Hangzhou Huarong Pharm Co.,Limited

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CERTIFICATE OF ANALYSIS

Product Name	Nebivolol Hydrochloride		
Batch No.	D5283-23-001	Batch Size	63.94Kg
Batch Type	Commercial	Report Date	2023-11-11
Retest Date	2025-8	Storage Condition	Preserve in well closed containers
Manufacture Date	2023-9-23	Reference	EDMF

Test Items	Specifications	Results
Appearance	White or off-white powder	White powder.
Identification	1) Infrared absorption spectrum corresponds to the spectrum obtained with Nebivolol Hydrochloride RS.	Conform
	2) The retention time of the major peak obtained from the test solution is concordant with that of the reference solution directed in the Assay.	Conform
	3) It gives reaction of chlorides.	Conform
Water	≤ 0.5%	0.1%
Chlorides	7.6~8.4%	8.0%
Sulfated ash	≤0.1%	<0.1%
Heavy metals	≤ 0.002%	<0.002%
Stereoisomeric purity (HPLC)	Single stereoisomeric impurity≤ 0.10%	N.D
	Total stereoisomeric impurities≤ 0.5%	N.D
	D/L-isomer (peak 1)between 48.5~51.5%	49.8%
	D/L-isomer (peak 2)between 48.5~51.5%	50.2%
Related substances (HPLC)	De-F impurity≤ 0.15%	0.11%
	Benzyl impurity≤ 0.15%	N.D
	Any unspecified impurity≤ 0.10%	<0.05%
	Total impurities≤ 0.6%	0.11%
Assay (HPLC)	98.0%~102.0% (calculated on anhydrous and solvent-free basis)	99.4%
Residual reagent	Pd≤10ppm	<LOD(LOD:1.0ppm)
Residual solvents(GC)	Toluene≤890ppm	12ppm
	Acetonitrile≤410ppm	N.D
	Ethanol≤5000ppm	70ppm
	1,2-Dimethoxyethane≤100ppm	N.D
	Isopropanol≤ 5000ppm	N.D
	Acetic acid≤5000ppm	<LOD(LOD:150ppm)
Conclusion	Complies with EDMF	

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