ACME LIFETECH. LLP
QUALITY CONTROL DEPARTMENT
RAW MATERIAL SPECIFICATION

11/12/2023

SPEC No.: RMS/009	LEVOFLOXACIN USP	Effective Date: 11/12/2023
Reference: USP		Review Date: 10/12/2026
Revision No.: 01		Page No.: 1 of 3
Supersedes: 00		

SAMPLING AND HANDLING

Sr. No.	Test	Specification
1	Storage	Store in airtight containers.
2	Sampling	Carry out the sampling as per SOP No. SOP/QC/012
3	Quantity of composite sample for analysis	15 g
4	Quantity of reserve sample	2 x 15 g
5	Retest period	One year
6	Hazardous and precautions, if any	Use hand gloves and nose mask while sampling.
7	Disposition of analytical sample	To be done according to SOP No.: SOP/QC/022

	Prepared by	Checked by	Approved by	Authorized by
Signature/ Date	11/12/2023	11/12/2023	11/12/2023	11/12/2023
Name	Anand Prakash	Shashi Kumar	Sushil Kumar	S.Dutta
Designation	EXECUTIVE QC	SR. ASST. MANAGER QC	HEAD QC	HEAD QA

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SPECIFICATION		
Sr. No.	**TEST**	**SPECIFICATION**
1.	Description	Light yellowish-white to yellow-white crystals or crystalline powder.
2.	Solubility	Slightly soluble in methanol and water, soluble in chloroform, acetic and dilute sodium hydroxide solution.
3.	Identification	
	Identification A (By IR)	The IR spectrum of the sample preparation is concordant with reference IR spectrum of Levofloxacin USP working standard or reference standard.
	Identification 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 Assay.
4.	Residue on ignition	NMT 0.2%
5.	Organic impurities By HPLC (Procedure 1)	
	N-Desmethyl Levofloxacin	NMT 0.3%
	Diamine derivative	NMT 0.3%
	Levofloxacin N-oxide	NMT 0.3%
	9-Desfluoro levofloxacin	NMT 0.3%
	D-Isomer	NMT 0.8%
	Any unknown Impurity	NMT 0.1%
	Total Impurities	NMT 0.5%
	Organic impurities By HPLC (Procedure 2)	
	Levofloxacin related compound A	NMT 0.2%
	Levofloxacin related compound B	NMT 0.13%
	Any unknown Impurity	NMT 0.10%
	Total Impurities	NMT 0.50%
	Organic impurities By HPLC (Procedure 3)	
	Enantiomeric Purity	NMT 1.0%

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6.	Specific optical rotation	-92° to -106° at 20°
7.	Water determination	2.0% – 3.0%
8.	Assay (By HPLC)	NLT 98.0% and NMT 102.0% of Levofloxacin on anhydrous basis

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