

neoFroxx GmbH

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Specification

Product	Methylene blue hydrate pure EP, USP (pharma grade) (C.I. 52015) (revised)
Product number	LC-8718
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
Retest period (months)	60

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

Parameter	Specification
Assay (USP)	97 - 103 %
Assay (EP)	93 - 102 %
Identity (USP, EP)	passes test
Appearance (EP)	dark blue or dark green, hygroscopic, crystalline powder with a metallic sheen
Solubility (EP)	passes test
Residue on ignition (Ash) (USP)	<= 0.15 %
Residue on ignition (Ash) (EP)	<= 0.25 %
Organic impurities	
Azure B (USP)	<= 2.5 %
Azure B (EP)	<= 5 %
unspecified impurities (each impurity) (USP, EP)	<= 0.1 %
total impurities (excluding Azure B) (USP, EP)	<= 0.5 %
Loss on drying (105°C, 5 h) (USP)	8 - 22 %
Loss on drying (105°C, 5 h) (EP)	8 - 24 %

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Parameter	Specification
TAMC	<= 100 cfu/g
TYMC	<= 10 cfu/g
Elemental impurities (EP)	
Aluminium (Al)	<= 0.01 %
Cadmium (Cd)	<= 0.0001 %
Chromium (Cr)	<= 0.01 %
Copper (Cu)	<= 0.03 %
Iron (Fe)	<= 0.02 %
Lead (Pb)	<= 0.001 %
Manganese (Mn)	<= 0.001 %
Mercury (Hg)	<= 0.0001 %
Molybdenum (Mo)	<= 0.001 %
Nickel (Ni)	<= 0.001 %
Tin (Sn)	<= 0.001 %
Zinc (Zn)	<= 0.01 %

Einhausen, 10.03.2025