



Bimal Pharma Pvt. Ltd. Mumbai, India

ISO 9001 : 2015



Cert. No.: 110661/A/0001/UK/En

TYPICAL CERTIFICATE OF ANALYSIS

Name of the Product : Calcium Carbonate, Granules (DC 90 %)

Batch No. : Typical COA

CAS No. : 471-34-1

Shelf Life : 5 Years

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Appearance	White Granules	Complies
2.	Odor	Odorless	Complies
3.	Solubility	Practically Insoluble in Water. Soluble in dilute HCl & Dilute Nitric Acid.	Complies
4.	Identification (EP)	Complies	Complies
5.	Substances Insoluble in Acetic Acid (BP)	NMT 0.2%	0.064%
6.	Substances Insoluble in HCL (USP)	NMT 0.2%	0.069%
7.	Fluoride (USP)	NMT 0.005%	<0.005%
8.	Sulphate (EP)	NMT 0.25%	<0.25%
9.	Barium (EP)	Must meet the requirement	Passes
10.	Heavy Metals (As Pb) (BP)	NMT 20.0 ppm	6.48 ppm
11.	Iron (BP)	NMT 200 ppm	<200 ppm
12.	Assay As CaCO_3 As Ca	NLT 90.0%	92.84%
		NLT 36.0%	37.14%
13.	Magnesium and Alkali Metals	NMT 1.0%	0.74%
14.	Sb + Cu + Cr + Zn + Ba	NMT 100.0 ppm	Complies
15.	Loss on Drying (BP)	NMT 2.0%	0.86%
16.	Organic Volatile Impurities (USP)	Must meet the requirement	Complies
Additional Test			
17.	Arsenic	NMT 0.6 ppm	<0.6 ppm
18.	Lead	NMT 0.2 ppm	<0.2 ppm
19.	Cadmium	NMT 0.4 ppm	Complies
Microbiological Specifications			
20.	1. Total Aerobic count 2. Total Yeasts and Moulds count 3. Escherichia Coli 4. Salmonella	NMT 1000 cfu/gms. NMT 100 cfu/gms. Absent Absent	120 cfu/gms. <10 cfu/gms. Absent Absent

Physical Analysis			
21.	Particle Size Sieve Analysis a) Retained on 30 Mesh b) Retained on 60 Mesh c) Retained on 240 Mesh	a) Max. 5.0% b) Max. 40.0% c) Min. 75.0%	a) 0.3% b) 36.8% c) 83.6%
22.	Bulk Density Tapped	Min. 0.95 gms/ml	1.20 gms/ml

Conclusion : The above product **Complies** to the prescribed standards of quality with respect to above tests as per **In-house specification** & also confirming to the standards of **BP / EP / USP**.