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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Potassium Citrate Monohydrate IP Page No.: 1 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/036
 00
 17/08/2021
 16/08/2024

Change Control No. NA

Name

Prepared By: _____ Date: <u>13/08/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: 14/08/2021

(Unit Head / Designee)

: Nilesh Shah_

Approved By: _____ Date: 16/08/2021

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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Format No. QC/017/F/01-00

Certified By (Sign/Date):

Pai

17/08/2021

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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Potassium Citrate Monohydrate IP 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: 324.4 gm/mol.

8.0 CATEGORY: Systemic alkaliser.

9.0 STORAGE: Store protected from moisture.

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 IP **Page No.:** 3 of 3

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

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: IP

| Sr. No. | TEST PARAMETER | SPECIFICATION | |
|---------|--|---|--|
| 1. | Appearance | White, granular crystals or a crystalline powder; odourless hygroscopic. | |
| 2. | Solubility | Very soluble in water, practically insoluble in ethanol (96 %). | |
| 3. | Identification A A gives the of potassium salts Identification B The solution gives the reactions of citrates. | To Pass test To Pass test | |
| 4. | Appearance of Solution | The solution is clear and colorless | |
| 5. | Acidity or alkalinity | 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. | |
| 6. | Arsenic | Max. 2 ppm | |
| 7. | Heavy metals | Max. 10 ppm | |
| 8. | Sodium | Max. 0.3 % | |
| 9. | Chloride | Max. 100 ppm | |
| 10. | Oxalates | Max. 300 ppm | |
| 11. | Sulfates | Max. 150 ppm | |
| 12. | Readily carbonisable substances | The solution is not more intensely colored than reference solution YS2 or GYS2. | |
| 13. | Water | 4.0 % to 7.0 % | |
| 14. | Assay % (Dried substance) | 99.0 % - 101.0 % | |

REVISION HISTORY:

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

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