



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	DY0291900125	MANUFACTURE DATE	Sep.21.2019
BATCH SIZE	500kg	TEST DATE OF APPLICATION	Sep.26.2019
QUANTITY	25Drums	RETEST DATE	Sep.20.2022
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°		-12.2°
4. Assay (on anhydrous basis)	95.0% ~ 101.0%		97.3%
5. pH	8.1 ~ 9.6		8.7
6. Water	8.5% ~ 11.5%		9.38%
7. Heavy Metals	≤20ppm		< 20ppm
8. Chloride	≤0.2%		< 0.2%
9. Impurity A	≤1.5%		0.47%

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

Supervisor: [Signature] 2020.01.09

Final Batch Disposition: [Signature]

Approved

By: [Signature] 2020.01.10