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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality	Control
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Title: Potassium Carbonate EP Page No.: 1 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0340013/08/202112/08/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_\_ Date: <u>10/08/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: 11/08/2021

Name : <u>Nilesh Shah</u> (Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: 12/08/2021

Name : Naresh Solanki\_\_\_\_\_

(QA/QC In Charge / Designee)

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**Certified By (Sign/Date):** 

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13/08/2021

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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 Carbonate EP Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0340013/08/202112/08/2024

**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:** 584-08-7

**6.0 MOLECULAR FORMULA:** K<sub>2</sub>CO<sub>3</sub>.

7.0 MOLECULAR WEIGHT: 138.2 gm/mol.

**8.0 CATEGORY**: Antacid; use in treatment of electrolyte deficiency.

**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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Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Potassium Carbonate EP Page No.: 3 of 3

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

 ACPL/FP/SP/034
 00
 13/08/2021
 12/08/2024

Change Control No. NA

# TEST PARAMETERS AND SPECIFICATIONS REF: EP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white granular powder, hygroscopic.	
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 %).	
3.	Identification A The solution is strongly alkaline Identification B 2 mL of the solution prepared for identification test A gives the reaction of carbonates and bicarbonates. Identification C 1 mL of the solution prepared for identification test A gives reaction (b) of potassium.	To pass test  To pass test  To pass test	
4.	Appearance of Solution.	Solution S is not more opalescent than reference suspension II and not more intensely colored than reference solution Y6.	
5.	Chlorides	Max. 100 ppm	
6.	Sulfates	Max. 100 ppm	
7.	Calcium	Max. 100 ppm	
8.	Iron (Fe)	Max. 10 ppm	
9.	Loss on drying	Max. 5.0 %	
10.	Assay %	99.0 % to 101.0 %	

#### **REVISION HISTORY:**

Revision No.	<b>Effective Date</b>	<b>Revision Description</b>	Change Control No.
00	13/08/2021	First Issuance	N A

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