

French Process 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° 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 and substances insoluble in acids | 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 monograph |

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

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