

## CERTIFICATE OF ANALYSIS

### Biperiden hydrochloride( CAS:1235-82-1)

<b>Batch No.:</b> DR20151201	<b>Quantity:</b> 5.0g
<b>Manufacture Date:</b> 2015.12.01	<b>Expiry Date:</b> 2018.11

**TESTS:**

Items	Specification	Results
Appearance	A White or almost white crystalline powder	Almost white crystalline powder
Identification	A)By IR: the obtained sample spectrum of Biperiden hydrochloride should compare with that of the Biperidin hydrochloride standard spectrum	Conforms
	B)By HPLC: absorbivities at 257nm, calculated on the dried basis, do not differ by more than 3.0%	Conforms
	C) Chloride: should comply	Conforms
Loss on drying (w/w)	≤0.5%	0.26%
Ordinary impurities (w/w)	Any other impurity ≤0.1% Total impurities ≤0.5%	<0.1% <0.5%
Residue on ignition	≤0.1%	0.03%
Assay by chemical (w/w) ( on the dried basis)	99.0%~101.0%	99.6%
Residual solvents by GC	Methanol ≤3000ppm Tetrahydrofuran ≤720ppm Isopropyl alcohol ≤5000ppm Dimethylchloride ≤600ppm Tert butyl methyl ether ≤5000ppm 1,4 dioxane ≤380ppm	48ppm N,D 242ppm N,D N,D N,D

**Conclusion: The results conform with the USP standard.**

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