



Certificate of analysis

Product name: Palonosetron hydrochloride

Cas number: 135729-62-3

Molecular Formula: $C_{19}H_{24}N_2O \cdot HCl$

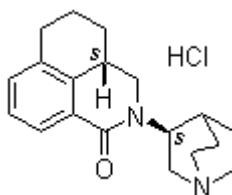
Molecular Weight: 332.87

Date of production: April. 18, 2018

Batch NO: 20180418

Expiry Date: April. 17, 2020

Chemical structure:



Items	Specifications	Results
Description	White to off-white crystalline powder	Conform
Identification	NMR HPLC	Conform
Solubility	Freely soluble in water, soluble in methanol and 0.1mol/L hydrochloric acid solution, hardly soluble in isopropyl alcohol.	Conform
Chloride(on dried basis)	9.6~11.7%	10.5%
Specific rotation	-93~-103°	-94.6°
RR-Isomer	0.2% max	N.D
Related substances	Diastereomer: 0.1% max	0.004%
	Nitrogen oxides: 0.1% max	0.005%
	Other individual impurity: 0.1% max	N.D
	Total impurities: 0.5% max	0.01%
PH	4.5-6.0	5.63
Clarity & color of solution	Clear and Colourless	Conform
Loss on drying	0.5% max	0.2%
Residue on ignition	0.1% max	0.05%
Heavy metals	10ppm max	Conform
Sulfate	0.06% max	Conform
Residual Solvents	Methanol ≤ 0.3%	N.D
	Ethanol ≤ 0.5%	0.06%
	Diethyl ether ≤ 0.5%	N.D
	Tetrahydrofuran ≤ 0.072%	N.D
	Ethyl acetate ≤ 0.5%	N.D
	Isopropanol ≤ 0.5%	N.D
	Chloroform ≤ 0.006%	N.D
	Toluene ≤ 0.089%	N.D
	N,N-Dimethylformamide ≤ 0.088%	N.D
Assay (on dried basis)	≥ 99.0%	99.60%

Conclusion: It complies with the USP39 Standard.