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TECHNICAL DATA SHEET

ZINC OXIDE GRADE 101USPL

Description

Zochem's Grade 101USPL:

- Manufactured in an FDA registered food manufacturing facility.
- Produced by the French (Indirect) Process.
- Meets USP Compendium Monograph specification for zinc oxide.
- Meets GMP (Good Manufacturing Practices) 21cfr110 for Food and excipients, and IPEC/ANSI/NSF 363 for excipients.

Grade 101USPL offers ultra-low lead (the lowest lead attainable), with medium m²/g surface area (SA) and is used where the lowest lead and higher SA is required and standard Grade 112USP is not suitable in the application.

Grade 101USPL is also available in an API (Active Pharmaceutical Ingredient) version "Grade 101USPL (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 101USPL" or "Grade 101USPL (API)"

Compendium Tests	Limit	Typical	Test Method*
Zinc Oxide (ZnO) Assay*	99.0% – 100.5%	99.7%	Titration
Arsenic (As)	6 ppm max	0 ppm	ICP or USP monograph
Loss on Ignition at 500 ^o C	1.0% max	0.2%	USP monograph
Alkalinity	Final solution is not red	Pass	USP monograph
Lead (Pb)	No Turbidity or precipitate	Pass	USP monograph
Iron (Fe) & Other Heavy Metals	White precipitates are formed	Pass	USP monograph
Carbonate & Color of Solution	Clear, colorless, no effervescence	Pass	USP monograph
Identification A (ID A)	Turns yellow when heated dissipates when cooled	Pass	USP monograph
Identification of zinc (ID B replacement)*	Response as zinc	Pass	AA, ICP-OES, or acid insol wht precipitate

Optional Non-Compendium Tests	Limit	Nominal	Test Method
Surface Area (m ² /g)	6.0 – 8.5	7	ASTM D4315
Lead as Pb (%)	0.001 max	0.0008	ICP or AA
Cadmium as Cd (%)	0.0003 max	0.0002	ICP or AA
Iron as Fe (%)	0.002 max	0.0003	ICP or AA
Fineness retained on 325 mesh (%)	0.03 max	0.008	ASTM D4315
Appearance	Fine white powder	Pass	Supplier

Product meets all USP monograph limits. *Zochem test methods for ZnO Assay, arsenic (by ICP), and Identification of Zinc, have been determined suitable under actual conditions of use for product to meet USP 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 101USPL effective 09Jan2020