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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test S ₁	pecifications
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Title: Potassium Bi Carbonate USP Page No.: 1 of 3

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

 ACPL/FP/SP/033
 00
 11/08/2021
 10/08/2024

Change Control No. NA

Prepared By: _____ Date: 07/08/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>09/08/2021</u>

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: _____ Date: 10/08/2021

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Pai

11/08/2021

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Quality Control

Standard Test Specifications

Title: Potassium Bi Carbonate USP Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0330011/08/202110/08/2024

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: 298-14-6

6.0 MOLECULAR FORMULA: KHCO₃

7.0 MOLECULAR WEIGHT: 100.12 gm/mol.

8.0 CATEGORY: Excipient.

9.0 STORAGE: Preserve in well-closed 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 100gm.

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Quality Control

Standard Test Specifications

Title: Potassium Bi Carbonate USP **Page No.:** 3 of 3

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/033 11/08/2021 10/08/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder or colorless crystals.
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 %)
3.	Identification A Test for Potassium Identification B Test for bicarbonates.	To pass test To pass test
4.	Assay (dried basis)	99.5 % – 101.5 %
5.	Loss on Drying	Max. 0.3 %
6.	Normal Carbonate(Measure the pH)	NMT 8.5

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	11/08/2021	First Issuance	N A

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11/08/2021