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TECHNICAL DATA SHEET

ZINC OXIDE USP GRADE 103 USPL

Description

Our Zinc Oxide USP product is produced by the French (Indirect) Process and meets the most stringent medicine safety laws and standards in the world including:

- FCC (Food Chemical Codex),
- API (Active Pharmaceutical Ingredient),
- GMP (Good Manufacturing Practices) ICH Q7,
- USP, EP, BP & other Compendium Monographs.

Grade 103 USPL offers ultra-low lead (the lowest lead attainable), with the lowest m²/g surface area (SA) available with discrete French Process. Grade 103 USPL is used when standard grade 112 USP is not suitable in the application.

Product Selection

Zochem offers several FDA approved grades:

- 103 USP (low 2-4 m²/g surface area "SA"),
- 112 USP (medium 3-6.5 SA),
- 101 USP (higher 6-8.5 SA),
- 102 USP (highest 8-10 SA),
- 112 EP-BP (European Union/British Pharmacopeias), the proper API GMP pharma grade for use outside the U.S.A.
- 104 is USFDA approved as GRAS (Generally Recognized As Safe) at 21cfr73.8991 and used For OTC, excipient (inactive ingredient), and wherever an FDA approved grade is required.

Grade 103 USPL replaces Grade ZOCO 103 USP Low Lead ("L" or "LL").

| USP Compendium Tests | Limit | Nominal | Test Method |
|--|---------------------|---------|------------------|
| Zinc Oxide (ZnO) | 99.0% – 100.5% | 99.9% | USP monograph |
| Arsenic (As) | 6 ppm max | 0 ppm | ICP or monograph |
| Loss at 500 ^o C | 1.0% max | 0.2% | USP monograph |
| Lead | No Turbidity | Pass | USP monograph |
| Iron & Other Heavy Metals | Precipitates formed | Pass | USP monograph |
| Alkalinity | Solution not red | Pass | USP monograph |
| Carbonate | No effervescence | Pass | USP monograph |
| Color of Solution | Clear & colorless | Pass | USP monograph |
| Identification B | Precipitates formed | Pass | USP monograph |
| Identification A: Turns yellow when heated, dissipates when cooled | | Pass | USP monograph |

| Additional Tests (not compendium) | Limit | Nominal | Test Method |
|---|------------|---------|-------------|
| Surface Area (m ² /g) | 2 – 4 | 3.2 | ASTM D4315 |
| Lead as Pb (%) | 0.0010 max | 0.009 | ASTM D4075 |
| Cadmium as Cd (%) | 0.0003 max | 0.0002 | ASTM D4075 |
| Iron as Fe (%) | 0.002 max | 0.0003 | ASTM D4075 |
| Fineness retained on 325 mesh (%) | 0.01 max | 0.003 | ASTM D185 |
| (Fineness passing through 325 mesh (%)) | 99.99 min | 99.997 | ASTM D185) |

Product meets all USP monograph limits.

Standard Packaging: 50 lb. Kraft paper bags on 2,000 to 2,500 lb net wt. pallet unit, or 2,000 lb FIBC.