

CERTIFICATE OF ANALYSIS

Product Name: Titanium Dioxide (Oil Disp) (Representative Sample, actual values will vary on lot number) Expiration Date: 5 years from Manf Date. Country of Origin: Canada Analysis Laboratory: Germany

The most stringent requirement of the pharmacopoeias mentioned above has been determined as specification limit.

USP Chapter <467> Residual Solvents

During the production process of Titanium Dioxide no solvents are used, so no residual solvents are to be expected in the final products.

Titanium Dioxide is in compliance with ICH Guideline Q3C (R6) on Impurities: Guideline for Residual Solvents. Is not exposed to any of the class 1,2, or 3 solvents (organics volatile impurities) addresses in the current US Pharmacopoeia (USP) chapter <467> during manufacturing,handling, or storage. Since there is no potential for the above named substances to be present, testing is not performed as prescribed in the current USP Chapter <467> If tested for residual solvents, Titanium Dioxide would comply with the standards established in the current USP chapter <467>

Property	Unit	Standard based on	Value	Limits
Identity		DIN EN 13925-3		complying
Assay, Titanium Dioxide (TiO2)	%(m)	DIN EN ISO 591-1		98.0 - 100.5
Assay, Titanium Dioxide (TiO ₂) (calc. to dried substance)	%(m)	DIN EN ISO 591-1		99.0 - 100.5
Appearance		EU No.231/2012	white to almost white powder	
Solubility		EU No.231/2012	meets specification El	J No. 231/2012
Clarity / Colour of Solution		Ph. Eur.		complying
Acidity / Alkalinity	ml	Ph. Eur.		<= 1.0
Water Soluble Substances	%(m)	USP		<= 0.25
Water Soluble Substances	%(m)	EU No.231/2012		<= 0.5
Acid (HCI 0.5 mol/I) Soluble Substances	%(m)	USP		<= 0.5
Loss on Drying (105 °C, 3 h)	%(m)	USP		<= 0.5
Loss on Ignition (800 °C)	%(m)	USP		<= 0.5
Lead (Pb), HCl soluble	mg/kg	FDA §73.575		<= 10



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Property	Unit	Standard based on Value	Limits
Arsenic (As), HCl soluble	mg/kg	FDA §73.575	<= 1
Antimony (Sb), HCI soluble	mg/kg	FDA §73.575	<= 2
Barium (Ba), total	mg/kg	USP <233>	<= 20
Arsenic (As), total	mg/kg	USP <233>	<= 1
Iron (Fe), total	mg/kg	USP <233>	<= 200
Antimony (Sb), total	mg/kg	USP <233>	<= 1
Lead (Pb), total	mg/kg	USP <233>	<= 5
Mercury (Hg), total	mg/kg	FCC	<= 0.2
Cadmium (Cd), total	mg/kg	USP <233>	<= 0.5
Cadmium (Cd), HCl soluble	mg/kg	EU No.231/2012	<= 1
Mercury (Hg), HCI soluble	mg/kg	EU No.231/2012	<= 1
Aluminium Oxide and/or Silicium Dioxide	%(m)	DIN 51418	<= 2
PLV Brightness		DIN 53163	>= 98.0
PLV Tone b*		DIN 53163	<= 1.50
pH Value in 10% Suspension		ISO 787-9	5.5 - 8.5
Nickel (Ni), total	mg/kg	USP <233>	<= 20
Cobalt (Co), total	mg/kg	USP <233>	<= 10
Copper (Cu), total	mg/kg	USP <233>	<= 10
Zinc (Zn), total	mg/kg	USP <233>	<= 30
Chromium (Cr), total	mg/kg	USP <233>	<= 20
Selenium (Se), total	mg/kg	USP <233>	<= 10
Vanadium (V), total	mg/kg	USP <233>	<= 10 /

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