Titanium Dioxide in Pharmaceutical Industries

Introduction

- It occupies the most Vital Role and plays an essential Role, from **C**olouring to Packaging, at all stages of a Pharmaceutical product's Lifecycle.

- It meets the most stringent of requirements governing the safety of Medicines, including those set by IP, BP, EP, JP & also USP.

- It performs a number of Important Functions that apply to all stages of a Pharma product's lifecycle,
  - From protecting the ingredients,
  - To making a Medicine easier to identify or take.

- It serves the following functions,

  - **As a Pigment :**

    It is used to add whiteness or accentuate the boldness of other colours.

    It helps tablets stand out for both Medical Professionals and Patients, to differentiate the strengths of the same Medication.

  - **In Coatings :**

    It is an essential component of the Tablet Coating, necessary to preserve the Safety, Efficacy and Quality of the Active Pharmaceutical Ingredient (APIs), and to provide Shelf-Life Stability.

    It offers protection for Photosensitive Ingredients, which could be damaged by visible light, and also offer protection to the APIs / Ingredients that may be vulnerable to Ultraviolet (UV) light degradation.

  - **In Packaging :**

    It is widely used in protective films for Tablet Strips and Blisters, as well as in external Cartons.

    This is because of its ability to scatter light and absorb UV rays, means it is routinely incorporated in the packagings of Medicines to maintain Shelf Life and prevent any Premature Degradation from Moisture, Heat or Light.

M/s. Bimal Pharma Pvt. Ltd.
Mumbai, India.

Technical Information

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

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 S_2, add 01ml of strong H_2O_2 solution R, an Orange Red color appears.

  C) To 5.0ml of solution S_2, 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)

M/s. Bimal Pharma Pvt. Ltd.
Mumbai, India.

- **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 Bags with single LDPE Liners
  : 25 kgs. Fibre Drum with PE Liner inside

Applications

- It is used in almost all Pharmaceutical Formulation because of its following characteristics ;
  - It adds Whiteness to Tablets & Capsules.
  - It is used to accentuate the Boldness of other Colours.
  - To differentiate the different strengths of the same Medicines.
  - In the coating it is used to preserve the Safety, Efficacy & Quality of the APIs.
  - It also provides Shelf Life Stability.
  - It offers Protection for Photosensitive Ingredients.
  - It is used in packagings of Medicines to maintain Shelf Life and prevent any Premature Degradation from Moisture, Heat or Light.

Examples : Tablets, Capsules, Pharma Pellets, Empty Hard Gelatin Capsule (EHGC), Ointments, Medical Sticky Tapes & Packagings like Strips & Blisters etc.

M/s. Bimal Pharma Pvt. Ltd.
Mumbai, India.

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 1,4-Dioxane Dichlormethane Trichlorethylene	-	 60 ug per gm 380 ug per gm 600 ug per gm 80 ug per gm	-	-	 <1 ug per gm <10 ug per gm <1 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

M/s. Bimal Pharma Pvt. Ltd.
Mumbai, India.

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