## **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Standard	<b>Test Specifications</b>	
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Title: Potassium Carbonate JP 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: 10/08/2021

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):** 



13/08/2021

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Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Potassium Carbonate JP 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**: 138.21 gm/mol.

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

**9.0 STORAGE:** Containers—Tight containers.

#### 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 Carbonate JP Page No.: 3 of 3

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

**Change Control No.** NA

# TEST PARAMETERS AND SPECIFICATIONS REF: JP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Description	White granules or powder.	
2.	Solubility	Very soluble in water, and practically insoluble in ethanol (95 %).	
3.	Identification A Responds to Qualitative Tests for potassium salt and for carbonate.	To pass test	
4.	Clarity and color of solution	The solution is clear and colorless.	
5.	Heavy metals	Max. 20 ppm	
6.	Sodium	To Pass test (no persisting yellow color is produced)	
7.	Arsenic	Max. 4 ppm	
8.	Loss on drying	Max. 1.0 %	
9.	Assay %	Min. 99.0 %	

#### **REVISION HISTORY:**

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

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13/08/2021