

SBF PHRMA

Mfg. Bulk Drug

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CERTIFICATE OF ANALYSIS

Product	Calcium Carbo	Calcium Carbonate					
Grade	Oyster Shell/ J	Oyster Shell/ JP					
Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.	
#05/23-24	#05/23-24	3000 kg	June-2023	5 Years	100 gm	G- 1498	
General Characteristics							

Properties	Specification	Result
Description	A White, Fine, Microcrystalline Powder	Complies
Solubility	Practically insoluble in water and in ethanol (95%), slightly soluble in water containing carbon dioxide or anyammonium salt. It is soluble with dilute acids	Complies
Identification (A)Reaction A and B ofCalcium Salt	 (i)Reaction A of Calcium Salts: A White, Crystalline Precipitate should be formed (ii)AWhite Precipitate should be obtained that is only sparingly soluble in dilute acetic but is soluble in hydrochloric acid. 	Complies Complies
(B)Reaction A of Carbonates	A White precipitate should be formed that dissolves onaddition of an excess of dilute hydrochloric acid	Complies
Substances insoluble in acetic acid	The residue should weigh not more than 10 mg	7 mg
Arsenic	Not more than 4 ppm	3 ppm
Heavy Metals	Not more than 20 ppm	13 ppm
Barium	The solution should remain clear for not less than 15 minutes	Complies
Iron	Not more than 200 ppm	166 ppm
Magnesium and alkali Metals	The residue weighs not more than 5 mg	3 ppm
Chloride	Not more than 250 ppm	188 ppm
Sulphates	Not more than 0.3%	0.1%
Loss on Drying (at 200°C)	Not more than 2.0%w/w	1.5%w/w
Assay (By Titrimetric)	It should contain not less than 98.0% and not more than 100.5% of C_aCO_3 calculated on the dry's basis	100.4%
Visible Foreign & Black Particles	The material should be free from visible foreign/ black particles	Complies
Particles Size	Not less than 99.0% should pass through 100 mesh	Complies
Bulk Density	Tapped density: Not less than 0.80 g/mL	0.89 g/mL
Total Aerobic microbial count	1,000 Cfu/g	Complies
Total yeast and mold count	100 Cfu/g	Complies
Escherichia Coli	Absent/g	Complies
Salmonella	Absent/10g	Complies
Pseudomonas Aeruginosa Salmonella	Absent/g	Complies
Staphylococcus aureus	Absent/g	Complies

Shelf Life					
Expiry/Re-Test Period:	5 Years after Date of Manufacture				
Quality Assurance/Certificate					
ISO	SBF Pharma Is ISO 9001:2015 Certified. Certificate No: 21DQHR27				
Halal	Our Product is Strictly Halal. Certificate No: 20ZKCM5040HL				
Kosher	Our Product is Strictly Kosher. Certificate No: UQ-1102101				
Note	All Certificates are Available on Request				
Certificate of Complian	nce				
GMO	The Product Does Not Contain any genetically Modified Organisms (GMO) or Raw Materials Used in Manufacturing of the same are also not Genetically Modified.				
Non – Irradiation	The Product was Never Subjected to any kind of Ionized Irradiation and Contains no Radioactivity not even in Monir Amounts.				
Allergens	The Product Does Not Contain any of the Below mentioned Allergens: Cereals Containing Gluten, Crustaceans, Eggs, Fish, Peanuts, Tree nuts, Soybeans, Milk, sesame, Seeds, Sulphur Dioxide and Sulphate (Concentrations > 10mg/kg)				
TSE/BSE	The Product is not Derived from animal/plant origin & hence this Product I free From Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). It is Synthetically Derived				
Residual Solvent	Class 1, Class 2, Class 3 & Table 4 Solvents are not used in the Production of Product.				
Vegetarians/Vegans	Our Product is Suitable for Consumption by Vegetarians and vegans				
Storage Recommendations	Store in a room temperature avoid direct sunlight.				

Analyzed By	Approved By
Kalpesh Nadiya	Kiran Mistry
Kolpesh	Kister