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Certificate of Analysis

Product Description: Methotrexate, USP Grade
Catalog Number: 102299
Lot: MR29429

Formula: $C_{20}H_{22}N_8O_5$
CAS #: 59-05-2
Physical Description: Yellow Powder

Formula Weight: 454.5
Storage: +4°C

Test	Specification	Result
Identity Test A	Passes	Passes
Identity Test B	Passes	Passes
Specific Rotation (anhydrous basis)	+19 to +24°	+22.98°
Water	≤12.0%	10.6%
Residue on Ignition	≤0.1%	<0.01%
Organic Impurities	Passes	Passes*
Methotrexate Content (anhydrous basis as $C_{20}H_{22}N_8O_5$)	98 - 102.0%	99.0%

Color of Solution L: 81
(R)-Methotrexate: 0.03%
Heavy Metals: <20 ppm

*Organic Impurities:

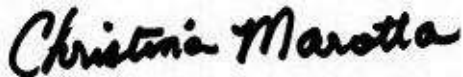
Aminopterin (Imp B): 0.01%
Methopterin (Imp C): 0.03%
4-Hydroxy-M-ptericoic Acid (Imp D): 0.01%
A-M-ptericoic Acid (Imp E): 0.01%
MTX-5-Monomethylester (Imp H): 0.07%
MTX-1-Monomethylester (Imp I): <0.02%
Unknown Single Impurity: 0.04%
Total Impurity (with exception of B,C,E): 0.2%
Total Impurity: 0.2%

Microbiological Purity:

Total Yeast and Mold Count: <10 cfu/g
Total Aerobic Microbial 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: 58 ppm



05/31/2012 - Christina Marotta
MP Biomedicals, LLC.
Technical Director

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