

neoFroxx GmbH

Marie-Curie-Str. 3
64683 Einhausen
+49 6251 989 240
coa@neofroxx.com
www.neofroxx.com

Certificate of Analysis

Product	Methylene blue hydrate pure EP, USP (pharma grade) (C.I. 52015)
Product number	LC-8718
Lot number	67E696A3
Synonyms	Methylthioninium chloride
Formula	$C_{16}H_{18}ClN_3S \cdot H_2O$
Molecular weight	319.86 g/mol (anhydrous)
CAS number	122965-43-9
Storage	below 25°C
Manufacturing date	March 2025
Retest period (months)	60
Retest date	March 2030

We herewith confirm that this product meets the requirements of the European Pharmacopoeia (EP) and the US Pharmacopoeia (USP) (revised).

Parameter	Specification	Result
Assay (USP)	97 - 103 %	98.23 %
Assay (EP)	93 - 102 %	98.23 %
Identity (USP, EP)	passes test	complies
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
Residue on ignition (Ash) (EP)	<= 0.25 %	complies
Organic impurities		
Azure B (USP)	<= 2.5 %	complies
Azure B (EP)	<= 5 %	complies
unspecified impurities (each impurity) (USP, EP)	<= 0.1 %	complies
total impurities (excluding Azure B) (USP, EP)	<= 0.5 %	complies

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Product	Methylene blue hydrate pure EP, USP (pharma grade) (C.I. 52015)	
Parameter	Specification	Result
Loss on drying (105°C, 5 h) (USP)	8 - 22 %	10.04 %
Loss on drying (105°C, 5 h) (EP)	8 - 24 %	10.04 %

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Product	Methylene blue hydrate pure EP, USP (pharma grade) (C.I. 52015)	
Parameter	Specification	Result
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 %	complies
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 %	0.0096 %

Einhausen, 23.04.2025

Quality control: M.F.

neoFroxx
For a greener laboratory

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E-Mail info@neofroxx.com | www.neofroxx.com



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neoFroxx GmbH, Marie-Curie-Str. 3, D-64683 Einhausen

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