

QUALITY CONTROL CERTIFICATE OF ANALYSIS

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PRODUCT NAME: LEVOFLOXACIN USP	BATCH SIZE	: 750.00 KGS
BATCH NO. : LFC/14070217	A.R. NO.	: FG/24/01117
MFG. DATE : JUL- 2024	ANALYSIS DATE	: 22/07/2024
EXP. DATE : JUN-2029	CAS NO	: [138199-71-0]

SR. NO.	TESTS	SPECIFICATION	RESULTS
1	Description	Light yellowish – white to yellow – white crystals or crystalline powder.	A yellowish powder
2	Solubility	Soluble in dimethyl sulphoxide and in acetic acid, sparingly soluble in water, in acetone and in methanol; practically insoluble in glycerine and in n-octanol.	Complies
3	Identification A. By I.R.	The IR of the sample should concordant with WS	Complies
	B. By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution ,as obtained in the test Assay.	Complies
4	Assay By HPLC	Not less than 98.00 % & not more than 102.0% on anhydrous basis.	100.53%
5	Residue on ignition	Not more than 0.2 %	0.050%
6	Organic Impurities (Procedure 1)		
	N - Desmethyl Levofloxacin	Not more than 0.30% (LOQ = 0.020%)	0.037%
	Diamine derivative	Not more than 0.30% (LOQ = 0.029%)	Below LOQ
	Levofloxacin N – Oxide	Not more than 0.30% (LOQ = 0.020%)	Below LOQ
	9 – Desfluoro Levofloxacin	Not more than 0.30% (LOQ = 0.023%)	Below LOQ
	D - Isomer	Not more than 0.80% (LOQ = 0.035%)	0.267%
	Any unknown impurity	Not more than 0.10% (LOQ = 0.031%)	0.058%
	Total impurities	Not more than 0.50%	0.154%



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SR. NO.	TESTS	SPECIFICATION	RESULTS
	Organic Impurities (Procedure 2)		
	Levofloxacin related compound A (N - Desmethyl Levofloxacin ^a)	Not more than 0.20% (LOQ = 0.010%)	0.018%
	Levofloxacin related compound B	Not more than 0.13% (LOQ = 0.020%)	Not Detected
	Any other impurity	Not more than 0.10% (LOQ = 0.008%)	0.080%
	Total impurities	Not more than 0.50%	0.174%
	Organic Impurities (Enantiomeric purity) (Procedure 3)		
	D- Ofloxacin	Not more than 1.0% (LOQ = 0.050%)	0.287%
7	Specific Optical Rotation	- 92 ° to -106 ° at 20 °	-100.222°
8	Water Content	Between 2.0% to 3.0%	2.78%
9*	Residual Solvent	Methanol : Not more than 3000 ppm (LOQ = 3.10 ppm)	14.41 ppm
10*	Bulk Density	For Information : Untapped :g/ml Tapped :g/ml	0.29 g/ml 0.63 g/ml



Aarti Drugs Limited

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11*	Microbial Limit Test		
1	Total Aerobic Microbial Count	Not more than 1000 cfu/gm	Complies
2	Total Yeasts and Mold count	Not more than 100 cfu/gm	Complies
	Test for specified microorganism		
3	Bile-Tolerant Gram - Negative Bacteria	Absent / g	Complies
4	Escherichia coli	Absent / g	Complies
5	Salmonella	Absent / 10 g	Complies
6	Pseudomonas aeruginosa	Absent / g	Complies
7	Staphylococcus aureus	Absent / g	Complies
8	Clostridia	Absent / 2 g	Complies
9	Candida albicans	Absent / g	Complies
10	Shigella	Absent / g	Complies
12*	Bacterial Endotoxin	Not more than 0.5 EU/mg	Complies
Remarks : The above material passes as per USPNF 2023 and IHTM* Specification			

Prepared By :

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Designation : Q.C. Officer

Sign & Date : 
13/08/2024

Checked By :

Name : Sandip U. Yadav

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Sign & Date : 
13/08/2024

Approved By :

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