

Certificate of Analysis

Leflunomide 来氟米特

Batch No. :	<u>20180201</u>	Date :	<u>FEB.9,2018</u>
Manufacture Date:	<u>JAN.30,2018</u>	Quantity:	<u>500KGS</u>
Expiry Date:	<u>JAN.29,2021</u>		

SPECIFICATIONS 规格	STANDARD USP39 按美国药典 39 版标准	ANALYSIS RESULTS 检验结果
APPEARANCE 外观	WHITE OR OFF-WHITE CRYSTALLINE POWDER	WHITE OR OFF-WHITE CRYSTALLINE POWDER
IDENTIFICATION 鉴别	UV: similar to reference standard(261+/-2nm) IR: similar to the reference standard	CONFORMS
RESIDE ON IGNITION	≤0.1%	0.04%
HEAVY METALS	≤20ppm	CONFORMS
LOSS ON DRYING	≤0.3%	0.12%
MELTING POINT	164-168℃	166.5-167.5℃
5-Methylisoxazole-carboxylic acid	≤0.1%	NONE
Leflunomide related compound A	≤0.01%	NONE
Leflunomide related compound B	≤0.3%	0.02%
N-(2'-Trifluoromethylphenyl)-5- methylisoxazole-4-carboximide	≤0.1%	NONE
2-Cyano-acetic acid-(4'- trifluoromethyl)-anilide	≤0.1%	NONE
Leflunomide related compound C	≤0.1%	NONE
Total impurities (excluding leflunomide related compound B and leflunomide related compound C)	≤0.2%	0.02%
Any other individual impurity	≤0.1%	0.02%
Total impurities	≤0.4%	0.03%
ASSAY	98.0-102.0%	99.9%
PACKAGING AND STORAGE	Preserve in a well-closed container,store at a temperature not exceeding 30℃.	
CONCLUSION: THE PRODUCT CONFORMS TO USP39 STANDARD		
结论: 本品符合美国药典 39 版标准规定		