



CERTIFICATE OF ANALYSIS

Product name	Donepezil HCl		
Batch No	20180805	CAS NO	120011-70-3
Report Date	2018.08.24	Expiry date	2020.08

Inspection Items	Accepted Standard	Results
Appearance	White crystalline powder	Complies
Solubility	Freely soluble in chloroform, soluble in water and glacial Acetic acid, slightly soluble in Acetonitrile and ethanol, practically insoluble in Ethylacetoacetate and n-hexane	Complies
Identification	A: By IR, To match with working standard.	Complies
	B: The retention time of the major peak of the sample should accord with that of the working standard.	Complies
	C:Test for chlorides. Reponds to the test for Chlorides.	Complies
Water	$\leq 0.4\%$	0.3%
Relative Substances	Desbenzyl donepezil ^a $\leq 0.2\%$	Not detected
	Hydroxydonepezil ^b $\leq 0.2\%$	Not detected
	Donepezil alkene pyridine <i>N</i> -oxide ^b $\leq 0.15\%$	Not detected
	Donepezil- <i>N</i> -oxide ^c $\leq 0.1\%$	Not detected
	Donepezil pyridine analog (DPMI) ^d $\leq 0.15\%$	Not detected
	3-Hydroxydonepezil ^e $\leq 0.15\%$	Not detected
	Hydroxydonepezil ^f $\leq 0.2\%$	Not detected
	Donepezil quaternary salt (donepezilbenzyl) ^g $\leq 0.15\%$	Not detected
	Donepezil related compound A $\leq 0.1\%$	Not detected
	Donepezil indene (dehydrodeoxy donepezil) ^h $\leq 0.15\%$	Not detected
	Deoxydonepezil ⁱ $\leq 0.15\%$	Not detected
	Any individual unspecified impurity $\leq 0.10\%$	0.06%
	Total $\leq 1.0\%$	0.08%
Residual Solvents	Methanol $\leq 0.3\%$	Not detected
	Ethanol $\leq 0.5\%$	Not detected
	Ethyl acetate $\leq 0.5\%$	Not detected
	Toluene $\leq 0.089\%$	Not detected
	Acetic acid $\leq 0.5\%$	Not detected
Residue on ignition	$\leq 0.1\%$	0.04%
Assay	98.0%-102.0%(On the anhydrous basis, C ₂₄ H ₂₉ NO ₃ HCl)	99.79%
Conclusion : Complies to USP40		

Analyst :shilijuan

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