



东北制药集团股份有限公司

NORTHEAST PHARMACEUTICAL GROUP CO., LTD



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CERTIFICATE OF ANALYSIS

Chloramphenicol EP

BATCH NUMBER	DY0092200140	MANUFACTURE DATE	Jun.26.2022
BATCH SIZE	1000kg	TEST DATE OF APPLICATION	Dec.26.2022
QUANTITY	40Drums	RETEST DATE	Jun.25.2027
Analysis Items		Specifications	Analysis Results
1.	Characteristics	White, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongated plates	Yellowish-white, fine, crystalline powder, elongated plates
2.	Identification	IR: Meets the requirements	Meets the requirements
3.	Specific Rotation	+18.5° ~ +20.5°	+20.0°
4.	Acidity or Alkalinity	Meets the Requirements	Meets the Requirements
5.	Assay (dried substance)	97.5% ~ 102.0%	100.3%
6.	Loss on Drying	≤0.5%	0.07%
7.	Related Substances	Impurity A≤0.2% Unspecified Impurities≤0.10% Total Impurities≤0.5%	0.02% 0.08% 0.21%
8.	Sulphated Ash	≤0.1%	0.03%
9.	Chloride	≤100ppm	<100ppm
10.	Residual Solvents	Methanol≤0.3% Ethanol≤0.5% Isopropyl alcohol≤0.5% Chlorobenzene≤0.036% Benzene≤0.0002%	0.0030% Not detected Not detected Not detected Not detected

We, Northeast Pharmaceutical Group Co. , Ltd., certify that this batch of Chloramphenicol meets the requirements of EP 10th .

Supervisor 路阳 2023.01.03
Final Batch Disposition

Approved

By:

邓微

2023年1月3日

METAPHARMACEUTICAL

N DE LOTE:

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26/01/2023

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