



Certificate of analysis

Product name: Pemetrexed disodium hepthydrate

Cas number: 357166-29-1

Molecular Formula: $C_{20}H_{19}N_5Na_2O_6 \cdot 7(H_2O)$

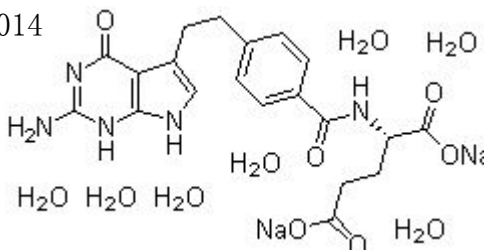
Molecular Weight: 597.49

Date of production: July. 17, 2014

Batch NO: 20140717

EXP DATE: July. 16, 2016

Chemical structure:



Items	Specifications	Results
Description	white or almost white powder	white powder
Solubility	Freely soluble in water, very slightly soluble in anhydrous ethanol, practically insoluble in methylene chloride	Conform
Identification	Spectrum sample should be consistent with spectrum of reference standard. It gives reaction of sodium Conforms to enantiomeric purity test. Conforms to water test.	Conform
PH	7.5~8.4	7.9
Appearance of solution	Solution S is not more opalescent than reference suspension II and not more intensely coloured than reference solution GY4 or Y4	Conform
Water	19.5~22.1%	20.2%
Enantiomeric(Impurity E)	Impurity E ≤ 0.3%	0.02%
Related substances	Impurity A ≤ 0.15% Impurity D ≤ 0.15% Unspecified impurity ≤ 0.10% Total impurities ≤ 0.6%	Not detected 0.007% 0.03% 0.09%
Residual solvents	Methanol ≤ 3000ppm Ethanol ≤ 5000ppm	Not detected 765ppm
Heavy metals	≤ 20ppm	Conform
Bacterial endotoxins	< 0.17IU/mg	Conform
Assay by HPLC	97.5%~102.0%	99.6%

Conclusion: It complies with the EP Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang