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TECHNICAL DATA SHEET

ZINC OXIDE USP GRADE 112 EP-BP

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,
- EP (European Pharmacopeia), and
- BP (British Pharmacopeia), the most recognized and most commonly used pharmaceutical standard around the world.

Grade 112 EP-BP replaces Grades Zinc Oxide LLC grade EP and ZOCO 112 EP-BP-Standard.

Product Selection

Use grade 112 EP-BP wherever an internationally recognized API grade zinc oxide is required.

If the application is for food contact and not an active drug ingredient, grades 104 or 400 should be used which are FDA approved as GRAS under 21CFR182.8991 (GRAS = Generally Recognized as Safe) and approved by the FDA wherever the use of a GRAS substance is authorized including an ingredient in food contact in rubber articles at 21CFR177.2600(c)(1); in food can linings and coatings at 21CFR175.300(b)(2); and in plastics at 21CFR170.30(d).

USP Compendium Tests	Limit	Nominal	Test Method
Zinc Oxide (ZnO)	99.0% – 100.5%	99.9%	EP-BP monograph
Arsenic (As)	5 ppm max	0 ppm	EP-BP monograph
Loss at 500 ^o C	1.0% max	0.2%	EP-BP monograph
Lead as Pb	50 ppm max	20 ppm	EP-BP monograph
Cadmium as Cd	10 ppm max	ppm	EP-BP monograph
Iron	50 ppm max	2 ppm	EP-BP monograph
Alkalinity	Solution not red	Pass	EP-BP monograph
Carbonate	No effervescence	Pass	EP-BP monograph
Color of Solution	Clear & colorless	Pass	EP-BP monograph
Identification B	Precipitates formed	Pass	EP-BP monograph
Identification A:	Turns yellow when heated, dissipates when cooled	Pass	EP-BP monograph

Additional Zochem Tests (not compendium)	Limit	Nominal	Test Method
Surface Area (m2/g)	3.0 – 6.5	5	ASTM D4315
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 EP and BP 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.