

Zochem LLC (Zochem South)
 600 Printwood Drive
 Dickson, TN 37055, USA
CustomerService@Zochem.com
 PHONE (615) 446-8791
 FAX (615) 446-8789
www.zochem.com



Zochem ULC (Zochem North)
 1 Tilbury Court, Brampton
 Ontario, L6T 3T4, Canada
CustomerCare@Zochem.com
 PHONE (800) 324-1806
www.zochem.com

TECHNICAL DATA SHEET

ZINC OXIDE GRADE 112EP

Description

Zochem's Grade 112EP:

- Manufactured in an FDA registered food manufacturing facility.
- Produced by the French (Indirect) Process.
- Meets EP Compendium Monograph specification for zinc oxide.
- Meets GMP (Good Manufacturing Practices) 21cfr110 for Food and excipients, and IPEC/ANSI/NSF 363 for excipients.

Grade 112EP is used in the European Union (EU) and wherever an internationally recognized pharma grade zinc oxide is required. This grade replaces Grades ZOCO 112USP-EP and Zinc Oxide LLC Grade EP.

Grade 112EP is also available in an API (Active Pharmaceutical Ingredient) version "Grade 112EP (API)" manufactured in an FDA registered drug establishment manufacturing facility which has been inspected by the FDA as compliant with ICH-Q7 GMP for API. The API version also meets 21cfr111 GMP for Dietary Supplements (DS).

When ordering, please specify standard "Grade 112EP" or "Grade 112EP (API)"

Compendium Tests	Limit	Typical	Test Method*
Zinc Oxide (ZnO) Assay	99.0% – 100.5%	99.7%	EP monograph
Loss on Ignition at 500 ^o C	1.0% max	0.2%	EP monograph
Lead (Pb)	10 ppm max	9 ppm	EP monograph
Cadmium (Cd)	5 ppm max	2 ppm	EP monograph
Iron (Fe)	200 ppm max	2 ppm	EP monograph
Thallium	5 ppm max	0 ppm	EP monograph
Alkalinity	Final solution is not red	Pass	EP monograph
Carbonate	Clear, colorless, no effervescence	Pass	EP monograph
and substances insoluble in acids			
Identification A:	Turns yellow when heated, dissipates when cooled	Pass	EP monograph
Identification B:	Response as zinc	Pass	EP monograph

Optional Non-Compendium Tests	Limit	Nominal	Test Method
Surface Area (m2/g)	3.0 – 6.5	5	ASTM D4315
Fineness retained on 325 mesh (%)	0.02 max	0.008	ASTM D185
Appearance	Fine white powder	Pass	Supplier

Shelf life 18 months from date of manufacturing. Standard Packaging 25 kg. Kraft paper bags on 1000 kg to 1250 kg net wt. pallet unit, or 1000 kg FIBC.

TDS 112EP effective 30March2023