

CERTIFICATE OF ANALYSIS

Product Name	PAZUFLOXACIN MESILATE	Batch NO.	RY180606
Production date	2018.06.06	Expired Date	2020.06.05
CAS NO.	163680-77-1	Standard	CP
Tests	Limits	Test results	
Appearance	White-like crystalline powder; odorless, bitter taste; hygroscopic; light gradient. This product is soluble in water, soluble in methanol, slightly soluble in glacial acetic acid, insoluble in chloroform.	Conforms	
Specific rotation	-61~65°	-63°	
Identification	HPLC: The retention time of the main peak of the test solution should be consistent with the retention time of the levo isomer in the main peak of the control solution.	Conforms	
	UV: Should have maximum absorption at wavelengths of 247nm and 333nm	Conforms	
	IR: The infrared absorption spectrum of this product is consistent with that of the pazufloxacin reference substance.	Conforms	
PH	3.2~3.8	3.5	
Solution clearance and solubility	Should conforms	Conforms	
The absorbance of the solution	8% water solution ≤ 0.037	0.015	
	4% water solution ≤ 0.024	0.010	
	1% water solution ≤ 0.011	0.001	
Related substance	The single impurity $\leq 0.10\%$	0.05%	
	The total impurities $\leq 0.20\%$	0.10%	
Optical isomer	$\leq 0.20\%$	0.09%	
	Methanol $\leq 0.3\%$	0.03%	
	Ethanol $\leq 0.5\%$	N.D.	

Residual solvent	Acetone \leq 0.5%	N.D.
	diethyl ether \leq 0.5%	N.D.
	ethyl acetate \leq 0.5%	N.D.
	1,4-Dioxane \leq 0.038%	N.D.
Water	\leq 0.5%	0.4%
Residue on ignition	\leq 0.1%	$<$ 0.1%
Heavy metals	\leq 10PPM	Conforms
Sulphate	\leq 0.05%	Conforms
Bacterial endotoxin	\leq 0.5EU/MG	Conforms
Microbial limit	Total anaerobic bacteria \leq 1000cfu/g	$<$ 100cfu/g
	Total of molds and yeasts \leq 100cfu/g	$<$ 10cfu/g
	escherichia coli should not be detected	N.D.
Assay	\geq 76%, Calculated by anhydrous substance	76.7%
Conclusion: This batch meets CP standard.		

Tested by: Esther

Checked by: Alice

Approved by: Mich

