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Certificate of Analysis

Product	Talc Powder					
Grade	IP/BP					
Report No.	Batch No.	Batch Qty.	Mfg.: Date	Exp: Date	Quantity	Drug lic no.
#06/23-24	#06/23-24	3000 kg	Nov-2023	5 Years	3000 KGS	G- 1498
General Characteristic/Chemical Analysis						
Test		Specification			Result	
Appearance		Light, homogeneous, white or almost white powder, greasy to the touch (non-abrasive)			Complies	
Solubility		Practically insoluble in water, in ethanol 96% and in the dilute solutions of acids and alkali hydroxides.			Complies	
Identification –A IR		The IR spectrum of a potassium bromide dispersion of it exhibits maxima at 3677 ± 2 cm^{-1} , at 1018 ± 2 cm^{-1} , and at 669 ± 2 cm^{-1} .			Complies	
Identification –B		A white, crystalline precipitate is formed.			Complies	
Identification –C		Gives the reaction of silicates			Complies	
Acidity and alkalinity		NMT 0.3 ml of 0.01 M sodium hydroxide is required to change the color of the indicator to pink			Complies	
Water soluble substances		Max 0.2%			Complies	
Lead		Max 10 ppm			<10	
Aluminum		Max 2.0 %			<2.0	
Iron		Max 0.25%			<0.25	
Magnesium		17.0 - 19.5%			18.54%	
Calcium		Max 0.9%			<0.9	
Loss on ignition(1050-1100 °C)		Max 7.0%			5.51	
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	0.40	0.45	0.41
pH	--	7	8	7.26
Mesh	%	Passing through 400#		99.51%
Asbestos	Talc should be free from tremolite and chrysotile form of asbestos. Investigation by X-Ray diffraction for amphiboles and serpentines.			Absent.

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 Compliance	
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
	