RENOVA LIFESCIENCES

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.

Sanjay

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	Prashant Justekar
Designation	officer - QC	Executive - QC	Asst. Manager QC
Signature			
Date	06/07/2017	06/07/2017	06/07/2017

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