

Address for correspondence:

Ranbaxy Laboratories Limited
Plot No. 89-90, Sector 32
Gurgaon - 122001
Haryana - INDIA
Phone : +91 124 4135000

RANBAXY

LABORATORIES LIMITED

Certificate of Analysis

PRODUCT NAME : OFLOXACIN Ph. Eur.

Batch No. : OFX130050

A. R. No. : OFXD130056

Manufactured : December 2013

Loan Lic. No : 1827-OSP

Sampling Date : 18.12.2013

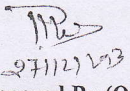
Retest : November 2016

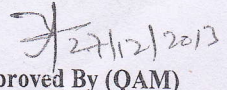
Quantity : 205.10 kg

Characteristics	Results	Specifications
Description	A pale yellow crystalline powder.	A pale yellow or bright yellow crystalline powder
Solubility	Complies	Slightly soluble in water, soluble in glacial acetic acid, slightly soluble to soluble in Methylene chloride, slightly soluble in methanol.
Identification - IR	Complies	The infrared absorption spectrum of a potassium bromide dispersion of the sample must be concordant with that of a similar preparation of Ofloxacin working standard/reference standard.
Absorbance at 440(nm)	0.158	NMT 0.25
Optical rotation	- 0.006 deg.	-0.10 deg to +0.10 deg
Impurity A (BY TLC)	Less than 0.2 %	NMT 0.2%
RELATED SUBSTANCES (BY HPLC)		
Impurity B	Not detected	NMT 0.2 %
Impurity C	Not detected	NMT 0.2 %
Impurity D	Not detected	NMT 0.2 %
Impurity E	Less than 0.05 %	NMT 0.2 %
Impurity F	Less than 0.05 %	NMT 0.2 %
Any unknown impurity	Less than 0.05 %	NMT 0.10 %
Total impurities	Less than 0.05 %	NMT 0.5 %

CONCLUSION: The batch complies with respect to the specifications as above i.e. Ofloxacin Ph.Eur.

Date of issue: 27.12.2013


27/12/2013
Prepared By (QA)


27/12/2013
Approved By (QAM)

Manufactured in India By : Ranbaxy Laboratories Limited
At: Saurav Chemicals Limited, Village Bhagwanpura, Barwala Road, Derabassi, Distt. Mohali-140507 Punjab - India
Tel. : +91-1762-506091-92

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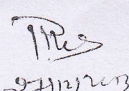
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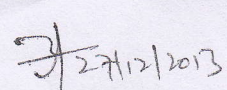
Quantity : 205.10 kg

Characteristics	Results	Specifications
Heavy metals	Less than 10 ppm	NMT 10 ppm
Loss on drying	0.09 % w/w	NMT 0.2 % w/w
Sulphated ash	0.04 % w/w	NMT 0.1% w/w
Assay	99.6 %w/w	99.0 - 101.0% w/w of $C_{18}H_{20}FN_3O_4$ on dried basis.
<u>Additional tests</u>		
Residual Solvents		
- Ethanol	36 ppm	NMT 500 ppm
- Methylene chloride	79 ppm	NMT 500 ppm
-Acetone	Not Detected	NMT 100 ppm
Bulk Density		
- Untapped density	0.35 gm/ml	NLT 0.30
-Tapped density (Campbell Apparatus, 350 taps)	0.67 gm/ml	NLT 0.60
Particle size (BY SIEVE ANALYSIS)		
Particles passing through 20 mesh	100 %	100 %
Particles passing through 60 mesh	82 %	NLT 80 %

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