

ADDRESS: 3-A, Shivsagar Estate, North Wing, Dr. Annie Besant Road, Worli, Mumbai 400018.

TEL: +91 22 6622 7575 / 576 | FAX: +91 22 6622 7500 / 600 | EMAIL: anuh@sk1932.com

CERTIFICATE OF ANALYSIS	FORMAT NO.: QC/F/233-00
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PRODUCT DETAILS	BATCH DETAILS
Item Name : Chloramphenicol USP	Batch No. : CL 039 J 20
Report No : F 2020 11 0162	Batch Quantity : 500.000 kg
Date : 12 / 11 / 2020	Manufacturing Date : OCT. 2020
	Expiry Date : SEP. 2025

TEST	RESULTS	SPECIFICATIONS AS PER USP 42 + IHS
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Description	Fine, white powder.	Fine, white to grayish-white or yellowish-white, needle-like crystals or elongated plates.
Solubility	Complies	Freely soluble in alcohol, in propylene glycol, in acetone and in ethyl acetate; slightly soluble in water. Its alcohol solution is dextrorotatory and its ethyl acetate solution is levorotatory.
Identification		
Identification A	Test A: Complies	Test A: IR spectrum of sample should be concordant to that of similarly recorded spectrum of WRS of Chloramphenicol.
Identification B	Test B: Complies	Test B: The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.
Melting Range	150.1°C to 151.4°C	Between 149°C to 153°C
Specific Rotation	+19.09°	Between +17.0° to +20.0°
Crystallinity	Complies	The particles show birefringence and extinction position, when the microscope stage is revolved.
pH	6.68	Between 4.5 to 7.5
Chromatographic purity (By TLC)		
Any Impurity	< 1.0%	Not more than 1.0%
Total impurity	< 2.0%	Not more than 2.0%
Assay (By HPLC)	99.52%	Between 97.0% to 103.0%
Residual solvents		
Methanol	Below detection limit	Not more than 3000 ppm

BATCH RELEASED
 BY (QN) ON:
12/11/20



Analyst : Nidhi Designation : QC Chemist Date : <u>12/11/2020</u>	 Sign.	Approved : Chandrakant pate Designation : Asst. Manager QC Date : <u>12/11/2020</u>	 Sign.
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Particle size	100% < 30 mesh	For information only
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REMARKS

The sample complies with the prescribed standards of quality as per USP 42 + IHS

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