIN	NG AND HANDLING :							
Use hand gloves,	Use hand gloves, goggles and apron during Handling.										
11.0 CONTROL SAMPLE: 3 X 100 gm.											
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Quality Control										
	Standard Test Specifications									
Title: Pota	tle: Potassium Citrate Monohydrate BPPage No.: 3 of 3									
Specification No.:RevisionACPL/FP/SP/03600			Effective Date 17/08/2021		Review Date 16/08/2024					
Change	e Control No.	NA								
	TEST PARAMETERS AND SPECIFICATIONS REF: BP									
Sr. No.	TEST PARA	AMETER			SPECIFICAT					
1.	Appearance	White or almost white, granular powder or transparent crystals, hygroscopic.								
2.	Solubility Very soluble in water, practically insoluble in ethanol (96 %			oluble in ethanol (96 %).						
3.	Identification A The solution give reaction of citrate Identification B	To Pass test To Pass test								
4.	solution S gives reaction (b) of potassium Appearance of Solution The solution is clear a				and colorloss					
5.		The solution is clear and colorless								
5.	рН	7.5 to 9.0.								
6.	Acidity or alkalir	Not more than 0.2 mL of 0.1 M hydrochloric add or 0.1 M sodium hydroxide is required to change the colour of the indicator.								
7.	Readily carbonisable substances		The solution is not more intensely colored than reference solution Y_2 or GY_2 .							
8.	Chloride	Max. 50 ppm								
9.	Oxalates		Max. 300 ppm							
10.	Sulfates	Max. 150 ppm								
11.	Sodium		Max. 0.3 %	Max. 0.3 %						
12.	Water	4.0 % to 7.0 %								
13.	Assay % (Dried s	99.0 % - 101.0 %								
	ON HISTORY:									
Revision No. Effective				on Description	Change Control No.					
	00 17/08/2021				st Issuance	N A				
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ormat No. QC/017/F/01-00 Certified By (Sign/Date) : 17/08/2021										