



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 USP/BP/EP

Specification Category:0402009107

BATCH NUMBER	DY0091900004	MANUFACTURE DATE	Nov.3.2019
BATCH SIZE	1000kg	TEST DATE OF APPLICATION	Nov.5.2019
QUANTITY	40Drums	RETEST DATE	Nov.2.2024
Analysis Items	Specifications	Analysis Results	Analysis Method
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	EP
2. Identification	IR:Meets the requirements	Meets the requirements	EP
3. Melting Point	149°C ~ 153°C	149.8°C ~ 151.8°C	EP
4. Specific Rotation	+18.5° ~ +20.0°	+19.3°	EP
5. Crystallinity	Meets the Requirements	Meets the Requirements	USP
6. Acidity or Alkalinity (pH)	5.0 ~ 7.5	5.5	USP
7. Assay	98.5% ~ 102.0%	99.8%	EP
8. Loss on Drying	≤0.5%	0.10%	EP
9. Related Substances	The any secondary spot≤0.5% Total≤2%	< 0.5% < 2%	USP
10. Sulphated Ash	≤0.1%	0.04%	EP
11. Chloride	≤50ppm	< 50ppm	EP
12. Residual Solvents	Ethanol≤0.5% Chlorobenzene≤0.036% Methanol≤0.3% Isopropyl alcohol≤0.5% Benzene≤0.0002%	Not detected Not detected 0.0034% 0.0048% Not detected	In-house

We, Northeast Pharmaceutical Group Co., Ltd., certify that this batch of Chloramphenicol meets the requirements of United States Pharmacopoeia 42, British Pharmacopoeia 2019 and European Pharmacopoeia 9th.

Supervisor

路阳

2020.02.17

Final Batch Disposition

Approved

By: 王春雨

2020.02.17

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