

Technical Data Sheet

Zano® 10 Plus

Zano® 10 Plus is manufactured and tested in compliance with GMP Part II / ICH Q7 requirements. Testing is done using EP/USP analytical methods or validated in-house analytical methods and is compliant to below mentioned specifications.

Specifications for Zano® 10 Plus

	Specification	Method
Loss on drying	≤1%	2 hours @ 105°C
Zinc oxide content	96.2% ± 0.5%	Mass balance calculations
Triethoxycaprylsilane content	3.8% ± 0.5%	Mass balance calculations

General characters (EP) for Zano® 10 Plus prior to surface treatment

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 product specifications for Zano® 10 Plus prior to surface treatment

	Specification	Method
Identification A, B	PASS	EP/USP
Zinc Oxide	99,0 – 100,5 %	EP/USP
Lead	≤0,0010 %	ICP-AES
Cadmium	≤0,0005 %	ICP-AES
Iron	≤0,0050 %	ICP-AES
Arsenic	≤0,0002 %	ICP-AES
Thallium	≤0,0005 %	ICP-AES
Iron and other heavy metals	PASS	USP
Alkalinity	PASS	EP/USP
Loss on Ignition	≤1,0 %	EP/USP
Carbonates and color of solution	PASS	USP
Carbonates and substances insoluble in acids	PASS	EP

Additional specifications for Zano® 10 Plus prior to surface treatment

	Specification	Method
Aluminium	≤0,0050 %	ICP-AES
Nickel	≤0,0010 %	ICP-AES
Chromium	≤0,0002 %	ICP-AES

Packaging: 14 – 20 kg bags in cardboard box



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