93

WRS
L11-2

Cipla
Bangalore

WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD

ITEM : LEVOFLOXACIN USP
(-)-(S)-9-Fluoro-2, 3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid, hemihydrate

EVALUATED WITH: USPRS/BL/L19/06
BATCH No. : H0L298

DATE OF QUALIFICATION : 12.03.2015
DIRECTION FOR STORAGE : Store between 2°C to 8°C in well closed container. Protect from light#.
DIRECTION FOR USE : Use as such.
VALIDITY OF USE : 11.03.2017
WORKING STANDARD No. : WS/C/L56/04
A. R. No. : BE1502174
SOURCE B. No. : FWC140285 SOURCE A. R. No. : BE1500054

REFERENCE : USP 37, PROTOCOL No.: WP/USP/WS/C/L56

Sr. No.	TESTS	STANDARDS	RESULTS
1)	DESCRIPTION	Light yellowish-white to yellow –white crystals or crystalline powder.	Complies
2)	SOLUBILITY	Soluble in dimethylsulfoxide and in acetic acid; Sparingly soluble in water, in acetone and methanol; Practically insoluble in glycerin and in n-ocatanol.	Complies
3)	USP STANDARDS IDENTIFICATION A *(By IR Spectrophotometry)	The infra-red spectrum of the sample is concordant with the spectrum obtained from similar determination of USP Levofloxacin RS.	Complies
	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.	Complies
4)	*ASSAY(By HPLC)	Levofloxacin contains not less than 98.0 % w/w and not more than 102.0 % w/w of $C_{18}H_{20}FN_3O_4$, calculated on the anhydrous basis.	99.9 % w/w
5)	IMPURITIES RESIDUE ON IGNITION	Not more than 0.20 % w/w.	0.03 % w/w

HEAD QUALITY CONTROL:
DATE : 12.03.2015

LAB QA HEAD:
DATE : 12.03.2015

QUALITY CONTROL DEPT.

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5 NOV 2015

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REFERENCE : USP 37, PROTOCOL No.: WP/USP/WS/C/L56

Sr. No.	TESTS	STANDARDS	RESULTS
6)	HEAVY METALS	Not more than 10 ppm	Complies
7)	*ORGANIC IMPURITIES, PROCEDURE 1 (By HPLC)	N-Desmethyl levofloxacin : Not more than 0.30 % Diamine derivative : Not more than 0.30 % Levofloxacin N-oxide : Not more than 0.30 % 9-Desfluoro Levofloxacin : Not more than 0.30 % D-isomer : Not more than 0.80 %. Any unknown impurity : Not more than 0.10 % Total impurities : Not more than 0.50 % (Excluding D-isomer)	0.01 % Not detected Not detected Not detected 0.26 % 0.01 % 0.04 %
	*ORGANIC IMPURITIES, PROCEDURE 2 (By HPLC)	Levofloxacin Related Compound B : Not more than 0.13 % Total impurities : Not more than 0.50 % (Total impurities Procedure 1+ Levofloxacin Related Compound B)	0.01 % 0.05 %
8)	SPECIFIC TESTS OPTICAL ROTATION, SPECIFIC ROTATION	Not less than –92.00° and Not more than –106.00°, at 20° C on anhydrous basis.	–99.05°
9)	WATER DETREMINATION (By KF)	Not less than 2.00 % w/w and not more than 3.00 % w/w.	2.57 % w/w

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WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD

ITEM : **LEVOFLOXACIN USP**
(-)-(S)-9-Fluoro-2, 3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid, hemihydrate

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BATCH No. : H0L298

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VALIDITY OF USE : **11.03.2017**
WORKING STANDARD No. : WS/C/L56/04
A. R. No. : BE1502174
SOURCE B. No. : FWC140285 **SOURCE A. R. No.** : BE1500054

REFERENCE : USP 37, **PROTOCOL No.**: WP/USP/WS/C/L56

Sr. No	TESTS	STANDARDS	RESULTS
		IN-HOUSE STANDARDS	
1)	RESIDUE ON IGNITION	Not more than 0.10 % w/w.	0.03 % w/w
2)	*ORGANIC IMPURITIES, PROCEDURE 1 (By HPLC)	N-Desmethyl levofloxacin : Not more than 0.20 % 9-Desfluoro Levofloxacin : Not more than 0.10 % Diamine derivative : Not more than 0.10 % Levofloxacin N-oxide : Not more than 0.10 % Chloromethyl ester impurity : Not more than 0.10 %. N-ethyl Levofloxacin : Not more than 0.10 %	0.01 % Not detected Not detected Not detected 0.01 % Not detected
	*ORGANIC IMPURITIES, PROCEDURE 2 (By HPLC)	Levofloxacin Related Compound B : Not more than 0.10 %	0.01%

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REFERENCE : USP 37, PROTOCOL No.: WP/USP/WS/C/L56

Sr. No	TESTS	STANDARDS		RESULTS
3)	RESIDUAL SOLVENTS (By GC)	Ethyl acetate	: Not more than 2000 ppm	Not detected
		Methanol	: Not more than 3000 ppm	132 ppm
		Methylene chloride	: Not more than 400 ppm	Not detected
		Isopropyl alcohol	: Not more than 4000 ppm	Not detected
		n-Butanol	: Not more than 2000 ppm	Not detected
4)	**PURITY (By Mass Balance Method)	Not Applicable		97.3 % (On as such basis) 99.9 % (On anhydrous basis)

REMARKS: *Tests qualified with USPRS. All other tests complies with USP 37 and certified to be used as Working Standard.

NOTE: # Third party may store as per specification. ** Purity calculated as per QCP 14 Version No. 12.

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