ROCHEM INTERNATIONAL, INC.

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PRODUCT SPECIFICATION

METHOTREXATE

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USP/EP

Version No.: 400075-000

Product Name:	Methotrexate USP/EP
CAS No.:	59-05-2
ITEMS	**SPECIFICATIONS**
Appearance (USP):	Yellow or orange-brown crystalline powder
Appearance (EP):	Yellow or orange, crystalline powder
Identification (IR):	The IR spectrum of sample exhibits maxima only at the same wavelength as that a similar preparation of methotrexate CRS.
Identification (UV):	Positive
Solubility:	Freely soluble in dilute solutions of alkali hydroxides and carbonates; slightly soluble in 6 N hydrochloric acid; practically insoluble in water, in alcohol, in chloroform, and in ether.
Related Substances (USP): Impurity B: Impurity C: Impurity E: MTX-1-monomethylester: MTX-5-monomethylester: Any Unknown Impurity: Total Unknown Impurities:	 NMT 0.3% NMT 0.5% NMT 0.3% NMT 0.2% NMT 0.2% NMT 0.10% NMT 0.5%
Related Substances (EP): Impurity B: Impurity C: Impurity E: Impurity H: Impurity I: Unspecified Impurities: Sum of Impurities other than B, C & E:	 NMT 0.3% NMT 0.5% NMT 0.3% NMT 0.2% NMT 0.2% NMT 0.05% NMT 0.5%
Enantiomeric Purity:	NMT 3.0%
Heavy Metals:	NMT 20 ppm
Water:	NMT 12.0%
Residue on Ignition/Sulphated Ash:	NMT 0.1%
Residual Solvents: Ethyl ether: Acetone: Ethanol:	 NMT 500ppm NMT 1000ppm NMT 2000ppm
Assay (USP): (on the Anhydrous Basis)	98.0% ~ 102.0%
Assay (EP): (on the Anhydrous Basis)	97.0% ~ 102.0%
Total Microbial Count:	NMT 100 CFU/g
Total Molds & Yeasts:	NMT 10 CFU/g

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Bacterial Endotoxin:	NMT 0.08 EU/mg
Retest Date:	3 Years

Rev. 07