

Certificate of Analysis

Product name: **Titanii dioxidum**

Batch number / Weight: **23C15-B04-235182 / 250 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23C15-B04 / INS-23-2410**

Reference Code / No.: **V01287 / 0056670**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	<= ref. susp. II / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Substances soluble in water	<=0,5	0,35	%	
Antimony	<= 2	<0,01	ppm	
Arsenic	<= 1	<0,01	ppm	
Barium	< = 20	1,80	ppm	
Lead	<= 5	<0,01	ppm	
Iron	<= 200	<200	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Titanium dioxide	98,0 - 100,5	100,07	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol, Eurofins

Release:

Ewelina Gadzinowska

Qualified Person

20-02-2024

Expiration: 13-09-2027

Conclusion: APPROVED

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