

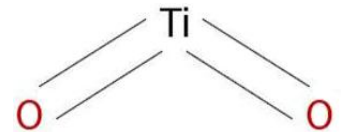
# Bimal Pharma Pvt. Ltd.



FSSAI LICENSE NO. : 10012022000599  
DRUGS LIC. NO. : 20-B : 256768 & 21-B : 256769  
CIN : U51397MH2002PTC137273  
GSTIN NO. : 27AABCB9186E1ZJ



## TITANIUM DIOXIDE, FOOD / PHARMA GRADE



### First Time in India

Approved for use in Food and Pharma Inds.  
Matching to E-171 / FCC / BIS & FDA 21 CFR  
Matching to IP / BP/ EP / USP

#### 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 (Food)



## Purity Requirements for Direct Addition to Human Food

- 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 <sub>2</sub> 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 <sub>2</sub> O <sub>3</sub> and/or SiO <sub>2</sub> [%]	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 etc...
- Cosmetics : Toothpaste and Sunscreen Cream.



## Purity Requirements for Direct use in Medicine

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%	<00.25%
5	Acid-soluble substances (%)	-	Max. 0.5	-	<00.35
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	-	<00.20
12	Loss on ignition(%)	-	Max. 0.5	-	<00.30
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

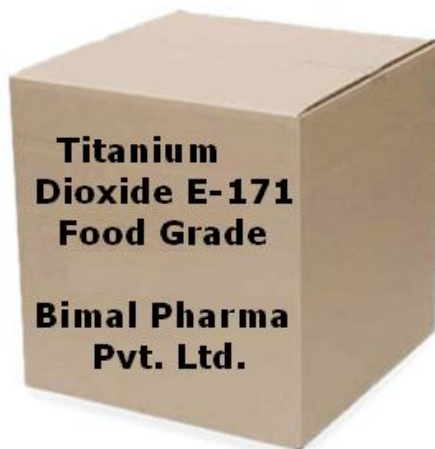
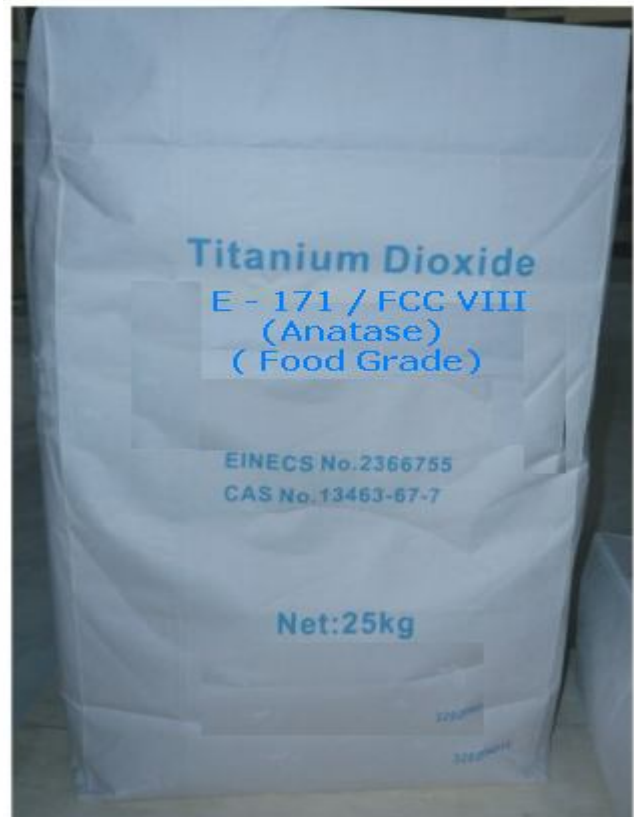
### Applications in Pharmaceuticals : Coloring Agent for

- Capsules   ● Films   ● Tablets   ● Coated Pills   ● Medical Sticky Tapes.
- Ointments   ● Lotions   ● Pharma Pellets



**Shelf Life : 5 Years**

Packing : 25 Kgs. Fibre Drums / PP Bags / 5 Kgs. Cartons



Food Safety and Standards Authority of India

FSSAI License No.: 10012022000599

## BIMAL PHARMA PVT. LTD.

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