



瑾 岚 医 药 技 术 开 发 有 限 公 司
JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED
Hangzhou ROYAL Import & Export Co.,Ltd.

Certificate of Analysis

Product name	FidaxoMicin Crystalline		
Batch No.	RY20190508	CAS No.	873857-62-6
Mfg. Date	2019.05.08	Exp. Date	2021.05.06
Standard	In-house	Quantity	20G

Tests	Specifications	Result
Appearance	White to off white powder	White powder
Specific rotation	-5.0°C ~ -10.0°C	-8.4°C
Identity	IR:sample and standard exhibit the same retention time.	Complies
	HPLC:Sample spectrum corresponds to that of standard spectrum	Complies
Water	≤3.0%	2.3%
Related substances I(on anhydrous and aceticacid free basis)	FM-R1 ≤0.15%	ND
	FM-R2≤0.15%	0.06%
	FM-R3≤0.15%	0.11%
	Single unknown impurity≤0.10%	0.05%
	Total impurities ≤1.0%	0.2%
Residual solvents	Methanol ≤3000ppm	123ppm
	Ethanol ≤5000ppm	58ppm
	Acetone ≤5000ppm	ND
	Isopropanol ≤5000ppm	ND
	Acetonitrile ≤410ppm	143ppm
	Dichloromethane ≤600ppm	ND
	Methyl tert-butyl ether ≤5000ppm	ND
	Ethyl acetate≤5000ppm	ND

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Residue on ignition	≤0.10%	0.02%
Heavy metals	≤20ppm	Complies
Assay	98.0%~102.0% (on anhydrous and solvents free basis)	100.8%
Conclusion : Conforms to In-house specification.		
Storage condition: Store in a tightly closed container and the Temp at 2~8°C		

Tested by: Alice

Checked by: Penny

Approved by: Michelle