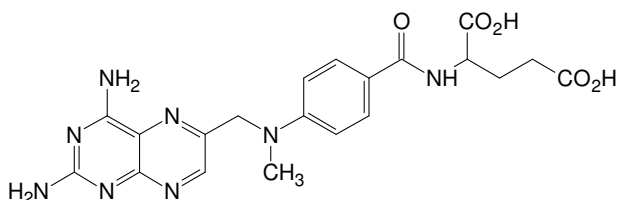


SPECIFICATIONS

cGMP METHOTREXATE USP

(S)-2-(4-[(2,4-Diaminopteridin-6-yl)methyl](methylamino)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	2-8°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](methylamino)benzoic acid

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

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

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

SPEC1322-0
October 4, 2013

BioVectra Inc.
 11 Aviation Avenue
 Charlottetown, PE
 Canada C1E 0A1

t: (866) 883-2872
 (902) 566-9116
f: (902) 628-2045

www.biovectra.com
 info@biovectra.com