Biochempartner
瀚香生物科技

Certificate Of Analysis

Product Name ： Nebivolol Hydrochloride　　Manufacture Date : September,2018

Batch number ： 20180926　　Retest Date: August, 2021

Test	Specifications	Results
Description	White to off white powder	White powder
Solubility	Sparingly soluble in Methanol.	Complies
Identification By IR: By HPLC:	 The infrared absorption spectrum of the substance being examined in potassium bromide disc should be concordant with the spectrum obstained form Nebivolol Hcl working standard. Retention time of the sample should match with that of working standard.	 Matches with standard. Complies
Loss on drying (determine on 1.0g at 100℃ -105℃ for 3Hrs.	Not more than 0.5% w/w.	0.33% w/w.
Specific optical rotation	Between –1.0° and +1.0°	+0.1°
Sulphated ash	Not more than 0.1% w/w.	0.048% w/w.
Heavy metals	Not more than 20 ppm	Less than 20 ppm
Related Subtances (by HPLC) A. Nebivolol isomer at about 0.88 RRT B. Nebivolol isomer at about 1.13 RRT C. Highest individual impurity D. Total impurities	 Not more than 0.15% Not more than 0.15% Not more than 0.10% Not more than 1.00%	 0.081% Below Detection limit Below Detection limit Below Detection limit
Chromatographic Chiral purity (By % area)	1.D-isomer between 48.5% and 51.5% 2.L-isomer between 48.5% and 51.5% 3.Total of DL-isomers:Not less than 99.0%	49.5% 50.2% 100.0%
Assay (By Potentiometry)	Between 98.0% and 102.0% w/w of $C_{22}H_{26}ClF_2NO_4$	100.1% w/w
Residual solvents A. Methanol B. Isopropyl Alcohol	 Not more than 1000 ppm Not more than 1000 ppm	 Between Detection limit Between Detection limit
Additional Test		
Particle size	For Information	90% particles are less than12 um
Palladium	NMT 20 ppm	Below detection limit

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