

CERTIFICATE OF ANALYSIS

Product Name:	Chloramphenicol		
Batch No.	20240108	Standard	BP2019/EP9.0
Manufacturing Date	January 8, 2024	Expiry Date TO	January 7, 2029
Batch size	1000KGS	Packing	25kg/drum
Analytical results			
Items	Specifications		Results
Appearance	A white, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongated plates.		A yellowsh-white, fine crystalline powder, needles
Solubility	Slightly soluble in water, freely soluble in alcohol and in propylene glycol. Its alcohol solution is dextrorotatory and its ethyl acetate solution is levorotatory.		Qualified
Identification	Melting range : 149C-153°C		151.7-152.8°C
	Infrared absorption spectrophotometry : IR spectrophotometry similar to which of Chloramphenicol CRS		Qualified
Acidity or alkalinity	To 0.1g add 20 ml of carbon dioxide-free water R, shake and add 0.1 ml of bromothymol blue solution RI. 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.		Qualified
Specific optical rotation	+18.5°-20.5°		+19.9°
PH	4.5-7.5		7.4
Related substances	≤0.5%		0.11%
Chlorides	≤0.01%		<0.01%
Loss on drying	≤0.3%		0.12%
Sulfated ash	≤0.1%		0.05%
Assay	98.0%-102.0%		99.40%
Microbial limit	Total aerobic microbial count : ≤10CFU/g		<10CFU/g
	Total yeasts and molds count : Absent per g		Absent
	Escherichia coli: Absent per g		Absent
	Pseudomonas aeruginosa & staphylococcus aureus : Absent per g		Absent
Packaging and storage	Preserve in well-closed containers, protected from light.		
Conclusion	The product complies to BP2019/EP9.0		

Inspector: Carlifor Wu

Verifier: Jack He