



M/s. BIMAL PHARMA PVT. LTD. MUMBAI (INDIA)	FINISHED PRODUCT INFORMATION
QUALITY CONTROL AND ASSURANCE	PRODUCT : TITANIUM DIOXIDE, IP / BP / EP / USP / JP
MSDS No.: BPPL 137 (Available on Request)	SPECIFICATION No.: FP-137 (Enclosed)

1. **NOMENCLATURE** : Titanium dioxide
: Titanium(IV) oxide
: Titanium white
: Titania
: Pigment White 6
2. **CAS NO.** : 13463-67-7
3. **HSN CODE** : 32061110
4. **EMPIRICAL FORMULA** : TiO_2
5. **MOL. WT.** : 79.87
6. **MELTING POINT** : 1843 °C
7. **STRUCTURAL FORMULA** : $O=Ti=O$
8. **DESCRIPTION** : White, Amorphous Powder
: Odorless Powder
9. **APPLICATION IN** : **Manufacturing of** Tablets, Ointments
And Lotions.
: **Manufacturing of EHGC** (Empty Hard
Gelatin Capsule)
: **Cosmetics** : For high Quality Eye and
Face make-ups, Lip sticks, Nail Lacquers,
Toothpastes etc.

M/s. Bimal Pharma Pvt. Ltd.

Website : www.titaniumdioxidepharmaindia.com

M/s. BIMAL PHARMA PVT. LTD. MUMBAI (INDIA)	FINISHED PRODUCT PHARMACOPOEIAL SPECIFICATION
QUALITY CONTROL AND ASSURANCE	PRODUCT : TITANIUM DIOXIDE, IP / BP / EP / USP / JP (US FDA : 21CFR:73.575)
MSDS No.: BPPL 137 (Available on Request)	SPECIFICATION No.: FP-137 (Enclosed)

1. **DESCRIPTION** : White, Amorphous Powder
: Odorless Powder
2. **SOLUBILITY** : Practically insoluble in water. It does not dissolve in dilute mineral acids but dissolves slowly in hot concentrated Sulphuric Acid.
3. **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 45min, the mixture has a Violet Blue color.
4. **ACIDITY OR ALKALINITY** : Not more than 1.0 ml of 0.01M HCl Acid or 0.01M NaOH is required to change the colour of the Solution.
5. **pH Value (10% Solution)** : 6.0 to 8.4
6. **LEAD** : NMT 10 mg / kg. (10 ppm Max.)
7. **ARSENIC** : NMT 1 mg / kg. (1 ppm Max.)
8. **ANTIMONY** : NMT 2 mg/kg. (2 ppm Max.)
9. **MERCURY** : NMT 1 mg / kg. (1 ppm Max.)

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10. CADMIUM	:	NMT 1 mg / kg. (1 ppm Max.)
11. BARIUM	:	Should comply
12. IRON	:	NMT 200 ppm
13. LOSS ON DRYING (105 °C, 3 hrs)	:	NMT 0.50%
14. LOSS ON IGNITION (800 °C)	:	NMT 0.50%
15. WATER SOLUBLE SUBSTANCE	:	NMT 0.25%
16. ACID SOLUBLE SUBSTANCE	:	NMT 0.50%
17. ASSAY	:	99.0 % to 100.5%
18. RETENTION OF MATERIAL ON 400 MESH	:	0.5% Max.
19. Al₂O₃ and / or SiO₂	:	0.5% Max.
20. WHITENESS	:	98.0% Min.

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**21. 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

22. MICROBIOLOGY TEST

TOTAL AEROBIC COUNT	100 cfu/gms. Max.
YEAST & MOULDS	100 cfu/gms. Max.

23. STORAGE : It can be stored at Room Temp. below 28°C

24. PACKING : 25 kgs. Fibre Drum with PE Liner inside.