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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department		Page No.	1 of 4
Name of Raw Material	Calcium Carbonate			
Specification No.	RM/SPEC/HM /083-01	Supersedes No.	RM/SPEC/083-01	
Reference	IP/BP/USP	Effective Date	10/04/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Mar'2030	

GENERAL INFORMATION

Pharmacopoeial reference : IP/BP/USP

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

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
100 g	200 g

Retest Period : 12 Months

Storage : Preserve in well closed container

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Mahajan
Sign/Date	10/04/25	10/04/25	10/04/2025
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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Name of Raw Material	Calcium Carbonate		
Specification No.	RM/SPEC/HM/083-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A fine, white microcrystalline powder.	IP
		White or almost white powder.	BP
		Fine, white, odorless, tasteless, microcrystalline powder. It is stable in air.	USP
02.	Solubility	Slightly soluble in water containing carbon dioxide or any ammonium salt; practically insoluble in water and in ethanol (95 %). It is soluble with effervescence in dilute acids.	IP
		Practically insoluble in water.	BP
		Practically insoluble in water, Insoluble in alcohol, Dissolves with effervescence in 1 N acetic acid, in 3 N hydrochloric acid and in 2 N nitric acid.	USP
03.	Identification		
	Test A: Reactions A & B of Calcium Salts	A) A White crystalline precipitate should be formed. B) A white precipitate should obtain that should only sparingly soluble in dilute acetic acid but should be soluble in hydrochloric acid.	IP/BP
	Test B: Reaction (A) of Carbonates	A white precipitate should form that dissolve on addition of an excess of dilute hydrochloric acid	IP/BP
	Test C: Calcium	A white precipitate should be formed which should be insoluble when 6 N acetic acid added but should be dissolve in Hydrochloric Acid	USP

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Name of Raw Material	Calcium Carbonate		
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SR. NO.	TEST	SPECIFICATIONS	REFERENCE
04.	Substances insoluble in acetic acid	The residue weigh should not more than 10 mg (NMT 0.2 %)	IP/BP
05.	Acid Insoluble Substances	NMT 0.2%; the weight of the residue should not exceed 10 mg.	USP
06.	Arsenic	NMT 4 ppm	IP
		NMT 3 ppm	USP
07.	Heavy Metals	NMT 20 ppm	IP
08.	Barium	The solution should be remains clear for not less than 15 minutes.	IP
		Should not impart a green color.	USP
09.	Iron	NMT 200 ppm	IP/BP
		NMT 0.1%; the absorbance of the solution from the Sample solution does not exceed that of the Standard solution.	USP
10.	Limit of Magnesium and alkali metals	The residue weight not more than 5 mg (NMT 1.0%).	IP/USP
		NMT 1.5 %	BP
11.	Limit of Fluoride	NMT 50 ppm	USP
12.	Chlorides	NMT 250 ppm	IP
		NMT 330 ppm	BP
13.	Lead	NMT 3 ppm	USP
14.	Mercury	NMT 0.5 ppm	USP
15.	Sulphates	NMT 0.3 %	IP
16.	Sulfates	NMT 0.25 %	BP

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novo EXCIPIENTS PVT. LTD.	**RAW MATERIAL SPECIFICATION** Quality Control Department	Page No.	4 of 4
Name of Raw Material	Calcium Carbonate		
Specification No.	RM/SPEC/HM/083-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
17.	Loss On Drying#	NMT 2.0 %	IP/BP/USP
18.	Assay# (on dried basis)	NLT 98.0 % to NMT 100.5 %	IP/USP
		98.5 % to 100.5 %	BP
# : Re-evaluation tests			

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	10/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	10/04/25	10/04/25	10/04/2025