

Tel: (0731)2421163 / 2421172

Telefax: (91-731) 2422082

Ipca Laboratories Limited



FACTORY & OFFICE: 89A-B/90/91, INDUSTRIAL ESTATE, POLOGROUND, INDORE - 452003 (M.P.)

QUALITY DIVISION CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : CHLOROQUINE PHOSPHATE USP

BATCH NO. : 18078C3MJ

A.R. NO. : B/180904 - JA

BATCH SIZE : 203.00Kgs.

DT. OF RECEIPT : 11/12/2018

MFG. DATE : OCT. 2018

DT. OF ANALYSIS : 13/12/2018

EXP. DATE : SEP. 2023

PROTOCOL OF TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	White crystalline powder, is discoloured slowly on exposure to light.	Conforms
SOLUBILITY	Its solutions have a *pH of about 4.5. Melting range between 193°C and 198°C	4.11 193.4°C - 196.2°C
IDENTIFICATION	Freely soluble in water, practically insoluble in alcohol; in chloroform and in ether. (A) The infrared absorption spectrum of sample and standard are concordant. (B) Ultra violet absorption Ratio for A343/A329, between 1.00 and 1.15 (C) 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.	Conforms Conforms Conforms
LOSS ON DRYING (At 105°C for 16 hours)	NMT 2.0% w/w	1.49%
ORGANIC IMPURITIES (BY HPLC)	Related Compound A : NMT 0.10% Related Compound D : NMT 0.50% Related Compound E : NMT 0.10% Related Compound G : NMT 0.10% Phenol : NMT 0.10% Hydroxychloroquine sulfate : NMT 0.10% Any unknown impurity : NMT 0.10% Total impurities : NMT 2.0%	Not Detected 0.22% Not Detected <0.05% Not Detected Not Detected 0.07% 0.29%
RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm Ethanol : NMT 5000 ppm Toluene : NMT 890 ppm	Below Detection Limit <400ppm Not Detected
ASSAY (BY HPLC)	98.0% - 102.0% (on dried basis).	99.4%
ADDITIONAL TEST PARTICLE SIZE	90% < 250 microns 100% < 400 microns	37.54µm 209.90µm

REMARKS: The sample **CONFORMS** with respect to above specification.

* Release criteria for pH will be → pH of 10% solution is 3.5 - 4.5

(ANALYST)

RADHARAMAN TIWARI

Date of Print: 09/01/2019

(MANAGER QUALITY CONTROL)

MANOJ DUBEY

Date of Print: 09/01/2019

Regd. Off.: 48, Kandivli Industrial Estate, Kandivli (West), Mumbai - 400 067. Phone: 6647 4444
Corporate Office.: 142-AB, Kandivli Industrial Estate, Kandivli (West), Mumbai - 400 067. Phone: 6647 4747