



# SBF PHARMA

Mfg. Bulk Drug

Block - 263/03, Santej  
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## Certificate of Analysis

Product	Talc Powder					
Grade	EP					
Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#09/24-25	#09/24-25	3000 kg	Nov-2024	5 Years	3000 KGS	G- 1498
General Characteristic/Chemical Analysis						
Test		Specification			Result	
Appearance		White or almost white powder			Complies	
Solubility		Practically insoluble in water and ethanol (96%)			Complies	
Identification – A IR		Matches Reference Spectrum			Complies	
Identification – B		Positive Reaction			Complies	
Identification – C		Positive Reaction			Complies	
Acidity and Alkalinity		pH within specified range			Complies	
Water Soluble Substances		NMT 0.1%			0.05%	
Lead (Pb)		NMT 10 ppm			2 ppm	
Aluminum (Al)		Positive Reaction			Complies	
Iron (Fe)		NMT 50 ppm			15 ppm	
Magnesium (Mg)		Positive Reaction			Complies	
Calcium (Ca)		Positive Reaction			Complies	
Loss on Ignition (1050-1100 °C)		NMT 8.0%			6.5%	
Microbiological Analysis						
A.	Total Aerobic Plate Count		100 cfu/g			Complies
B.	Total yeast & Mould Count		50 cfu/g			Complies

TEST	UNIT	LIMIT		RESULT
		Min.	Max.	
Whiteness	%	98	--	98.40%
Bulk Density	g/ml	0.2	0.5	0.41
pH	--	7	9	7.26
Mesh	%	99% passing through 200 mesh		Complies
Asbestos		Talc should be free from tremolite and chrysotile form of asbestos. Investigation by X-Ray diffraction for amphiboles and serpentines.		Absent.

<b>Shelf Life</b>	
Expiry/Re-Test Period: 5 Years after Date of Manufacture	
<b>Quality Assurance/Certificate</b>	
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
<b>Certificate of Compliance</b>	
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.

<b>Analyzed By</b>	<b>Approved By</b>
Kalpesh Nadiya	Kiran Mistry
	