



陕西顶点医药化工有限公司

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Certificate Of Analysis

Product Name	THIAMPHENICOL INJECTION GRADE	
Batch No.	P-051CN20141201	Quantity Base 450kg
Date of Production	2014.12.17	Analysis Date 2014.12.17
Grade	BP2012	Expire Date 2016.12.16
Item	Requirements	Test Results
CHARACTERS	Fine, white or yellowish-white, crystalline powder or crystals.	Complies
SOLUBILITY	Slightly soluble in water, very soluble in dimethylacetamide, freely soluble in acetonitrile and in dimethylformamide, soluble in methanol, sparingly soluble in acetone and in anhydrous ethanol, slightly soluble in ethyl acetate. A solution in anhydrous ethanol is dextrorotatory and a solution in dimethylformamide is laevorotatory.	Complies
IDENTIFICATION	A. Infrared absorption spectrophotometry Comparison thiamphenicol CRS. B. Thin-layer chromatography C. To 50 mg in a porcelain crucible add 0.5 g of anhydrous sodium carbonate R. Heat over an open flame for 10 min. Allow to cool. Take up the residue with 5 ml of dilute nitric acid R and filter. To 1 ml of the filtrate add 1 ml of water R. The solution gives reaction (a) of chlorides.	Complies
ACIDITY OR ALKALINITY	Not more than 0.1 ml of 0.02 M hydrochloric acid or 0.02 M sodium hydroxide is required to change the colour of the indicator.	Complies
SPECIFIC OPTICAL ROTATION	- 21° to - 24° (dried substance).	-22°
MELTING POINT	163°C to 167 °C	164.5-165.5°C
ABSORBANCE	Specific absorbances at the absorption maxima: — at 266 nm: 25 to 28 for test solution (a); — at 273 nm: 21.5 to 23.5 for test solution (a); — at 224 nm: 370 to 400 for test solution (b).	26 22.7 382
CHLORIDES	Maximum 200 ppm.	<200 ppm
HEAVY METALS	NMT 10PPM	<10PPM
LOSS ON DRYING	Not more than 1.0 per cent, determined on 1.000 g	0.05%
SULPHATED ASH	Not more than 0.1 per cent, determined on 2.0 g.	0.05%
STERILITY	Should conform to requirements	Complies
BACTERIAL ENDOTOXINS	Should conform to requirements	Complies
TOTAL PLATE COUNT	Should conform to the requirements	Complies
TOTAL YEAST & MOLD	Should conform to the requirements	Complies
E.COLI	Negative	Complies
SALMANELLA	Negative	Complies
STAPHYLOCOCCUS	Negative	Complies
ASSAY(C₁₂H₁₅CL₂NO₅S)	98.0 per cent to 100.5 per cent (dried substance).	99.8%
CONCLUSION	Meet the BP2012 standard requirements	