

CERTIFICATE OF ANALYSIS

Product Name	Methotrexate
CAS No.	59-05-2
Batch No.	20160904
Quantity	25KGS
Manufacturing Date	Sep. 04, 2016
Expiration Date	Sep. 03, 2019
Test Standard	BP2013

Items	Specifications	Results
Appearance	Yellow or orange, crystalline, hygroscopic powder.	Conforms
Solubility	Practically insoluble in water, in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides and carbonates.	Conforms
Identification	Infrared absorption spectrophotometry	Conforms
Related substances (By HPLC)	Imp. C: NMT 0.5%	0.26%
	Imp. B: NMT 0.3%	Conforms
	Imp. E: NMT 0.3%	0.20%
	Imp. I: NMT 0.2%	Conforms
	Imp. H: NMT 0.2%	Conforms
	Unspecified impurities: NMT 0.05%	Conforms
	Sum of impurities other than B, C and E: NMT 0.5%	Conforms
	Enantiomeric Purity: NMT 3%	2.4%
Heavy Metals	NMT 50ppm	Conforms
Water	NMT 13.0%	10.97%
Sulfated ash	NMT 0.1%	Conforms
Assay	Between 97.0% to 102.0%	99.75%
CONCLUSION: Conform to BP2013.		