



azienda chimica e farmaceutica

TECHNICAL DATA SHEET

Product: **TITANIO BIOSSIDO ANAT. Ph.Eur.-USP-E 171**

INCI NAME Titanium Dioxide / CI77891
CAS 13463-67-7
EINECS / ELINCS 236-675-5
FORMULA TiO₂

TEST	METHOD	min - max	u.m.
Titolo (dopo essiccazione)		99,0 - 100,0	%
Perdita all'essiccamento		<=0,50	%
Perdita all'ignizione		<=0,50	%
Sostanze solubili in acqua calda		<=0,50	%
Sostanze solubili in acqua fredda		<=0,25	%
Sostanze solubili in acido		<=0,50	%
Arsenico		<=1,00	ppm
Piombo		<=10,00	ppm
Antimonio		<=50,00	ppm
Mercurio		<=1,00	ppm
Al ₂ O ₃		<=2,00	%
Arsenico solubile in acido		<=1,00	ppm
Piombo solubile in acido		<=10,00	ppm
Antimonio solubile in acido		<=2,00	ppm
Bario solubile in acido		<=5,00	ppm
Cadmio		<=1,00	ppm
Ferro		<=200,00	ppm
Zinco		<=50,00	ppm
pH		6,50 - 8,00	
Impurezze organiche volatili (O.V.I.)		nessun solvente organico usato nella produzione	
SiO ₂		<=2,00	%
Rev.		1	
Approval Date		15/10/2013	



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The categorization limits related to purity criteria are set up such as to conform to the following monographs as stated in the certificate of analysis:

- EU Food Color Specification E 171 - Reg. 231/2012
- Cosmetic Regulation EC 1223/2009
- European Pharmacopoeia 7th Ed.
- USP 35 / NF 30
- FDA 21 CFR Ch. 1 part. 73
- Japanese Pharmacopoeia 16th. Ed.

Microbiological properties: The nature of the product and the manufacturing process, using acidic conditions for ore digestion, high temperature for crystallization and steam treatment above 150 °C, reduce the likelihood of microbiological contamination and/or growth.

Microbiological testing is carried out regularly, historical data show:

- Microbiological content: < 10 cfu/g
- Pathogenic bacteria: < 10 cfu/g.
- Particle size (geometric mean): 0.38 µm
- Particle size distribution (d50, d90): 0.36 µm, 0.54 µm
- Cristal size: 0.20 µm