

CHANGZHOU HANGYU PHARMACEUTICAL TECHNOLOGY CO., LTD

CERTIFICATE OF ANALYSIS

Product Name: Leflunomide			
Batch No.:	20130503	Quantity:	125kgs
Manu. Date:	May 10, 2013	Expiry Date:	May 9, 2016
Date of Report:	May 12, 2013	Package:	As required

Item	Specification	Results
Appearance	White or off-white crystalline powder	Conforms
Identification	UV: similar to reference standard(258+/-2nm) IR: similar to reference standard	Conforms
Residue on Ignition	0.1% Max	0.05%
Heavy Metals	20ppm Max	Conforms
Loss on Drying	0.3% Max	0.15%
Melting Point	164 to 168°C	166 to 167°C
5-Methylisoxazole-carboxylic acid	0.1% Max	Conforms
Leflunomide related A	0.01% Max	Conforms
Leflunomide related compound B	0.3% Max	Conforms
N-(2'-Trifluoromethylphenyl)-5-methylisoxazole-4-carboxamide	0.1% Max	Conforms
2-Cyano acetic acid-(4'-trifluoromethyl) anilide	0.1% Max	Conforms
Leflunomide related compound C	0.1% Max	Conforms
Any other individual impurity	0.1% Max	Conforms
Total impurities	0.4% Max	Conforms
Particle Size	90% Particle not more than 80M	Conforms
Assay	98.5% to 102.0%	99.80%
Conclusion:		Up to Standard for USP34

