



Certificate of Analysis

Product Name	Apremilast		
Batch No.	SW231223	Production Unit	Xi'an Sonwu Biotech Co.,Ltd
Manuf. Date	Dec.23.2023	Analysis date	Dec.27.2023
Shelf Life	2 Years	Report Date	Dec.23.2025

Test Items	Inspection Specifications	Test Results
Appearance	White powder	Conform
Related substances	Any single unknown impurity $\leq 0.1\%$ Total impurity $\leq 0.5\%$	0.09% 0.13%
Enantiomer	0.05% max	0.12%
Loss on drying	0.05% max	0.03%
Melting point	154~158 °C	Conform
Residue on ignition	0.5% max	0.01%
Residual solvents	Methan < 3000ppm Ethanol < 5000ppm THF < 720ppm Acetonitrile < 410ppm Aceton < 5000ppm Dichloromethane < 600ppm	560ppm N.D. N.D. 66ppm 800ppm N.D.
Assay	99.0% min	99.87%

Packing description:	In plastic lining steel drums (5kg/drum,25kg/drum,50kg/drum).
Storage:	Store in cool & dry place not freeze., keep away from strong light and heat
Shelf life:	2 years when properly stored

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