

SBF PHRMA

Mfg. Bulk Drug

Block - 263/03, Santej Ta-Kalol, Dis.-Gandhinagar, Gujarat - 382721. Phone-+91 79460 48549

Web: www.sbfpharma.com Certificate of Analysis Mail: info@sbfpharma.com

Product	Calcium Carbonate DC granules	Grade	IP/BP/USP

Report No.	Batch No.	Mfg.: Date	Exp: Date	Q	uantity	у	Drug lic no.	
#03/23-24	#03/23-24	June-2023	-		100 gm		G- 1498	
		General C	haracteristics					
		Wh	te Crystalline Po	wder		C	omplies	
Appearance Solubility		lı	In Water – Insoluble				Complies	
		In Dilute I	In Dilute Hydrochloric Acid – Soluble					
		In Dil	In Dilute Nitric Acid - Soluble				Complies	
		Chemic	al Analysis				<u> </u>	
Properties		Test Method	Unit	Min		Max	Result	
Identification		IH		To Com with Te		To Complies with Test	Complies	
Chloride		IH	ppm				<330	
Fluoride		USP	%	0.00		0.005	0.0025	
Sulphate		IH	%			0.25	<0.25	
Arsenic		IH	ppm		3.0		<3.0	
Barium		IH		To Com with Te		To Complies with Test	Complies	
Heavy Metals (as	s Pb)	IH	ppm			20	<20	
Iron		BP	Ppm			200	<200	
Lead		ICP-MS	ppm			0.125	Complies	
Cadmium		ICP-MS	Ppm			1.0	Complies	
Mercury		ICP-MS	Ppm		0.5		Complies	
Assay as CaCO ₃		IH	%	92.5			92.6	
As Ca			%	37.0	37.0		37.32	
Magnesium and Alkali Metals		IH	%		2.0		0.62	
Sb+Cu+Cr+Zn+Ba		E170	mg/kg	g 100		100	Complies	
Loss on Drying(1	g.105°,4H)	IH	%			2.0	0.74	
Organic Volatile Impurities		USP	%			To Complies with Test	Complies	
*Test Done at Re	egular Interval.							

Physical Analysis				
Particle Size/Sieve Analysis	IH	2.0% Max Retained on 16#	0.0	
		75.0% Max Retained on 60#	43.7	
		80.0% Max Retained on 200#	85.0	
Tapped Density	IH	0.95g/ml Min	1.40	
Storage Conditions	Meets shelf life if properly stored in a cool, dry conditions; unopened containers and no contamination has taken place.			

OPINION: The above product is declared as standard quality.

Binder Maltodextrin: The Raw Material Used i.e., Calcium Carbonate and Maltodextrin is of Pharmaceuticals Grade

Contaminants Results

Microbiological Analysis					
Properties		Unit	Minimum	Maximum	Result
Total Aerobic Microbial Count	IH	Cfu/gm	-	1000	Complies
Yeast & Mold		Cfu/gm	-	100	Complies
E. coli		Negative/g m	-	Negative/gm	Complies
Salmonella		Negative/g m	-	Negative/gm	Complies
Staphylococcus Aureus		Negative/g m	-	Negative/gm	Complies

Shelf Life				
Expiry/Re-Test Period: 5 Years after Date of Manufacture				
Quality Assurance/Co	ertificate			
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	nnce			
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		
rospesh	Kistery		