

CERTIFICATE OF ANALYSIS

PRODUCT: Norfloxacin

QUANTITY:	<u>950kg</u>	BATCH NO.:	<u>FP165202110009</u>
PACKING:	<u>25kg/Barrel</u>	TEST DATE:	<u>2021.10.11</u>
SOURCE:	<u>Warehouse</u>	REPORT DATE:	<u>2021.11.07</u>
MANUFACTURING DATE:	<u>2021.10.06</u>	RETEST DATE:	<u>2024.10.06</u>

Test	Limit	Results
Appearance	white or pale yellow crystalline powder	Pale yellow crystalline powder
Solubility	slightly soluble in acetone and in Ethanol(96 percent), insoluble in water.	Complies
Identification	IR:comparing with the spectrum obtained with norfloxacin CRS	Complies
Clarity of solution	≤Sol.II	Complies
Colour of solution	≤B7	Complies
Related Substances (%)	Total Impurities	≤0.5 0.2
	Impurity E	≤0.15 <0.04
	Impurity K	≤0.15 0.07
	Unspecified Impurities	≤0.10 0.04
Water (%)	≤1.0	0.3
Sulfated ash (%)	≤0.1	0.04
Assay (%) (calculated to anhydrous substance)	99.0~101.0	100.2
Residual Solvents: Ethanol(ppm)	≤5000	<52
Polymorphic form (XRPD)*	Complies	Complies



*: XRPD :Consignment inspection

Conclusion: The product complies with NO. R1-CEP 2006-037-Rev 03.

 Q.C.Director 李 Collator 陈 Analyst 丁

Add: NO.29 Binhai Road, Jiaojiang dist; Taizhou City, Zhejiang Province China.

Tel: 0086-576-88582505 Fax: 0086-576-88582505 P.C.: 318000

Version: QS741-3-E



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Test		Limit	Results
Particle size: (µm)	D(0.9)	---	258
	D(0.5)	---	125
	D(0.1)	---	56.2
Bioburden (cfu/g)	Total Aerobic Microbial Count	$\leq 10^3$	<1000
	Total Combined Mold and Yeast Count	$\leq 10^2$	<20



Conclusion: The product complies with prescribed enterprise standard

Q.C. Director 杨 Collator 陈欢 Analyst 丁恩莉

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ZHEJIANG LEPU

