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TECHNICAL DATA SHEET

ZINC OXIDE USP GRADE 101 USP

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:

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

Grade 101 USP offers medium-high m²/g surface area (SA) and is used when standard grade 112 USP is not suitable in the application.

Grade 101 USP replaces Zinc Oxide LLC grade USP20.

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 and 101 non USP grades are 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.

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)	6.0 – 8.5	7	ASTM D4315
Lead as Pb (%)	0.002 max	0.0015	ASTM D4075
Cadmium as Cd (%)	0.001 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.