

Kalchem International

Chemicals & Compounding Supplies

QUALITY ASSURANCE CERTIFICATE OF ANALYSIS

B. NO:06542013-CPP	NAME OF PRODUCT	A.R. NO: CPP/14/013/06542
MFG DATE: February 2015	CHLORAMPHENICOL PALMITATE USP	Quantity :300kg
EXP DATE: January 2019		CAS NO: 530-43-8
TESTING DATE: 24/02/2015		RELEASE DATE: 26/02/2015

SR. NO	TEST	SPECIFICATION	OBSERVATION
01	Description	A fine, white unctuous, crystalline powder, having a faint odor and a bland, mild taste	A white , fine, unctuous powder
02	Solubility	Insoluble in water, freely soluble in acetone and in chloroform, soluble in ether, sparingly soluble in alcohol, very slightly soluble in solvent hexane.	Complies
03	Identification	Should comply the test	Complies
04	Melting Range	Between 87°C and 95°C	88.5°C - 90.5°C
05	Specific Optical Rotation	Between + 21° to + 25 °	+ 22.28 °
06	Crystallinity	Meets the requirements	Complies
07	Loss on Drying	Not more than 0.5 %	0.15 %
08	Acidity	Should comply the test	Complies
09	Free Chloramphenicol	Absorbance is not more than 0.268	0.249
10	Assay	Not less than 555 µg and Not more than 595 µg of Chloramphenicol (C ₁₁ H ₁₂ N ₂ O ₃) per mg	571 µg/mg

REMARK: The product complies as per USP 37 specifications.

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