



Certificate of analysis

Product name: Apremilast

Cas number: 608141-41-9

Molecular Formula: $C_{22}H_{24}N_2O_7S$

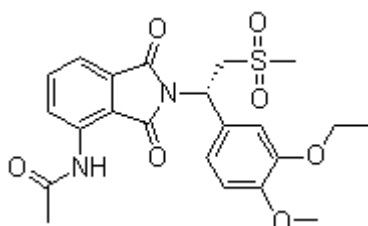
Molecular Weight: 460.50

Date of production: Dec. 12, 2018

Batch NO: 20181212

EXP DATE: Dec. 11, 2020

Chemical structure:



Items	Specifications	Results
Description	White or off-white powder	Conform
Identification	NMR HPLC	Conform
Water	$\leq 0.5\%$	0.12%
Solvent residue	ethyl alcohol ≤ 5000 ppm Acetone ≤ 5000 ppm	700ppm 1100ppm
Residue on Ignition	$\leq 0.2\%$	0.01%
Heavy metals	≤ 20 ppm	Conform
Enantiomeric excess	$\leq 0.15\%$	0.15%
Single impurity	$\leq 0.5\%$	0.03%
Total impurities	$\leq 1.0\%$	0.4%
Assay	$\geq 98\%$	99.6%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang

