



M/s. BIMAL PHARMA PVT. LTD.
Mumbai, India

TYPICAL CERTIFICATE OF ANALYSIS

Name of Product : TITANIUM DIOXIDE, IP / BP / EP / USP / JP

Batch No. : Typical COA

Standards : IP / BP / EP / USP / JP

Shelf Life : 5 Years

CAS No. : 13463-67-7

Sr. No.	Item	Specification	Result
1.	Characteristics	White or Almost White Odorless Powder	White Odorless Powder
2.	Identification	a) When strongly heated, it becomes Pale Yellow, the colour disappears on cooling. b) To 5.0ml of solution S ₂ , add 0.1ml of strong H ₂ O ₂ solution R, an Orange Red colour appears. c) To 5.0ml of solution S ₂ , add 0.5gm of Zinc R in granules, after 45min, the mixture has a Violet Blue colour.	Conforms
3.	Solubility	Practically insoluble in water. It does not dissolve in dilute mineral acids but dissolves slowly in hot concentrated Sulphuric Acid.	Conforms
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.	Conforms
5.	Appearance of Solution	Colorless, Not more opalescent than Reference Solution.	Conforms
6.	Loss on Drying	0.5% Max. (105°C, 3Hrs.)	0.27%
7.	Loss on Ignition	0.5% Max. (800°C)	0.30%
8.	pH Value (10% Solution)	6.0 – 8.4	7.22
9.	Water Soluble Substance	0.25% Max.	0.16%
10.	Acid Soluble Substance	0.5% Max.	0.24%
11.	Lead (0.5N HCl Soluble)	10 ppm Max.	3.25 ppm
12.	Arsenic (0.5N HCl Soluble)	1 ppm Max.	0.60 ppm
13.	Antimony (0.5N HCl Soluble)	2 ppm Max.	0.57 ppm
14.	Mercury (0.5N HCl Soluble)	1 ppm Max.	< 0.01 ppm
15.	Cadmium (0.5N HCl Soluble)	1 ppm Max.	< 0.01 ppm
16.	Barium	Opalescent Not More Intense Than Reference	Conforms
17.	Iron	200 ppm Max.	25.51 ppm
18.	Retention of Material on 400 Mesh	0.5% Max.	0.01%
19.	Al ₂ O ₃ and / or SiO ₂	0.5% Max.	<0.1%
20.	Whiteness	98.0% Min.	98.60%
21.	Assay (TiO ₂)	99.0 - 100.5%	99.20%

22.	Organic Volatile Impurities Chloroform 1, 4- Dioxane Dichloromethane Trichloroethylene	60 µG Per G Max. 380 µG Per G Max. 600 µG Per G Max. 80 µG Per G Max.	<1 µG Per G <10 µG Per G <1 µG Per G <1 µG Per G
23.	Microbiology Test Total Aerobic Count Yeast & Moulds	100 cfu/gms. Max. 100 cfu/gms. Max.	Conforms Conforms
24.	Enterobacteriaceae, E.coli, Salmonella, P.aeruginosa, S. auerus, Clostridia	Not Detected	Conforms
Conclusion : Complies with IP / BP / EP / USP / JP			