WRS
L36-1

CENTURION LABORATORIES PVT.LTD.

FORM 39 RULE 150E (f)

THE DRUG & COSMETIC ACT.1940 & THE RULES THERE UNDER.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF WORKING STANDARD

Material Name	:	**Levofloxacin Hemihydrate USP**			
Batch No.	:	CLR-05098-15-16	Mfg. Date	:	08/2015
Date of Preparation	:	10/10/2015	Exp. Date	:	07/2019
Specification	:	USP	Retest Date	:	10/10/2016

Sr. No	Test	Result	Specification
1.	Description	Light yellowish-white to yellow-white crystals or crystalline powder.	Light yellowish-white to yellow-white crystals or crystalline powder.
2.	Solubility	Soluble in dimethylsulfoxide and in acetic acid; sparingly soluble in water, in acetone, and in methanol; practically insoluble in glycerin and in *n*-octanol.	Soluble in dimethylsulfoxide and in acetic acid; sparingly soluble in water, in acetone, and in methanol; practically insoluble in glycerin and in *n*-octanol.
3.	Identification A: By IR	The IR spectrum of test preparation matches with that of the standard preparation	The IR spectrum of test preparation matches with that of the standard preparation
	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.*	The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution, as* obtained in the *Assay.*
4.	Water Determination	2.48 %	2.0%- 3.0%
5.	Optical rotation	- 98.0°	Between -92.0° to -106.0°, at 20° C.
6.	Residue on ignition	0.02 %	Not More Than 0.2% w/w
7.	Heavy metals	Less than 10 ppm	Not More Than 10 ppm
8.	Organic impurities		
	N-desmethyl	Not detected	NMT 0.3 %