



MFG. AT: 136, 137, G.I.D.C ESTATE, WADHWAN CITY, GUJARAT


**Q.C. DEPARTMENT
CERTIFICATE OF ANALYSIS OF CHLORAMPHENICOL**

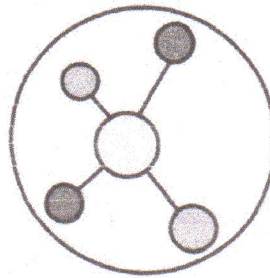
NAME OF RAW MATERIAL		CHLORAMPHENICOL USP			
Product Code	1CHLO02	Qty received	15000.00 GM	Receipt Date	17/01/2018
Batch No.	LT-OCHL/013/17-18M			Analysis Date	18/01/2018
Mfg Date	06/2017	Qty sampled	20.0 GM	Report Date	18/01/2018
Exp Date	05/2022			A.R. NO.	IWAIORM1700398.2
Sr. No.	TEST	RESULT		SPECIFICATION	
1	Description	White, fine crystalline powder		Fine, white to grayish-white or yellowish-white, needle-like crystals or elongated plates	
2	Solubility	Freely soluble in alcohol, in propylene glycol, in acetone, and in ethyl acetate, slightly soluble in water.		Freely soluble in alcohol, in propylene glycol, in acetone, and in ethyl acetate, slightly soluble in water.	
3	Identification (A) By IR (B)	Complies Complies		To comply as per USP The retention time of major peak in the chromatogram of the assay preparation is corresponds to that in the chromatogram of the standard preparation as obtained in assay.	
4	Melting Range	149.3°C		Between 149°C to 153°C	
5	Specific Rotation	+18.90°		Between +17.0° to +20.0°	
6	Crystallinity	Complies		To comply as per USP	
7	Sterility	Complies		To comply as per USP	
8	pH	5.54		4.5 to 7.5	
9	Chromatographic Purity	Complies		Individual impurity: NMT 1.0% Total impurity: NMT 2.0%	
10	Assay	100.40%		NLT 97.0% and NMT 103.0%	

NOTE: The above Sample complies as per the monograph of USP.


Q. C. CHEMIST


Q. A. OFFICER


Q. A. HEAD



MEHTA
API PVT. LTD.

CERTIFICATE OF ANALYSIS

Name of the product : Chloramphenicol USP			
Batch No	: LT-OCHL/013/17-18M	Batch size	: 275.0 Kg
Mfg. Date	: Jun -2017	A. R. No.	: 2017-18/QCP/FGM/00155
Release Date	: 06/07/2017	Exp. Date	: May-2022

Sr. No	TEST	OBSERVATION	SPECIFICATION
01	Description	Yellowish-white, fine, crystalline powder	A white, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongated plates,
02	Solubility	Slightly soluble in water, freely soluble in alcohol and in propylene glycol, slightly soluble in ether.	Slightly soluble in water, freely soluble in alcohol and in propylene glycol, slightly soluble in ether.
03	Identification A) By IR	Concordant with its working standard.	Should be Concordant with its working standard.
	B) By HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation obtained in assay.	The retention time of the major peak in the chromatogram of the assay preparation should be corresponds to that in the chromatogram of the standard preparation obtained in assay.
04	Melting Range	151.6°C to 152.4°C	Between 149.0 °C and 153.0 °C
05	Specific Rotation	+18.6°	+17.0° to +20.0°
06	Crystallinity	Complies	Meets the requirement.
07	pH	4.83	Between 4.5 to 7.5
08	Chromatographic Purity		
	i) Single Impurity	Less than 1.0 %	Not more than 1.0%
	ii) Total Impurity	Less than 2.0 %	Not more than 2.0%
09	Assay by HPLC	100.6%	97.0% to 103.0%
Additional Test			
10	Residual solvent (By GC)		
	Methanol	8 ppm	Not more than 3000 ppm
11	Particle Size by Malvern	6.75µm	95% less than 20 microns

Remark: The above sample complies as per USP specification no: FG/009/04.

	Prepared By	Reviewed By	Approved By
Name	Rahul Patil	Utpal Sanure	Bashant Jurekar
Designation	Officer - QC	Executive - QC	Asst. Manager QC
Signature			
Date	06/07/2017	06/07/2017	06/07/2017

FRM/QCD/053/06/00

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