



CERTIFICATE OF ANALYSIS

PRODUCT NAME : ENROFLOXACIN (BASE)

MFG DT: JAN 2010 EXP DT: DEC 2012

BATCH NUMBER: 456FG10

<u>TESTS</u>	<u>RESULTS</u>	<u>SPECIFICATION</u>
DESCRIPTION	LIGHT YELLOW COLOUR POWDER	LIGHT YELLOWISH TO YELLOW COLOUR POWDER
SOLUBILITY	COMPLIES	1 GRAM SAMPLE DISSOLVE IN 100 ML OF 0.05 N HCL
IDENTIFICATION	COMPLIES 223 – 225°C	A) UV B) MELTING RANGE (222 – 226°C)
LOSS ON DRYING	0.41 %	NOT MORE THAN 1.0%
COLOR OF SOLUTION [10% SOLUTION IN 1.25% SODIUM HYDROXIDE]	0.040	NOT MORE THAN 0.15 AT 450 NM
RESIDUE ON IGNITION	0.063 %	NOT MORE THAN 0.1%
HEAVY METALS	< 20 PPM	NOT MORE THAN 20 PPM
FLUOROQUINOLONIC ACID	< 0.2 %	NOT MORE THAN 0.2 %
CHROMATOGRAPHIC PURITY	0.12 % 0.32 %	A) INDIVIDUAL IMPURITY PEAK IS NOT MORE THAN 0.5% B) SUM OF ALL THE IMPURITIES IS NOT MORE THAN 1.0%
ASSAY		
a) BY TITRIMETRY	99.52 %	IT CONTAINS NLT 98.0 % & NMT 102.0 % OF C ₁₉ H ₂₂ FN ₃ O ₃ CALCULATED ON DRIED BASIS
b) HPLC	99.07 %	