

SPECIFICATION OF TITANIUM DIOXIDE, PHARMA GRADE (IP / BP / EP / USP / JP)



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ISO 9001 : 2015 & AEO T1 Certified

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URS : UKAS

Technical Information

- **NOMENCLATURE** : Titanium dioxide
: Titanium (IV) oxide
: Titanium white
: Titania
: Pigment White 6 (PW6)
- **HSN CODE** : 32061110 / 28230000
- **CAS NO.** : 13463-67-7
- **EMPIRICAL FORMULA** : TiO_2
- **MOL. WT.** : 79.87
- **MELTING POINT** : 1843 °C
- **STRUCTURAL FORMULA** : $O=Ti=O$

Technical Specification

- **DESCRIPTION** : White, Amorphous Powder
: Odorless Powder
- **SOLUBILITY** : Insoluble in Water
- **IDENTIFICATION** : A) When strongly heated, it becomes Pale Yellow, the color disappears on cooling.
B) To 5.0ml of solution S₂, add 01ml of strong H₂O₂ solution R, an Orange Red color appears.
C) To 5.0ml of solution S₂, add 0.5gm of Zinc R in granules, after 45 min, the mixture has a Violet Blue color.
- **pH (50% Water Suspension)** : 6.0 to 8.0
- **LEAD** : NMT 10 mg / kg. (10 ppm Max)
- **ARSENIC (As)** : NMT 1 mg / kg. (1 ppm Max)

- **ANTIMONY** : NMT 2 mg / kg. (2 ppm Max)
- **MERCURY** : NMT 1 mg / kg. (1 ppm Max)
- **BARIUM** : Should Comply
- **IRON** : NMT 200 ppm
- **LOSS ON DRYING**
(105°C, 3 hrs) : NMT 0.50%
- **LOSS ON IGNITION (800°C)** : NMT 0.50%
- **WATER SOLUBLE SUBSTANCES** : NMT 0.25%
- **ACID SOLUBLE SUBSTANCES** : NMT 0.50%
- **ASSAY** : 99.0% to 100.5%
- **ORGANIC VOLATILE IMPURITIES** :
 - CHLOROFORM** 60 µG Per G Max
 - 1, 4- DIOXANE** 380 µG Per G Max
 - DICHLOROMETHANE** 600 µG Per G Max
 - TRICHLOROETHYLENE** 80 µG Per G Max
- **PACKING** : 25 Kgs. PP Bag with single LDPE Liners
: 25 kgs. Fibre Drum with PE Liner inside

Comparison of Parameters under different Standards & our Top-Notch Quality

Sr. No.	Particulars	BP/ EP	USP	IP	JP	OUR QUALITY
1	Characters	White Powder	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%	NMT 0.25%	<00.25%
5	Acid Soluble Substances (%)	-	Max. 0.5	-	NMT 0.5	<00.35
6	Antimony (HCL soluble) (ppm)	Max. 100	-	-	-	<2.00
7	Arsenic (HCL soluble) (ppm)	Max. 5	Max. 1	Max. 5	Max.1.3	<1.00
8	Barium	As per BP /EP	-	As per IP	-	Complies
9	Heavy Metals (HCL soluble) (ppm)	Max. 20	-	Max. 20	Max. 10	<10.00
10	Iron (ppm)	Max. 200	-	Max. 200	-	Complies
11	Loss on Drying (%)	-	Max. 0.5	-	Max. 0.5	<00.20
12	Loss on Ignition (%)	-	Max. 0.5	-	Max. 0.5	<00.30
13	Assay (%)	98.0 -100.5	99.0 -100.5	98.0 -100.5	99.0 -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

Heavy Metals Contents, Tested by Independent Professional Testing Laboratory, NABL & FSSAI approved (By one Lab.)

Sr. No.	Parameters	Units	Results of Analysis	Limits as per FCC
1	Lead	mg/kg	BLQ	Max. 10
2	Cadmium	mg/kg	BLQ	Not Specified
3	Copper	mg/kg	BLQ	Not Specified
4	Arsenic	mg/kg	BLQ	Max. 1
5	Tin	mg/kg	BLQ	Not Specified
6	Methyl Mercury as Mercury	mg/kg	BLQ	Not Specified
7	Mercury	mg/kg	BLQ	Max. 1

BLQ - Below Limit of Quantification

LOQ (Limit of Quantification) for Heavy Metals = 0.5mg/kg

FCC : Food Chemical Codex

Heavy Metals Contents & Other Critical Parameters, Tested by Independent Professional Testing Laboratory, NABL & FSSAI approved (By the other Lab.)

Sr. No.	Test Parameters	Test Results	Specification
1	Loss on Drying	0.31%	NMT 0.5%
2	Loss on Ignition	0.26%	NMT 1.0%
3	Water Soluble Substance	0.17%	NMT 0.5%
4	Acid Soluble Substance	0.31%	NMT 0.5%
5	Lead	Not Detected	NMT 10.0 mg/kg
6	Cadmium	Not Detected	NMT 1.0 mg/kg
7	Mercury	Not Detected	NMT 1.0 mg/kg
8	Arsenic	Not Detected	NMT 1.0 mg/kg

