

Certificate of Analysis and Conformity Zano® 10

Product name:	Zano® 10	Batch size:	500 kg
Material Number:	7634	Batch number:	Z107107
Production date:	01 Aug 2017	Retest date:	30 Jan 2020

Undersigned hereby declares that above mentioned batch of Zano® 10 was manufactured and tested in compliance with GMP Part II / ICH Q7 requirements. Testing of the batch was performed with EP/USP analytical methods or validated in-house analytical methods and shows compliance to below mentioned specifications.

General characters (EP) for Zano® 10

Appearance : soft, white or faintly yellowish-white, amorphous powder, free from gritty particles.

Solubility : practically insoluble in water and in ethanol (96 per cent). It dissolves in dilute mineral acids.

Zinc oxide EP/USP products specifications for Zano® 10

	Specification	Result	Method
Identification A	Pass	Pass	EP/USP
Identification B	Pass	Pass	EP/USP
Zinc oxide	99,0 – 100,5%	99,9 %	EP/USP
Lead	≤0,0010 %	0,0002 %	ICP-AES
Cadmium	≤0,0010 %	0,0001 %	ICP-AES
Iron	≤0,0050 %	0,0000 %	ICP-AES
Arsenic	≤0,0002 %	0,0000 %	ICP-AES
Iron and other heavy metals	Pass	Pass	USP
Alkalinity	Pass	Pass	EP/USP
Loss on ignition	≤1,0 %	0,9 %	EP/USP
Carbonates and color of solution	Pass	Pass	USP
Carbonates and substances insoluble in acids	Pass	Pass	EP

Additional specifications for Zano® 10

	Specification	Result	Method
Aluminium	≤0,0050 %	0,0002 %	ICP-AES
Nickel	≤0,0010 %	0,0000 %	ICP-AES
Chromium	≤0,0002 %	0,0000 %	ICP-AES
Specific Surface Area after production	≥25 m ² /g	30,3 m ² /g	BET