



东北制药集团股份有限公司

NORTHEAST PHARMACEUTICAL GROUP CO., LTD

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CERTIFICATE OF ANALYSIS

Fosfomycin Calcium EP

BATCH NUMBER	DY0291900122	MANUFACTURE DATE	Sep.18.2019
BATCH SIZE	500kg	TEST DATE OF APPLICATION	Sep.23.2019
QUANTITY	25Drums	RETEST DATE	Sep.17.2022
Analysis Items		Specifications	Analysis Results
1.	Characteristics	White or almost white powder	White powder
2.	Identification	IR: Complied Ca: Positive	Complied Positive
3.	Specific Rotation (on anhydrous basis)	-11.0° ~ -13.0°	-12.3°
4.	Assay (on anhydrous basis)	95.0% ~ 101.0%	97.4%
5.	pH	8.1 ~ 9.6	8.6
6.	Water	8.5% ~ 11.5%	9.50%
7.	Heavy Metals	≤20ppm	< 20ppm
8.	Chloride	≤0.2%	< 0.2%
9.	Impurity A	≤1.5%	0.61%

We, Northeast Pharmaceutical Group Co., Ltd., certify that this batch of Fosfomycin Calcium meets the requirements of European pharmacopoeia 9th.

Supervisor

Final Batch Disposition

Approved

By: 魏凌 2019.12.10