

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Chloramphenicol

Batch No.: DR20140115	Piece: 50kg
Manufacture Date: 2014.01.15	Expiry Date: 2017.12

TESTS:

Items	Specification	Results
Description	White or Yellow-white crystalline power	Yellow -white crystalline power
Characters	Slightly soluble in water, freely soluble in alcohol and in propylene glycol. a solution in ethanol is dextrorotatory and a solution in ethyl acetate is laevorotatory.	Conforms
Identification	Appear positive reaction the solution gives reaction of chlorides	Conforms
Melting range	149.0°C~153.0°C	150.0~151.0°C
Specific optical rotation	+17.0~+20.0°	+19.7°
IR chromatogram	IR spectrum corresponds to that of the reference standard	Conforms
Thin-Layer chromatogram	The principal spot in the chromatogram of the Test solution is similar in position and size to the principal spot in the chromatogram of The reference solution	Conforms
Related substances(TLC)	≤0.5%	Not detected
Chloride	≤100ppm	Conforms
Acidity or alkalinity	4.5~7.5	Conforms
Loss on drying	≤0.5%	0.0%
Sulphated ash	≤0.1%	0.01%
Residual solvents	methanol≤0.3% methyl dichloroacetate≤0.3% benzoic aldehyde≤0.5%	Conforms
Microbial limit	Bacteria: ≤10piece/g Mold & yeast: Absent per g Escherichia coli: Absent per g Pseudomonas aeruginosa & staphylococcus aureus: Absent per g	Conforms
Assay	97.0%—103.0%	99.20%



Conclusion: The results conform with USP36.

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