



东北制药集团股份有限公司
NORTHEAST PHARMACEUTICAL GROUP CO., LTD.

No. 37 Zhonggong Bei Street, Tixi District, Shenyang, China. Post code: 110026 FAX: 024-22724536 TEL: 024-22721818

CERTIFICATE OF ANALYSIS
Chloramphenicol USP/BP/EP

Lot: (0507)

BATCH NUMBER	DY 00911004	MANUFACTURE DATE	Jan.9.2011
BATCH SIZE	1000 kg	TEST DATE	Jan.9.2011
QUANTITY	40 Drums	RETEST DATE	Jan.8.2016

Analysis Items		Specifications	Analysis Results
1.	Characteristics	Fine, white to greyish white or yellowish white, needle-like crystals or elongated plates	Yellowish white, needle-like crystals, elongated plates
2.	Identification	IR: Meets the requirements	Meets the requirements
3.	Melting Point	149°C ~153°C	149.2°C ~151.2°C
4.	Assay	98.5%~102.0%	99.3%
5.	Loss on Drying	≤0.5%	0.02%
6.	Residue on Ignition	≤0.1%	0.02%
7.	Acidity or Alkalinity (pH)	5.0~7.5	5.33
8.	Specific Rotation	+18.5°~+20.0°	+19.6°
9.	Heavy Metals	≤0.0010%	<0.0010%
10.	Related Substances	The any secondary spot≤0.5% Total≤2%	The any secondary spot<0.5% Total<2%
11.	Chloride	≤0.0050%	<0.0050%
12.	Crystallinity	Meets the requirements	Meets the requirements
13.	Residual Solvents	Isopropyl alcohol: ≤0.5% Methanol: ≤0.3% Chlorobenzene: ≤0.0036% Benzene: ≤0.0002%	Isopropyl alcohol: Not detected Methanol: Not detected Chlorobenzene: Not detected Benzene: Not detected

We, Northeast Pharmaceutical Group Co., Ltd., certify that this batch of Chloramphenicol meets the requirements of United States Pharmacopoeia 33, British Pharmacopoeia 2010 and European Pharmacopoeia 7th.

Analysts 张晶晶

张美银

Checker

Supervisor

张美银

Final Batch Disposition

Approved

By:

张晶晶

