

ZINC SULFATO CRISTAL HEPTAHIDRATO (EUR. PH.) (EUR-GMP)

PRODUCT CODE: 1932	CAS Nº: 7446-20-0	ANALYSIS Nº: 021/25
MANUFACTURER BATCH: ZSH0217	CERTIFICATE ID: 44.893	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/04/2024	
METAPH BATCH: 0210125	RETEST DATE: 01/04/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless, transparent crystals, efflorescent	Colourless, transparent crystals, efflorescent
Solubility	Very soluble in water, practically insoluble in ethanol (96 per cent)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	4.4 - 5.6	5.3 (*)
Chlorides	=< 300 ppm	< 300 ppm (*)
Iron	=< 100 ppm	< 100 ppm (*)
Assay	99.0 - 104.0 %	101.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Zinc Sulfate Heptahydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Store in a cool, well-ventilated place, away from sources of heat.

Analysis date: 06/02/2025
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000557
 MACCO ORGANIQUES S.R.O.
 Zahradní 1442/46
 792 01 Bruntál
 Bruntál(Txeca, República)

