Hangzhou Huarong Pharm Co.,Limited

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CERTIFICATE OF ANALYSIS

Product : Apremilast(APS)
Quantity : 14.4Kg
Batch NO. : APS-707-230702
Test Basis : SOP-QC-API-105-4
Manufacturing Date : Jul.04,2023
Retest Date : Jul.04,2026

Tests	Specifications	Results
Appearance	White or off-white powder	White powder
Identification	A. Retention Time: Similar to Reference Substance	Complies
	B. IR: Similar to Reference Substance	Complies
	C. The X-ray diffraction patterns of this product have diffraction peaks at 2 theta as follows: 10.1 °、12.4 °、13.5 °、20.8 ° and 27.0 °.	Complies
Loss on drying	≤0.5%	0.11%
Residue on ignition	≤0.1%	0.06%
Related substances	APS-B ≤0.15%	Not Detected
	Single impurity ≤0.10%	Not Detected
	Total impurities ≤0.5%	Not Detected
Residual solvents	Toluene≤0.089%	Not Detected
	Tetrahydrofuran≤0.072%	0.0121%
	Methanol≤0.3%	0.0153%
	Dichloromethane≤0.06%	Not Detected
	N-hexane≤0.029%	Not Detected
	Acetonitrile≤0.041%	Not Detected
	Acetone≤0.5%	0.0521%
	Ethylbenzene≤0.03%	Not Detected
Enantiomer	APS-A≤0.15%	Not Detected
Assay	98.0%～102.0%（Calculated on the dried basis）	100.6%

The results above meet all requirements under **Apremilast(APS)** in **In-House Standard.**

HANGZHOU HUARONG PHARMACEUTICAL CO., LTD. 杭州华嵘医药有限公司 QC