Certificate of Analysis

Product name	Nystatin	**Manufacture date**	Jul.20.2024
Batch number	FQ240720	**Analysis date**	Jul.23.2024
Batch quantity	500kg	**Expire date**	Jul.20.2026

Test items		Standard	Result
Description		Yellow Fine powder	Conforms
Identification	IR	IR spectrum of sample is the same as working standard	Conforms
	HPLC	HPLC RT of the sample is the same as the working standard	Conforms
Melting point		165.0°C~169.0°C	165.8°C~167.0°C
Optical rotation		-23°~-29°	-27.4°
Loss on drying		NMT 1.0 %	0.17%
Residue on ignition		NMT 0.1 %	0.03%
Heavy metals		NMT 20ppm	Conforms
Related substances			
Impurity A		NMT 0.1 %	Not detected
Impurity B		NMT 0.1 %	Not detected
Impurity C		NMT 0.1 %	0.02%
Single impurity		NMT 0.2 %	0.17%
Total impurity		NMT 1.0 %	0.60%
Assay		NLT 99.0%	99.0%

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in a tightly closed container ,in a cool and dry place
Shelf life:	2 years when properly stored

Quality Assurance Officer: 李强　　Corrector: 佟丽华　　Analyst: 方琼

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