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CERTIFICATE OF ANALYSIS

NO: DYC071711241

Product name	Chloroamphenicol
CAS Number	56-75-7
Molecule	óн
Structure	ON HIN O CI CI
Molecule Formula	C11H12C12N2O5
Batch number	20171022
Manufacture date	2017-11-02
Testing date	2017-11-02

Items	Standard	Test Result
Appearance	A white, greyish-white or	A yellowsh-white, fine
	yellowish-white, fine, crystalline	crystalline powder,
	powder or fine crystals, needles or	needles.
	elongated plates.	
Character	Slightly soluble in water, freely	Qualified
	soluble in alcohol and in	
	propylene glycol. Its alcohol solution	
	is dextrorotatory and its ethyl	
	acetate solution is levorotatory.	
Melting range	Between 149℃ and 153℃	149.3∼151.6℃
Infrared absorption	IR spectrophotometry similar to	Qualified
spectrophotometry	which of Chloramphenicol CRS	
Acidity or alkalinity	To 0.1 g add 20 ml of carbon	Qualified
	dioxide-free water R, shake and add	
	0.1 ml of bromothymol blue solution	
	R1. 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.	
Specific optical rotation	Between + 18.5° and + 20.5°	+19.5 °
Related substances	Individaul impurity≤0.5%	<0.5%
Chlorides	≤0.01%	<0.01%
Loss on drying	≤0.3%	0.08%
Sulfated ash	≤0.1%	0.02%
Assay	98.0% to 102.0%	100.7%

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Microbial limit			
Total Aerobic Microbial	≤10cfu/g	<10CFU/g	
Count			
Total Yeasts and Molds	Absent per g	Absent	
Count			
Escherichia coli	Absent per g	Absent	
Pseudomonas aeruginosa &	Absent per g	Absent	
staphylococcus aureus			
Conclusion	The product complies to EP9.0/BP2017.		



CHECK:姚仙娟

INSPECTOR: 刘清风

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