Hangzhou Huarong Pharm Co.,Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.
TEL: 0086-571-86758373 FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

Product Name: OLOPATADINE HYDROCHLORIDE
Batch No.: OLOR-230401 Mfg. Date: Apr.11th.2023
Quantity: 10.96kg Retest Date: Apr.10th.2025
Test No.: OLOR230401 Report Date: May.25th.2023
Analysis Reference: USP2021 incld. In-house specifications

Item		Specification	Result
Appearance		White crystalline powder	White crystalline powder
Identification		IR: Identical versus reference spectrum	Conform
		The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Conform
		Reaction of chloride: Positive	Conform
pH		2.0~4.0	2.7
Loss on drying		≤0.3%	0.06%
Residue on ignition		≤0.1%	0.04%
Heavy metals		≤10ppm	<10ppm
Related substances	α-Hydroxy Olopatadine	≤0.2%	Undetected
	Olopatadine E-isomer	≤0.10%	<0.05%
	Single unknown impurity	≤0.10%	0.08%
	Total impurities	≤0.25%	0.10%
Residual solvents	Ethanol	≤5000ppm	<1.8ppm（LOD）
	Acetone	≤5000ppm	1618ppm
	Tetrahydrofuran	≤720ppm	<0.6ppm（LOD）
	1-Butanol	≤5000ppm	<7.2ppm（LOD）
	Toluene	≤890ppm	<1.1ppm（LOD）
	Hexane	≤290ppm	<1.1ppm（LOD）
	Ethyl acetate	≤5000ppm	<1.0ppm（LOD）
	Dichloromethane	≤600ppm	<2.2ppm（LOD）
Microbiological limit tests	TAMC	≤1000CFU/g	<1 CFU/g
	TYMC	≤100CFU/g	<1 CFU/g
	Staphylococcus aureus and P. aeruginosa	Absent	Absent
Assay		98.0%~102.0% (dried substance)	100.2%
Conclusion: Conform to USP2021 incld. In-house specifications			

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