

No.: BPAP-601-A-00/3.0

CERTIFICATE OF ANALYSIS

Product Name	Donepezil Hydrochloride	CAS No.	120011-70-3
Batch No.	P010260119A	Mfg. Date	Feb. 10, 2019
Quantity	200kg	Retest Date	Feb. 09, 2021
Packing	25kg/Drum	Report Date	Feb. 15, 2019
Specification	USP37		

ITEM	SPECIFICATION	RESULT
Appearance	Off white to white crystalline powder	Complies
Solubility	Freely soluble in chloroform, soluble in water and Acetic acid, slightly soluble in Acetonitrile and ethanol, insoluble in Ethylacetoacetate and n-hexane	Complies
Identification	A. By IR absorption, to match with working standard	Complies
	B. The retention time of the major peak of the sample corresponds to that of the standard solution, as obtained in Assay	Complies
	C. Chloride, responds to the test for Chlorides	Complies
Assay(on Anhydrous basis)	98.0%~102.0%	99.51%
Heavy Metals	≤ 20ppm	Complies
Residue on Ignition	≤ 0.1%	0.04%
Organic Impurities		
Desbenzyl donepezila	≤0.15%	Undetected
Donepezil pyridine analogb	≤0.15%	Undetected
Donepezilzilbenzyl bromidec	≤0.15%	Undetected
Dehydrodeoxy donepezild	≤0.15%	Undetected
Deoxy donepezile	≤0.15%	Undetected
Any Individual Unspecified impurity	≤0.1%	0.03%
Total Impurities	≤0.5%	0.08%
Water	≤0.4%	0.16%
Residual Solvents		
Methanol	≤3000ppm	Undetected
Ethanol	≤5000ppm	Undetected
Ethyl Acetate	≤5000ppm	Undetected
Toluene	≤890ppm	Undetected
Acetic acid	≤5000ppm	Undetected
Conclusion	Comply with the specification.	
Storage	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: