

Certificate of Analysis

Product	Methylene blue hydrate pure EP, USP (pharma grade) (C.I. 52015) (revised)
Product number Synonyms Formula	LC-8718 Methylthioninium chloride $C_{16}H_{18}ClN_3S \cdot H_2O$
Molecular weight	319.86 g/mol (anhydrous)
CAS number	122965-43-9
Storage	below 25°C
Retest period (months)	60

Nous confirmons par la présente que ce produit répond aux exigences de la Pharmacopée européenne (PE) et de la Pharmacopée américaine (USP) (révisée).

Parameter	Specification	Result
Assay (USP)	97 - 103 %	99 %
Appearance (EP)	dark blue or dark green, hygroscopic, crystalline powder with a metallic sheen	complies
Solubility (EP)	passes test	complies
Residue on ignition (Ash) (USP)	<= 0.15 %	complies
Organic impurities		
Azure B (USP)	<= 2.5 %	complies
total impurities (excluding Azure B) (USP, EP)	<= 0.5 %	complies
Loss on drying (105°C, 5 h) (USP)	8 - 22 %	8.23 %
Loss on drying (105°C, 5 h) (EP)	8 - 24 %	8.23 %
TAMC	<= 100 cfu/g	complies
TYMC	<= 10 cfu/g	complies
Elemental impurities (EP)		
Aluminium (Al)	<= 0.01 %	complies
Cadmium (Cd)	<= 0.0001 %	complies
Chromium (Cr)	<= 0.01 %	complies
Copper (Cu)	<= 0.03 %	complies
Iron (Fe)	<= 0.02 %	complies
Lead (Pb)	<= 0.001 %	0.00018 %
Manganese (Mn)	<= 0.001 %	complies
Mercury (Hg)	<= 0.0001 %	complies
Molybdenum (Mo)	<= 0.001 %	complies
Nickel (Ni)	<= 0.001 %	complies
Tin (Sn)	<= 0.001 %	complies
Zinc (Zn)	<= 0.01 %	complies

Frédéric Fallourd

Fabriqué en Allemagne
Pour : Croq'Nature Néonat
Romorantin Lanthenay le : 21 juin 2025

