

## SBF PHARMA

Mfg. Bulk Drug

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## **Certificate of Analysis**

Product	Calcium Carbonate
Grade	IP/BP/USP(Heavy)

Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#01/ 24-25	#01/24-25	3000 kg	April-2024	5 Years	100 gm	G-1498

## **General Characteristics**

Properties	Specification	Result
Description	A White or almost white powder.	Complies
Solubility	Practically insoluble in water	Complies
Identification (A)Carbonate Test (B)Calcium Test	Must Comply with the test Must Comply with the test	Complies Complies
Substances insoluble in acetic acid	Max. 0.2%	0.1%
Arsenic	Not more than 3 ppm	2 ppm
Barium	Must Comply with the test	Complies
Iron	< 0.02 %	0.01%
Heavy Metals	Not more than 20 ppm	10 ppm
Lead	Not more than 3 ppm	2 ppm
Magnesium and alkali Metals	The residue weighs not more than 1.0%	1.0%
Chloride	NMT 250 ppm	Complies
Fluoride	50 ppm	37 ppm
Mercury	0.5 ppm	Complies
Sulphate	NMT 0.3%	Complies
Residual Solvents	meets the requirement	Complies
Loss on Drying	Not more than 2.0%, Determined on 1.000 g	1.3%
Assay (Dried Substance)	98 % to 100.5%	100.2%
In-house Specification – pH (10% W/v aqueous dispersion)	8.0 - 10.0	9.5
In-house specification - Bulk Density	Not less than 0.55 g/ml	0.55 g/ml

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 Complia	ince				
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
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