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	Quality Control Department			
Name of Raw Material	Sodium Bicarbonate			
Specification No.	RM/SPEC/HM/088-01	Supersedes No.	RM/SPEC/088-01	
Reference	IP/USP	Effective Date	05/04/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Mar'2030	

GENERAL INFORMATION

Pharmacopoeial reference : IP/USP

Special requirement of pack : Material should be packed in Laminated bag

Approved vendor : Please refer current approved vendor list.

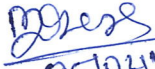
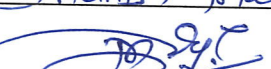
Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
110 g	220 g

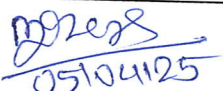
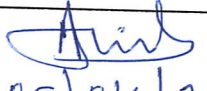
Retest Period : 12 Months

Storage : Store protected from moisture and preserve in well closed container

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Apurva S. Shinde	Manish Mahajan
Sign/Date	 05/04/25	 05/04/25	 05/04/25
Designation	SO. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

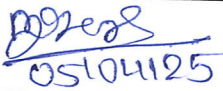
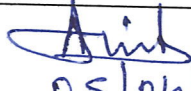
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Specification No.	RM/SPEC/HM/088-01			

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A white crystalline powder or small, opaque, monoclinic Crystals. It gradually forms sodium carbonates on heating in the dry state or in solution.	IP
		White, crystalline powder.	USP
02.	Solubility	Freely soluble in water, practically Insoluble in ethanol (95%).	IP
		Soluble in water, Insoluble in alcohol	USP
03.	Identification		
	Test A	A pale pink colour should be produced. On heating, a gas should evolved and the solution becomes red.	IP
	Test B : Reaction of Bicarbonates	Should liberate Carbon dioxide	IP
		A white precipitate should be produces immediately.	USP
	Test C: Solution A gives reaction of Sodium salts / Reaction of sodium	A dense white precipitate should be formed.	IP/USP
04.	Appearance of Solution	Solution A should be clear and colourless	IP
05.	Insoluble Substances	The resulting solution should be complete and clear.	USP
06.	Normal Carbonate #	The solution should not be assume more than a faint pink color immediately.	USP
07.	Arsenic	NMT 2 ppm	IP/USP
08.	Aluminum	NMT 2 µg/g	USP

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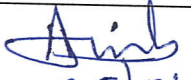
SR. NO.	TEST	SPECIFICATIONS	REFERENCE
09.	Calcium	Solution should be clear	IP
		NMT 0.01%	USP
10.	Heavy Metals	NMT 5 ppm	IP
11.	Carbonate [#]	pH should not more than 8.6	IP
		NMT 0.23%	USP
12.	Chlorides	NMT 200 ppm	IP
13.	Sulphates	NMT 150 ppm	IP
14.	Chloride and Sulfate	NMT 0.015%	USP
15.	Limit of sulfur compounds	NMT 0.015%	USP
16.	Magnesium	NMT 0.004%	USP
17.	Copper	NMT 1 ppm	USP
18.	Iron	NMT 20 ppm	IP
		NMT 5 ppm	USP
19.	Limit Of Ammonia	NMT 20 ppm	USP
20.	Limit of Organics	NMT 0.01%	USP
21.	Loss On Drying [#]	NMT 0.25 %	USP
22.	Assay [#] (On dried basis)	NLT 99.0 % to NMT 101.0 %	IP
		99.0 % to 100.5 %	USP
# : Re-evaluation tests			

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Sign/Date	 05/04/25	 05/04/25	 05/04/25

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REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	1) New pharmacopoeial grade document prepared as per approved Change control No. CC/QC/23/002 2) SPEC and ATR prepared as per approved change control No. CC/QC/25/008	05/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 05/04/25	 05/04/25	 05/04/25