

SBF PHRMA

Mfg. Bulk Drug

Block - 263/03, Santej Ta-Kalol, Dis.-Gandhinagar, Gujarat - 382721. Phone-+91 79460 48549 Web: www.sbfpharma.com Mail: info@sbfpharma.com

Certificate of Analysis

Taste Odor Tasteless Odorless Practically insoluble in water and in them of (96 percent) It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric acid and in dilute nitric acid It Dissolve in dilute hydrochloric hydrochloric acid It Dissolve in dilute hydrochloric	Product	Dibasic Calcium Phosphate Dihydrate														
#05/23-24 #05/23-24 June-2023 5 Years 100 gm G- 1498 General Characteristics Appearance Taste Odor Gomplie Tasteless Odor Odores Practically insoluble in water and in ethanol (96 percent) It Disolve in dilute hydrochloric acid and in dilute nitric acid Complie Complie Solubility Unit Mini Maxi Result Properties Unit Mini Maxi Result Identification A, B & C - - Complies Acid insoluble substances % - 0.1 0.074 Carbonates - - Complies Complies Fluorides % - 0.25 <0.125	Grade	Direct Compressible (IP/BP/USP Grade)														
Appearance Taste White or almost white, crystalline granules Tasteless Compli Compli Odor Solubility Tasteless Compli Compli Practically insoluble in water and in ethanol (96 percent) It Dissolve in dilute hydrochloric acid and in dilute nitric acid Compli Compli Properties Unit Mini Maxi Result Identification A, B & C - Complies Acid insoluble substances % 0.1 0.074 Carbonates Complies Chlorides % 0.5 <0.5 Sulphates % 0.5 <0.5 Arsenic Ppm Complies Heavy metals (as Pb) Ppm 3.0 <3.0 Iron Ppm 400 <400 Loss on ignition (800°C to 825°) % 24.5 26.5 25.94 Assay % 98.0 105.0 100.14 *Test done at regular interval In House Cfu/gm - 1.000 Complies Complies Carbon	Report No.		Batch No.			Mfg.: Date		Exp: Date				Quantity		Drug lic no.		
Appearance Taste Odor White or almost white, crystalline granules Solubility Complie Complies Solubility Tasteless Odorless Odorless Solubility Complies Complie Solubility Practically insoluble in water and in ethanol (96 percent) It Dissolve in dilute hydrochloric acid and in dilute nitric acid Complies Complies Properties Unit Mini Maxi Result Complies Acid insoluble substances % 0.1 0.074 Carbonates 0.25 <0.125 Fluorides % 0.5 <0.125 Sulphates % 0.5 <0.125 Arsenic Ppm <- <0.5 Arsenic Ppm 3.0 <3.0 <3.0 Itera and mold count Ppm 3.0 <3.0 <3.0 Itera and mold count In House Cfu/gm - 1.000 Complies Salmonella In House 0.5% Maxi Retained on 200#BSS (500 micron) 0.0.8 Complies Salmonella <t< th=""><th colspan="3">#05/23-24 #05/23-24</th><th></th><th colspan="2">June-20</th><th></th><th colspan="2">5 Years</th><th></th><th colspan="2">100 gm</th><th></th><th colspan="2">G- 1498</th></t<>	#05/23-24 #05/23-24				June-20			5 Years			100 gm			G- 1498		
Taste Tasteless Odorless Unit Itage is a state is a						Genera	al Chara	acteri	stics					·		
PropertiesUnitMiniMaxiResultIdentification A, B & CCompliesAcid insoluble substances $\%$ 0.10.074Carbonates0.25CompliesChlorides $\%$ 0.250.125FluoridesPpm5021Sulphates $\%$ 0.50.5ArsenicPpm3.0< 3.0	Taste Odor			ר כ ק	Tasteless Odorless Practically insoluble in water and in ethanol (96 percent) It Dissolve in dilute hydrochloric acid and in dilute nitric acid							d	Complies Complies Complies Complies Complies			
Identification A, B & CCompliesAcid insoluble substances%0.10.074Carbonates0.25<0.125						CHE	r	ANAL	YSIS					[
Acid insoluble substances % 0.1 0.074 Carbonates Complies Chlorides % 0.25 <0.125	•			Unit	Unit			Mini			Maxi					
$ \begin{array}{ c c c c } Carbonates & & & & & Complies \\ \hline Chlorides & \% & & 0.25 & <0.125 \\ \hline Fluorides & Ppm & & 50 & 21 \\ \hline Sulphates & \% & & 0.5 & <0.5 \\ \hline Arsenic & Ppm & & 3.0 & <3.0 \\ \hline Barium & & & & & Complies \\ \hline Heavy metals (as Pb) & Ppm & & 30 & <30 \\ \hline Iron & Ppm & & 400 & <400 \\ \hline Loss on ignition (800°C to 825°) & \% & 24.5 & 26.5 & 25.94 \\ \hline Assay & \% & 98.0 & 105.0 & 100.14 \\ \hline *Test done at regular interval & $V'' & 98.0 & 105.0 & 100.14 \\ \hline *Test done at regular interval & $V'' & Absent/g \\ \hline Salmonella & & Physical Analysis & Cfu/gm \\ \hline Salmonella & & & & \\ \hline Particle size/Sieve analysis & In House & $0.5\% Maxi Retained on 200# BSS (500 micron) \\ \hline Particle size/Sieve analysis & & \\ \hline In House & & & & \\ \hline Di House & & & & \\ \hline Occ Maxi Retained on 200# BSS (500 micron) \\ \hline 90.0\% Mini Retained on 200# BSS (500 micron) \\ \hline 90.0\% Mini Retained on 200# BSS (550 micron) \\ \hline 99.2 \\ \hline \end{array}$														-		
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	Acid insoluble substances			%	%						0.1					
FluoridesPpm5021Sulphates%0.5<0.5																
Sulphates $\%$ 0.5 <0.5ArsenicPpm 3.0 <3.0																
Arsenic Ppm 3.0 <3.0 Barium Complies Heavy metals (as Pb) Ppm 30 <30																
BariumCompliesHeavy metals (as Pb)Ppm 30 <30																
Heavy metals (as Pb) Ppm 30 <30 Iron Ppm 400 <400				Ppm	Ppm											
Iron Ppm 400 <400 Loss on ignition (800°C to 825°) % 24.5 26.5 25.94 Assay % 98.0 105.0 100.14 *Test done at regular interval Microbiological Analysis Total Aerobic microbial count Total yeast and mold count Escherichia Coli Salmonella In House Cfu/gm Cfu/gm Absent/g 1,000 Complies Complies Physical Analysis District Size/Sieve analysis In House 0.5% Maxi Retained on 20# BSS (500 micron) 90.0%Mini. Retained on 200#BSS (75 micron) 98.0% 98.1 99.2 87.2 98.1 99.2																
Loss on ignition (800°C to 825°) % 24.5 26.5 25.94 Assay % 98.0 105.0 100.14 *Test done at regular interval Microbiological Analysis 100.14 Total Aerobic microbial count Total yeast and mold count Escherichia Coli Salmonella In House Cfu/gm 1,000 Complies Complies Particle size/Sieve analysis In House 0.5% Maxi Retained on 20# BSS (500 micron) 0.08 Particle size/Sieve analysis In House 0.5% Maxi Retained on 200#BSS (75 micron) 98.0% 98.1 Mini Retained on 300# BSS (53 micron) 99.2																
Assay % 98.0 105.0 100.14 *Test done at regular interval Microbiological Analysis Total Aerobic microbial count Total yeast and mold count Escherichia Coli Salmonella In House Cfu/gm Cfu/gm Absent/g 1,000 Complies Complies Complies Complies Particle size/Sieve analysis In House 0.5% Maxi Retained on 20# BSS (500 micron) 60.0%Mini. Retained on 200#BSS (75 micron) 98.0% 90.0%Mini Retained on 300# BSS (53 micron) 0.08 87.2				-												
*Test done at regular interval Microbiological Analysis Total Aerobic microbial count Total yeast and mold count Escherichia Coli Salmonella Particle size/Sieve analysis Particle size/Sieve analysis Mini Retained on 20# BSS (53 micron) Mini Retained on 300# BSS (53 micron) Mini Retained on 300# BSS (53 micron) 99.2																
Microbiological Analysis Total Aerobic microbial count In House Cfu/gm 1,000 Complies Total yeast and mold count Cfu/gm 100 Complies Escherichia Coli Absent/g Absent/g Complies Salmonella Physical Analysis Absent/g Complies Particle size/Sieve analysis In House 0.5% Maxi Retained on 20# BSS (500 micron) 0.08 60.0%Mini. Retained on 200#BSS (150 micron) 87.2 98.1 90.0%Mini Retained on 300# BSS (53 micron) 98.1 99.2				%	%			98.0			105.0			100.14		
Total Aerobic microbial count Total yeast and mold count Escherichia Coli SalmonellaIn HouseCfu/gm Cfu/gm 1,000Complies Complies Complies Absent/g Particle size/Sieve analysisIn House0.5% Maxi Retained on 20# BSS (500 micron) 90.0%Mini Retained on 200#BSS (75 micron) 98.0% 99.20.08Mini Retained on 300# BSS (53 micron)99.2	Test done at	regular i	llerval			Microh	niologic	al Ana	alvsis							
Particle size/Sieve analysisIn House0.5% Maxi Retained on 20# BSS (500 micron)0.0860.0%Mini. Retained on 100#BSS (150 micron)87.290.0%Mini Retained on 200#BSS (75 micron) 98.0%98.1Mini Retained on 300# BSS (53 micron)99.2	Total yeast and mold count Escherichia Coli			In			Cfu/g Cfu/g Abser	Cfu/gm Cfu/gm Absent/g		10 At) sent/g	Con Con	Complies Complies		
60.0%Mini. Retained on 100#BSS (150 micron) 87.2 90.0%Mini Retained on 200#BSS (75 micron) 98.0% 98.1 Mini Retained on 300# BSS (53 micron) 99.2				T		Phy	sical Aı	nalysi	S							
	Particle size/Sieve analysis			In Ho	60.0% 90.0%Mi			Mini. Retained on 100#BSS (150 micron) ni Retained on 200#BSS (75 micron) 98.0%					8 6 9	87.2 98.1		
	,			In ho	ouse	g/ml			0.70				0.84			
6/····	Tapped Opinion: The Above Product is Declared a						ml 0.			J.85			0.94			

Shelf Life					
Expiry/Re-Test Period	d: 5 Years after Date of Manufacture				
Quality Assurance/C	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 Compli	ance				
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	Kistery