



TECHNICAL DATA SHEET

0435-TDS-ENG-2023

COBRE SULFATO CRISTAL (5 hdtos) PH.EUR.		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: 7758-99-8	EC Nº: 616-477-9	AEMPS CODE: ---
MOL. WEIGHT: 249.68	MOL. FORMULA: CuSO4·5H2O	ARTICLE CODE: 0435

ATTRIBUTES	SHOULD BE
Appearance	Blue, crystalline powder or transparent, blue crystals
Solubility	Freely soluble in water, soluble in methanol, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Appearance of solution	Clear
Chlorides	=< 100 ppm
Elemental impurities	
Cobalt	=< 1 ppm
Lead	=< 20 ppm
Nickel	=< 20 ppm
Iron	=< 100 ppm
Loss on drying	35.0 - 36.5 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed. Store in a fresh, cool and well-ventilated place.

REMARKS

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

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.