

WRS
L9-2

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CERTIFICATE OF ANALYSIS

Working standard name	Levofloxacin Hemihydrate	Raw material source	Zhejiang apeloakanguu pharma. Ltd
Working standard number	WRS LN15-275	Raw material B/No	KY-LFA-M20131126
Effective date	10/2015	Raw material Mfg date	11/2013
Valid up to	10/2016	Raw material Exp date	11/2017
Reference standard batch number	HOL298	Reference standard source	USP
Test(s) qualified for	Assay	Certificate No:	WRS-0345
Test protocol	USP 38 NF33		
ITEMS	SPECIFICATIONS	RESULTS	
Description	Light yellowish-white crystalline powder	Light yellowish-white to yellowish white crystals or crystalline powder	
Identification: A. IR absorption spectrum B. Heavy metals Optical Rotation Residue on Ignition Water	A. The IR absorption spectrum of the material is concordant with that of the reference spectrum. B. The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay. NMT 20ppm -92 ^o to -106 ^o NMT 0.2% 2.0% - 3.0%	A. The IR absorption spectrum of the material is concordant with that of the reference spectrum. B. The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay. ≤ 20ppm -99.76 ^o 0.142% 2.04%	
Assay (% w/w on as is basis)	98.0% -102.0%	99.92%	
Storage	Kept in tightly closed container, protected from light and stored in a cool dry place		

The above referred material **complies /does-not-comply** with the **USP 38 NF33** specifications

Name: Simeon Kojim
Signature: [Signature]
Date: 13/10/15

Name: LUCALIA K.
Signature: [Signature]
Date: 13/10/15

Name: DR. G. MURICH
Signature: [Signature]
Date: 13/10/15

ANALYST

QUALITY CONTROL MANAGER

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