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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 Europeans 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
Arsenic (As)	5 ppm max	0 ppm	EP monograph
Loss on Ignition at 500 ^o C	1.0% max	0.2%	EP monograph
Lead (Pb)	50 ppm max	20 ppm	EP monograph
Cadmium (Cd)	10 ppm max	2 ppm	EP monograph
Iron (Fe)	50 ppm max	2 ppm	EP monograph
Alkalinity	Final solution is not red	Pass	EP monograph
Carbonate, HCl insol., Color of sol.	Clear, colorless, no effervescence	Pass	EP monograph
Identification A:	Turns yellow when heated, dissipates when cooled	Pass	EP monograph
Identification B:	Response as zinc	Pass	EP, Spectrometry or Spectrophotometer

Optional Non-Compendium Tests	Limit	Nominal	Test Method
Surface Area (m2/g)	3.0 – 6.5	5	ASTM D4315
Fineness retained on 325 mesh (%)	0.015 max	0.008	ASTM D185
Appearance	Fine white powder	Pass	Supplier

Product meets all EP monograph limits. *Zochem alternate instrument test method for Identification B has been determined suitable under actual conditions of use for product to meet EP acceptance criteria. Shelf life 18 months from date of manufacturing. Standard Packaging 50 lb. Kraft paper bags on 2,000 to 2,500 net wt. pallet unit, or 2,000 lb FIBC.

TDS 112EP effective 09Jan2020