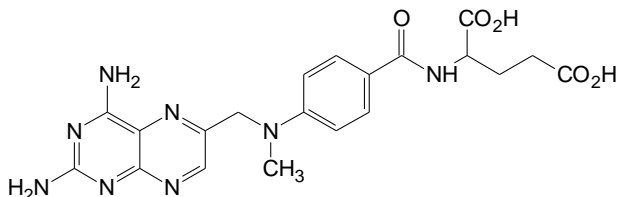


## SPECIFICATIONS

### METHOTREXATE USP

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



<b>Catalogue Number</b>	<b>1322</b>
<b>CAS Registry Number</b>	<b>59-05-2</b>
<b>Molecular Formula</b>	<b>C<sub>20</sub>H<sub>22</sub>N<sub>8</sub>O<sub>5</sub></b>
<b>Molecular Weight</b>	<b>454.44 g.mol<sup>-1</sup></b>
<b>Identification (IR)</b>	<b>Conforms to reference</b>
<b>Identification (UV)</b>	<b>Conforms to reference</b>
<b>Assay (w/w%)</b>	<b>98.0 – 102.0%</b>
<b>Related Compounds</b>	
<b>Related Compound B</b>	<b>NMT 0.3%</b>
<b>Related Compound C</b>	<b>NMT 0.5%</b>
<b>Related Compound E</b>	<b>NMT 0.3%</b>
<b>Methotrexate Dimethylamide and Related Compound I</b>	<b>NMT 0.2%</b>
<b>Related Compound H</b>	<b>NMT 0.2%</b>
<b>Unspecified Impurity</b>	<b>NMT 0.10%</b>
<b>Total Impurities</b>	<b>NMT 1.0%</b>
<b>R-Methotrexate</b>	<b>NMT 3.0%</b>
<b>Residue on Ignition</b>	<b>NMT 0.1%</b>
<b>Heavy Metals</b>	<b>NMT 20 ppm</b>
<b>Water Content</b>	<b>NMT 12.0%</b>
<b>Residual Solvents</b>	
<b>Acetone</b>	<b>NMT 500 ppm</b>
<b>Methanol</b>	<b>NMT 500 ppm</b>
<b>Dimethylformamide</b>	<b>NMT 200 ppm</b>
<b>Microbial Limit Test</b>	
<b>Total Aerobic Microbial Count</b>	<b>NMT 100 CFU/g</b>
<b>Total Yeast and mold Count</b>	<b>NMT 10 CFU/g</b>
<b>Bacterial Endotoxins</b>	<b>NMT 0.2 EU/mg</b>
<b>Storage</b>	<b>15-30°C</b>

**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