

Technical Data Sheet

ZINC OXIDE Pharma EP-grade GMP

Zinc Oxide Pharma EP-grade is manufactured and tested in compliance with GMP Part II / ICH Q7 requirements

Product information

Zinc oxide Pharma-EP-grade is a high purity zinc oxide product for use as **API and excipient in pharmaceutical and personal care applications**. The Zinc Oxide Pharma-EP grade is covered by an official GMP certificate and CEP. Further it meets the specifications of the European Pharmacopoeia 10.6 monograph for zinc oxide (0252).

General Characters

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.

Product Specifications

	Specification	Method
Identification A, B	PASS	EP- monograph 0252
Zinc Oxide	99,0 – 100,5 %	EP 2.5.11
Lead (Pb)	0,0010 % max	EP 2.4.20
Cadmium (Cd)	0,0005 % max	EP 2.4.20
Iron (Fe)	0,0200 % max	EP 2.4.20
Thallium (Tl)	0,0005 % max	EP 2.4.20
Alkalinity	PASS	EP- monograph 0252
Loss on Ignition	1,0 % max	EP- monograph 0252
Carbonates & substances insoluble in acids	PASS	EP 2.2.1 & 2.2.2

Additional Specifications

Specific surface area	4,5 – 7,5 m ² /g	BET – ISO5794-1
Sieve residue 45µm	0,010% max	ISO787-18
Metallic zinc content	virtually free	Antrachinon method
Storage	dry warehouse	
Packaging (UN approved)	25kg paper bags →	Material number 8650
	1000kg big bags →	8651

Material Safety Data Sheet available on request