



(Approved Chemist)

CERTIFICATE OF ANALYSIS

ange Owley No.			
P.O. Date	Our Reference No.	Generation Date Of C.O.A.	Test Report No.
04.02.2023	140		21-22/MB-USP/002
Batch No.	Month of MFG.		
21-22/MB/002	DEC - 2021		Test Report Date 12.02.2022
	Batch No.	P.O. Date Our Reference No. 04.02.2023 140 Batch No. Month of MFG.	04.02.2023 140 15.03.2023 Batch No. Month of MFG. Month of Re-test

TEST		SPECIFIC	CATION	Pi	ESULTS	
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					
Relative Solubility	Slightly Soluble			C	Complies	
IDENTIFICATION					ompiles	
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 Zine NMT 100 ppm of Zinc and NMT 200 ppm of		200 ppm of Copper	Zinc	0.54 ppm		
	PC 39-64			Copper	1.00 ppm	
	Name	Relative RT	Acceptance Criteria NMT (%)			
	Azure B	0.8	2.5	1	.94%	
	Methylene Blue	1.0	10000			
Organic Impurities	Unspecified impurity- 01	0.5	0.10	0.01%		
	Unspecified impurity- 02	0.6	0.10	0.07%		
ý × .	Total Impurities (Excluding Azure-B)	J#.	0.5	0.08%		

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CERTIFICATE OF ANALYSIS

Purchase Order No.	Purchase Order No. P.O. Date Our Refere		no No Consul' Di Otopi I		
DO 43 00404		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		
Methylene Blue USP-43	21-22/MB/002	DEC - 2021		Test Report Date	
		DEC - 2021	NOV - 2024	12.02.2022	

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			
 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. E.coli	Should be absent/g	Absent	
b. Salmonella	Should be absent/10g	Absent	
c. Staphylococcus aureus	Should be absent/g	Absent	
d. Pseudomonas aeruginosa	Should be absent/g	Absent	
e. Candida albicans	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
- Methylene Blue must be subjected to further processing during the preparation of injectable dosage forms
 to ensure acceptable levels of bacterial endotoxins.

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