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Certificate of Analysis

Product Description: Methotrexate, USP and EP Grade
Catalog Number: 199855
Lot: SR05276

Formula: C₂₀H₂₂N₈O₅**CAS #:** 59-05-2**Physical Description:** Yellow to Orange Powder**Formula Weight:** 454.46**Storage:** 2 - 8°C, desiccate, protect from light

Test	Compendium	Specification	Result
Identity Test A Identity Test C	USP EP	Passes Passes	Passes Passes
Identity Test A	EP	Passes	Passes
Identity Test B	USP	Passes	Passes
Identity Test B	EP	Passes	Passes
Specific Rotation (anhydrous basis)	USP	+19° to +24°	+22.81°
Water	USP	≤12.0%	10.26%
Water	EP	≤13.0%	10.26%
Related Substances	EP	Passes	Passes - see below
(R)-Methotrexate	EP	≤3.0%	0.08%
Heavy Metals	EP	≤50 ppm	<20 ppm
Sulfated Ash, Residue on Ignition	EP, USP	≤0.1%	<0.01%
Organic Impurities	USP	Passes	Passes - see below
Methotrexate Content (anhydrous basis as C ₂₀ H ₂₂ N ₈ O ₅)	USP	98 - 102.0%	99.2%

Color of Solution L: 87

Related Compounds LC:

- Aminopterin: 0.01%
- Methopterin: 0.03%
- 4-Hydroxy-M-ptericoic Acid: 0.01%
- A-M-ptericoic Acid: 0.01%
- MTX-5-Monomethylester: 0.06%
- MTX-1-Monomethylester: 0.02%
- Unknown Single: 0.03%
- Total (with the exception of B, C, E): 0.2%
- Total: 0.2%

Total Aerobic Microbial Count: <10 cfu/g

Total Yeast and Mold Count: <10 cfu/g

Pseudomonas aerug.: 0 cfu/g

Staphylococcus aureus: 0 cfu/g

Endotoxins (LAL): <0.120 EU/mg

Residual Solvents:

- Acetone: <1 ppm
- Methanol: 2 ppm
- Dimethylformamide: 30 ppm

FTIR: Conforms to standard

Recommended Retest Date (MM/DD/YYYY): 03/10/2025



03/14/2022 - Lily Meng
MP Biomedicals, LLC.
QC Chemist

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