



Certificate of analysis

Productname: Methotrexate

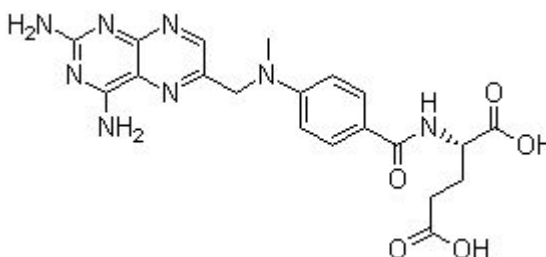
Cas number: 59-05-2

Molecular Formula: C₂₀H₂₂N₈O₅

Molecular Weight: 454.44

Date of production: Jul. 08, 2013

Chemical structure:



| Items | Specifications | Results |
|---------------------------|--|----------|
| Characteristic | Orange or yellow crystalline powder | Conforms |
| Identification | A. Infrared absorption 197K B. Ultraviolet absorption 197U | Conforms |
| Water | Method 921 | |
| determination | Not more than 12.0% | 11.00% |
| Residue on ignition(281) | Not more than 0.1% | 0.02% |
| Chromatographic | Total: Not more than 2.0% | 0.25% |
| purity(related compounds) | ndividual: Not more than 0.5% | 0.15% |
| Optical rotation | Specific rotation (781S): +19° and +24° a 2-dm polarimeter tube being used | +22.8° |
| Organic | Ethanol: not more than 0.5% | 0.30% |
| volatile impurities | Aether : not more than 0.5% | 0.15% |
| Assay | Between 98.0% and 102.0% | 99.50% |
| Solubility | practically insoluble in water, chloroform, ethanol and ether, freely soluble in watery alkali, soluble in watery hydrochloric acid. | |
| Heavy metals | 50 ppm max | Conforms |

Conclusion: It complies with the USP34 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F

