浙江乐普 ZHEJIANG LEPU

# ZHEJIANG LEPU PHARMACEUTICAL CO.,LTD.

## CERTIFICATE OF ANALYSIS

PRODUCT:Norfloxacin

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

| 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 |

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*: XRPD :Consignment inspcition

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

Q.C.Director Collator 陈双 Analyst 丁思莉

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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 |

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Conclusion: The product complies with prescribed enterprise standard

Q.C.Director 王 Collator 陈 Analyst 丁

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