

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT: MOXIFLOXACIN HCL

MFG DT: JULY 2010 EXP DT: JUNE 2013

BATCH NUMBER: PMX-VII041007

TEST	SPECIFICATION	RESULTS
DESCRIPTION	LIGHT YELLOW TO YELLOW POWDER	YELLOW POWDER
SOLUBILITY	SPARINGLY SOLUBLE IN WATER AND PRACTICALLY INSOLUBLE IN ACETONE	SPARINGLY SOLUBLE IN WATER AND PRACTICALLY INSOLUBLE IN ACETONE
IDENTIFICATION BY		
HPLC	THE RETENTION TIME OF PRINCIPLE PEAK IN THE SAMPLE CHROMATOGRAM SHOULD BE CONCORDANT WITH THAT OF THE PRINCIPLE PEAK IN THE WORKING STANDARD CHROMATOGRAM OBTAINED FROM ASSAY BY HPLC TEST	THE RETENTION TIME OF PRINCIPLE PEAK IN THE SAMPLE CHROMATOGRAM IS CONCORDANT WITH THAT OF THE PRINCIPLE PEAK IN THE WORKING STANDARD CHROMATOGRAM OBTAINED FROM ASSAY BY HPLC TEST
CHLORIDE TEST	A CURDLED WHITE PRECEPITED SHOULD BE FORMED IN THE PRESENCE OF CHLORIDE IONS	A CURDLED WHITE PRECIPITATE IS FORMED IN THE PRESENCE OF CHLORIDE IONS
WATER BY KF (W/W, DETERMINED ON 0.1G)	NOT MORE THAN 6.0%	3.5%
SULPHATED ASH (W/W, DETERMINED 1.0G AT 600°C)	NOT MORE THAN 0.1%	0.04%
HEAVY METALS	NOT MORE THAN 20 PPM	LESS THAN 20 PPM
RELATED SUBSTANCES BY HPLC (BY AREA NORMALISATION) a) SINGLE MAJOR IMPURITY b) TOTAL IMPURITIES	NOT MORE THAN 0.5%	0.05%
	NOT MORE THAN 1.0%	0.11%
ASSAY BY HPLC (W/W, ON ANHYDROUS BASIS)	NOT LESS THAN 98.0% AND NOT MORE THAN 102%	99.7%