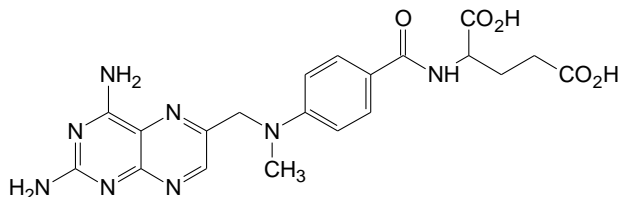


SPECIFICATIONS

METHOTREXATE USP

(S)-2-(4-[[2,4-Diaminopteridin-6-yl)methyl](methyl)amino}benzamido}pentanedioic acid



Catalogue Number	1322
CAS Registry Number	59-05-2
Molecular Formula	C₂₀H₂₂N₈O₅
Molecular Weight	454.44 g.mol⁻¹
Identification (IR)	Conforms to reference
Identification (UV)	Conforms to reference
Assay (w/w%)	98.0 – 102.0%
Related Compounds	
Related Compound B	NMT 0.3%
Related Compound C	NMT 0.5%
Related Compound E	NMT 0.3%
Methotrexate Dimethylamide and Related Compound I	NMT 0.2%
Related Compound H	NMT 0.2%
Unspecified Impurity	NMT 0.10%
Total Impurities	NMT 1.0%
R-Methotrexate	NMT 3.0%
Residue on Ignition	NMT 0.1%
Heavy Metals	NMT 20 ppm
Water Content	NMT 12.0%
Residual Solvents	
Acetone	NMT 500 ppm
Methanol	NMT 500 ppm
Dimethylformamide	NMT 200 ppm
Microbial Limit Test	
Total Aerobic Microbial Count	NMT 100 CFU/g
Total Yeast and mold Count	NMT 10 CFU/g
Bacterial Endotoxins	NMT 0.2 EU/mg
Storage	15-30°C

Related Compound B = (S)-2-[4-[(2,4-Diaminopteridin-6-yl)methylamino}benzamido}pentanedioic acid

Related Compound C = (S)-2-[4-[(2-Amino-4-oxo-1,4-Dihydropteridin-6-yl)methylamino]-N-methylbenzamido}pentanedioic acid

Related Compound E free acid = 4-[[2,4-Diaminopteridin-6-yl)methyl](methyl)amino}benzoic acid

Related Dimethylamide = 2-(4-[[2,4-Diaminopteridin-6-yl)methyl](methyl)amino}benzamido)-5-(dimethylamino)-5-oxopentanoic acid

Related Compound I = (S)-4-(4-[[2,4-Diaminopteridin-6-yl)methyl](methyl)amino}benzamido)-5-methoxy-5-oxopentanoic acid

Related Compound H = (S)-2-(4-[[2,4-Diaminopteridin-6-yl)methyl](methyl)amino}benzamido)-5-methoxy-5-oxopentanoic acid