

CERTIFICATE OF ANALYSIS

Chloramphenicol USP/BP/EP

Specification Category:0402009107

BATCH NUMBER	DY0092100024	MANUFACTURE DATE	Jun.11.2024
BATCH SIZE	1000kg	TEST DATE OF APPLICATION	Jun.14.2024
QUANTITY	40Drums	RETEST DATE	Jun.10.2027
Analysis Items	Specifications	Analysis Results	Analysis Method
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°	+19.6°	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%	99.9%	EP
8. Loss on Drying	≤0.5%	0.06%	EP
9. Related Substances	The any secondary spot≤0.5% Total impurities≤2%	< 0.5% < 2%	USP
10. Sulphated Ash	≤0.1%	0.01%	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 0.0063% 0.0027% Not detected	In-house

this batch of **Chloramphenicol** meets the requirements of **United States Pharmacopoeia 2021**, **British Pharmacopoeia 2021** and **European Pharmacopoeia 9th**.