



Certificate of Analysis

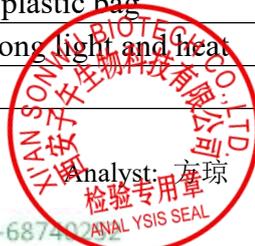
Product name	Pimecrolimus	Manufacture date	Sep.23.2023
Batch number	SW230923	Analysis date	Sep.24.2023
Batch quantity	500kg	Expiry date	Sep.23.2025

Analysis	Specification	Result
Appearance	Off-white Powder	Conforms
Identification	A:IR B:HPLC	Conforms Conforms
Assay	≥98%	99.2%
Specific Optical Rotation	-105.0° ~110.0°	-107.06°
Water Content	≤2.0%	0.60%
Heavy Metals	≤10ppm	Conforms
Residual on Ignition	≤0.10%	0.06%
Residual Solvents	Acetonitrile≤410ppm Acetone≤5000ppm Methanol≤3000ppm Dichloromethane≤600ppm n-Heptane≤5000ppm	ND 615ppm ND ND 1271ppm
Related Substances	Impurity A:≤0.50% Impurity B:≤0.50% Impurity C:≤0.15% Impurity D:≤0.50% Each of Unspecified impurity:≤0.10% Total Impurities:≤1.00%	ND 0.24% ND 0.15% 0.04% 0.44%
Microbial Limit	Total Aerobic:≤100cfu/g Total Yeasts and Molds:≤100cfu/g Staphylococcus Aureus:Absent Pseudomonas Aeruginosa:Absent	<10cfu/g <10cfu/g Absent Absent
PSD	D50:≤40 μ m	12.65 μ m
	D90:≤100 μ m	42.80 μ m
Conclusion	Conforming to Enterprise Standard	

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place. keep away from strong light and heat
Shelf life:	2 years when properly stored

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