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# Specification

## Technical Data Sheet

<b>Product Name</b>	L-(+)-Amethopterin hydrate (Methotrexate)
<b>Product No</b>	30186373
<b>CAS Number</b>	59-05-2
<b>Storage Temperature</b>	-15 to -20 °C
<b>Molecular Weight</b>	454.44
	<b>Specification</b>
<b>Grade</b>	Ph. Eur. 8.3
<b>Water</b>	<13%
<b>Impurity B</b>	NMT 0.3%
<b>Heavy metals</b>	NMT 20ppm
<b>Bacterial endotoxin</b>	NMT 0.1 EU/mg
<b>Acetone</b>	NMT 1000 ppm
<b>Impurity C</b>	NMT 0.5%
<b>Solubility</b>	Practically insoluble in water, in ethanol (96%) and in methylene chloride. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides and carbonates
<b>Assay</b>	98 - 102%
<b>Sulphated Ash</b>	NMT 0.1%
<b>Ethanol</b>	NMT 2000 ppm
<b>Appearance</b>	Yellow or orange crystalline, hygroscopic powder
<b>Enantiomeric Purity</b>	NMT 3.0%
<b>Identification (IR)</b>	The IR spectrum of sample exhibits maxima only at the same wavelength as that of a similar preparation of methotrexate CRS
<b>Impurity E</b>	NMT 0.3%
<b>Impurity H</b>	NMT 0.2%
<b>Impurity I</b>	NMT 0.2%
<b>Ethyl Ether</b>	NMT 500 ppm