

CERTIFICATE OF ANALYSIS

Purchase Order No.	P.O. Date	Our Reference No.	Generation Date Of C.O.A.	Test Report No.
PO-23-00196	04.02.2023	140	15.03.2023	21-22/MB-USP/002
Product Name	Batch No.	Month of MFG.	Month of Re-test	Test Report Date
Methylene Blue USP-43	21-22/MB/002	DEC - 2021	NOV - 2024	12.02.2022

TEST	SPECIFICATION	RESULTS
Appearance and Odor	Dark Green or Blue crystals or crystalline Powder having a bronze-like luster. Is odorless or practically so, and is stable in air. Its Solution in water and in alcohol are deep blue in color	Complies
Relative Solubility	Slightly Soluble in Water and in Alcohol	Complies

IDENTIFICATION TEST:

A. Infrared(IR) Absorption	The IR Spectrum is concordant with the reference spectrum of Methylene Blue	Matches
B. Retention Time (RT)	The RT of the major peak of the Sample solution corresponds to that of the Standard Solution. As obtained in the Assay.	Complies
C. Identification of Chloride	Meets the Requirements	Complies
Assay By HPLC (On Dried Basis)	97.0% - 103.0%	100.47%

IMPURITIES:

A. Residue on Ignition	NMT 0.15%	0.05%
B. Arsenic	NMT 8 ppm	3.85 ppm
C. Copper or Zinc	NMT 100 ppm of Zinc and NMT 200 ppm of Copper	Zinc 0.54 ppm
		Copper 1.00 ppm

Organic Impurities	Name	Relative RT	Acceptance Criteria NMT (%)	
	Azure B	0.8	2.5	1.94%
	Methylene Blue	1.0	-----	-----
	Unspecified impurity- 01	0.5	0.10	0.01%
	Unspecified impurity- 02	0.6	0.10	0.07%
	Total Impurities (Excluding Azure-B)	-	0.5	0.08%

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TEST	SPECIFICATION	RESULTS
SPECIFIC TEST:		
Loss on Drying (LOD)	8.0% to 22.0%	15.37%
Bacterial Endotoxin Test	NMT 2.5 USP Endotoxin Units/mg	< 2.5 EU/mg
MICROBIAL ENUMERATION TEST:		
• Total aerobic microbial count (TAMC)	NMT 10 ² cfu/g	15 cfu/g
• Total combined yeasts and molds counts (TYMC)	NMT 10 ¹ cfu/g	< 10 cfu/g
• Specified Microorganism	SPECIFICATION	RESULTS
a. <i>E.coli</i>	Should be absent/g	Absent
b. <i>Salmonella</i>	Should be absent/10g	Absent
c. <i>Staphylococcus aureus</i>	Should be absent/g	Absent
d. <i>Pseudomonas aeruginosa</i>	Should be absent/g	Absent
e. <i>Candida albicans</i>	Should be absent/g	Absent

REPORT: Certified that the material referred above confirms to the following specifications:

1. Manufacturing specification of Macsen Drugs.
2. Pharmacopeia – USP-43 NF-38
3. Methylene Blue must be subjected to further processing during the preparation of injectable dosage forms to ensure acceptable levels of bacterial endotoxins.