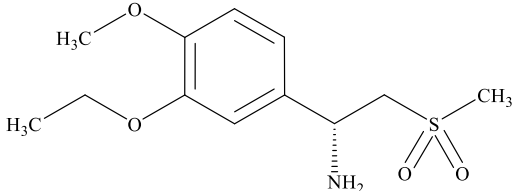


Certificate of Analysis

Certificate No.: 20200810019

Date: August 10, 2020

Retest date: July 30, 2023

Compound Name:	Apremilast Impurity 1	
Synonyms:	(R)-1-(3-ethoxy-4-methoxyphenyl)-2-(methylsulfonyl)ethan-1-amine	
TLC Catalogue Number:	A-182003	
CAS Number:	608142-27-4	
Molecular Weight:	273.35	
Molecular Formula:	C ₁₂ H ₁₉ NO ₄ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3968-050A1	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Purity (Chiral HPLC)	Not less than 98.0%	99.4%
Water Content (KF)	N/A	0.1%
Optical Rotation	N/A	$[\alpha]_D^{25.0}(c=0.63, \text{CHCl}_3): -10.6^\circ$
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.3%
Recommendation:	Released. The compound contains 0.6% Apremilast Impurity 2 (RT 14.52, TLC No. A-182004) according to its Chiral HPLC.	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.