



TECHNICAL DATA SHEET

ZINC OXIDE GRADE 112 USPL-Generichem

Zochem's Grade 112USPL - Generichem is:

- 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, IPEC/ANSI/NSF 363 for excipients, and
- Meets FCC (Food Chemical Codes).

This Grade offers the lowest lead attainable), and is used where the lowest lead is required and standard USP grades are not suitable in the application.

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Grade 112USPL - Generichem is a special product manufactured to Generichem's special specification limits. This product is not API (Active Pharmaceutical Ingredient). An API version is available "Grade 112USPL - Generichem (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).

Compendium Tests	Limit	Typical	Test Method*
Zinc Oxide (ZnO) Assay*	99.0% – 100.5%	99.7%	Titration
Arsenic (As)	3 ppm max	<1ppm	ICP or USP monograph
Loss on Ignition at 500° 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 (m2/g)	3.0 – 6.5	5	ASTM D4315
Lead as Pb (%)	0.0010 max	0.0009	ICP or AA
Cadmium as Cd (%)	0.0002 max	0.0001	ICP or AA
Iron as Fe (%)	0.001 max	0.0003	ICP or AA
Mercury as Hg (ppm)	0.3 max	<0.2	ICP (EPA 200.7)
Fineness retained on 325 mesh (%)	0.01 max	0.003	ASTM D185
Appearance	Fine white powder	Pass	Supplier

Micro Levels	Limit	Nominal	Test Method
Yeast and mold	< 100	Pass	Third party lab
TPC (bacteria count)	< 1000 cfu	Pass	Third party lab
E. Coli	Negative/10g	Pass	Third party lab
Salmonella	Negative/25g	Pass	Third party lab

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 when kept dry and stored in factory stretch-wrapped pallet units. Standard Packaging 50 lb. Kraft paper bags on 2,000 to 2,500 net wt. pallet unit, or 2,000 lb FIBC.

Grade 112USPL - Generichem effective 22July2024

