

Bimal Pharma Pvt. Ltd.



FSSAI LICENSE NO. : 10012022000599

DRUGS LIC. NO. : 256768 & 256769 | GSTIN NO. : 27AABCB9186E1ZJ

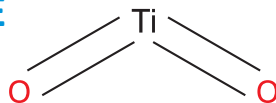
CIN : U51397MH2002PTC137273 | AEO T1 NO.: INAABCB9186E1F180

TITANIUM DIOXIDE (PIGMENT WHITE 6)

FOOD / PHARMA GRADE



First Time in India



Approved for use in Food, Pharma & Cosmetic Industries Matching to
E-171 / FCC IX / BIS & FDA 21 CFR Matching to IP / BP / EP / USP / JP

PURITY STANDARDS

It meets the chemical purity specifications of the major Pharmacopoeia and the EEC and US Federal and Indian BIS requirements for pigments in the Food and Cosmetics sector.

Commission Directive 95/45/EC	E-171 (for use in Food Stuff)
FDA Regulation 21 CFR	73.1575 (Pharma) 73.575 (Foods) 73.2575 (Cosmetics)
Indian FSSAI Rules	Matching to BIS spec.
European / British / Indian Pharmacopoeia	EP / BP / IP
Pharmacopoeia of the USA	USP (Pharma) FCC IX (Food)



HEALTH CERTIFICATE



COO by IMC

Certificates :



FEDERATION OF INDIAN
EXPORT ORGANISATIONS
Setup By Ministry Of Commerce, Governments Of India

FSC (FREE SALE CERTI.)
BY FIEO

Purity Requirements for Direct Addition to Human Foods

● E-171: In Europe ● FDA 21 CFR : In United States ● BIS : In India

Sr. No	Particulars	E-171	FDA 21 CFR	BIS	OUR QUALITY
1	TiO ₂ content [%]	Min. 99.00	Min. 99.00	Min. 99.0	>99.00
2	Loss on drying [%]	Max. 0.50	-	Max. 0.5	<00.20
3	Loss on ignition [%]	Max. 0.50	Max.0.50	Max 0.50	<00.30
4	Al ₂ O ₃ and/or SiO ₂ [%]	Max. 2.00	Max. 2.00	Max. 2.0	<00.02
5	Acid soluble salts [%]	Max. 0.50	Max. 0.50	Max 0.35	<00.35
6	Water soluble salts (hot) [%]	Max. 0.50	Max. 0.50	Max. 0.25	<00.25
7	Cadmium (Total content) [mg/kg]	Max. 1.00	-	-	< 1.00
8	Antimony (Total content) [mg/kg]/ppm	Max. 50.00		Max. 2.00	<2.00
9	Antimony (HCL soluble) [mg/kg]/ppm	-	Max.2.00	-	<2.00
10	Arsenic (Total content) [mg/kg]/ppm	Max. 3.00		Max 1.00	<1.00
11	Arsenic (HCL soluble) [mg/kg]	-	Max. 1.00	-	<1.00
12	Lead (Total content) [mg/kg]	Max. 10.00		Max. 10	<10.00
13	Lead (HCL soluble) [mg/kg]	-	Max. 10.00		<10.00
14	Mercury (Total content) [mg/kg]	Max. 1.00		Max. 1	<1.00
15	Mercury (HCL soluble) [mg/kg]	-	Max. 1.00	-	<1.00
16	Zinc (Total content) [mg/kg]	Max. 50.00	-	Max. 50	<10.00

Applications in Foodstuffs:

- As Colorant for sugar products, Candy, Chewing gum, Coffee whitener.
- As Colorant for Cakes and Mayonnaise , Cookies, Biscuits and White Chocolate, Mints, Edible Icing Sheets etc.
- Cosmetics : Toothpaste and Sunscreen.



Purity Requirements for Direct use in Medicines

Sr. No	Particulars	BP / EP	USP	IP	OUR QUALITY
1	Characters	White Powder	White Powder	White Powder	White Powder
2	Appearance of the solution	As per BP/ EP	-	As per IP	Complies
3	Acidity or Alkalinity	As per BP/ EP	-	As per IP	Complies
4	Water-soluble substances	Max. 25 mg	Max 0.25%	NMT 0.5%	<0.25%
5	Acid-soluble substances (%)	-	Max. 0.5	-	<0.35
6	Antimony (HCl soluble) ppm	Max. 100	-	-	<2.00
7	Arsenic (HCl soluble) (ppm)	Max. 5	Max. 1	Max. 5	<1.00
8	Barium	As per BP /EP	-	As per IP	Complies
9	Heavy metals (HCl soluble) (ppm)	Max 20	-	Max.20	<10.00
10	Iron (ppm)	Max 200		Max. 200	Complies
11	Loss on drying (%)	-	Max 0.5	-	<0.20
12	Loss on ignition(%)	-	Max. 0.5	-	<0.30
13	Assay (%)	98.0 - 100.5	99.0 – 100.5	98.0 – 100.5	>99.00
14	Organic volatile impurities	-		-	
	Chloroform		60 ug per gm		<1 ug per gm
	1,4-Dioxane		380 ug per gm		<10 ug per gm
	Dichlormethane		600 ug per gm		<1 ug per gm
	Trichlorethylene		80 ug per gm		<1 ug per gm

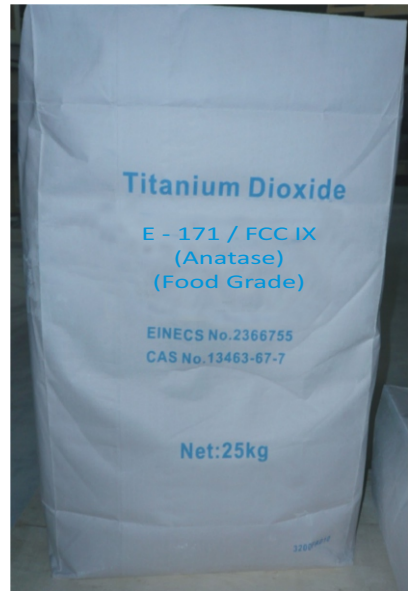
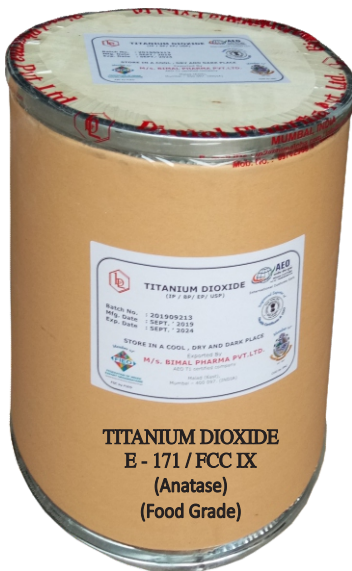
Applications in Pharmaceuticals : Coloring Agent for

- Capsules
- Films
- Tablets
- Medical Sticky Tapes.
- Ointments
- Lotions
- Coated Pills
- Pellets
- Empty Hard Gelatin Capsule (EHGC)



Shelf Life : 5 Years

Packing : 25 Kgs. Fibre Drums / PP Bags



USES IN FOOD & PHARMA INDUSTRIES



Cake Glazes



Pharma Pellets



Using Edible icing sheets



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