

CERTIFICATE OF ANALYSES

NAME OF THE PRODUCT:
CIPROFLOXACIN HYDROCHLORIDE USP31

TEST	RESULT	SPECIFICATION
DESCRIPTION	FAINTLY YELLOWISH COLOURED POWDER	FAINTLY YELLOWISH TO LIGHT YELLOW COLOURED POWDER
SOLUBILITY	COMPLIES	SOLUBLE IN WATER, SLIGHTLY SOLUBLE IN ACETIC ACID AND IN METHANOL, VERY SLIGHTLY SOLUBLE IN ETHANOL, PRACTICALLY INSOLUBLE IN ACETONE, IN ACETONITRILE, IN ETHYL ACETATE, IN HEXANE & IN DICHLOROMETHANE.
IDENTIFICATION	PASSES THE TEST PASSES THE TEST PASSES THE TEST	1. IR 2. TLC 3. CHLORIDES
PH (1G IN 40ML IN WATER)	3.80	3.0 – 4.5
WATER (BY KF)	5.67%	4.7% -6.7%
RESIDUE ON IGNITION	0.057%	0.1% MAX
SULPHATES	LESS THAN 0.04%	NMT 0.04% (W/W)
HEAVY METALS	LESS THAN 20 PPM	NMT 20 PPM
FLUOROQUINOLINI C ACID	LESS THAN 0.2%	NMT 0.2%
CHROMATOGRAPHY C PURITY BY HPLC A. ETHYLENE DIAMINE ANALOG B. ANY INDIVIDUAL IMPURITY C. SUM OF IMPURITIES INCLUDING ANALOG	0.08% 0.16% 0.39%	NMT 0.2% NMT 0.2% NMT 0.5%
ASSAY (ON ANHYDROUS BASIS)	99.74%	98.0% -102.0%