

ROCHEM INTERNATIONAL, INC.

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PRODUCT SPECIFICATION

METHOTREXATE

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:	NMT 0.3%
Impurity C:	NMT 0.5%
Impurity E:	NMT 0.3%
MTX-1-monomethylester:	NMT 0.2%
MTX-5-monomethylester:	NMT 0.2%
Any Unknown Impurity:	NMT 0.10%
Total Unknown Impurities:	NMT 0.5%
Related Substances (EP):	
Impurity B:	NMT 0.3%
Impurity C:	NMT 0.5%
Impurity E:	NMT 0.3%
Impurity H:	NMT 0.2%
Impurity I:	NMT 0.2%
Unspecified Impurities:	NMT 0.05%
Sum of Impurities other than B, C & E:	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:	NMT 500ppm
Acetone:	NMT 1000ppm
Ethanol:	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