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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test S	Specifications
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Page No.: 1 of 3 Title: Potassium Citrate Monohydrate USP

Revision No.: Specification No.: Review Date Effective Date ACPL/FP/SP/036 00 17/08/2021 16/08/2024

Change Control No. NA

> Prepared By: Date: 13/08/2021

Name : Pankaj Patel_

(QC Officer / Designee)

Reviewed By: Date: 14/08/2021

Name : Nilesh Shah_ (Unit Head / Designee)

Approved By: Date: 16/08/2021

Name : Naresh Solanki____

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):

17/08/2021

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Quality Control

Standard Test Specifications

Title: Potassium Citrate Monohydrate USP Page No.: 2 of 3

 Specification No.:
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 ACPL/FP/SP/036
 00
 17/08/2021
 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: 6100-05-6

6.0 MOLECULAR FORMULA: C₆H₅K₃O₇.H₂O

7.0 MOLECULAR WEIGHT: 324.41 gm/mol.

8.0 CATEGORY: Systemic alkaliser.

9.0 STORAGE: In an airtight container.

10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING:

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: Potassium Citrate Monohydrate USP **Page No.:** 3 of 3

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Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION		
1.	Appearance	White or almost white, granular powder or transparent crystals, hygroscopic.		
2.	Solubility	Very soluble in water, practically insoluble in ethanol (96 %).		
3.	Identification A Test for citrates and potassium	To Pass test		
4.	Assay % (Dried substance)	99.0 % - 100.5 %		
5.	Tartrate	To Pass test (No crystalline precipitate is formed)		
6.	Alkalinity	The Sample solution is alkaline to litmus. No pink color is produced after the addition of phenolphthalein.		
7.	Loss on Drying	3.0 % - 6.0 %		

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	17/08/2021	First Issuance	N A

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