

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Doxylamine succinate (CAS:562-10-7)

Batch No.: DR20131123	Piece: 53kg
Manufacture Date: 2013.11.23	Expiry Date: 2016.10.23

TESTS:

Items	Specification	Results
Appearance	White crystal	Conforms
Solubility	Soluble in water/methanol/alcohol/slightly soluble in benzene and ether.	Conforms
Identification	Melting range: 103~108℃	104.5~106.0℃
	Ultraviolet absorption: UV max=262.0nm calculated on the anhydrous basis do not differ by more than 3.0%	0.46%
	The IR spectrum of the sample was confirmed wording standard spectrum	Conforms
	Test for succinic acid Melting range: 184~188℃	186~188℃
Loss on drying	≤0.5%	0.35%
Residue on ignition	≤0.1%	0.05%
Heavy metals	≤0.002%	N,D
Volatile related compounds (by GC)	Total impurities ≤2.0%	0.32%
	Single maximum unknown impurity≤1.0%	0.06%
Residual solvents	Diethyl ether ≤0.5%	N,D
	Acetone ≤0.5%	N,D
	Ethanol ≤0.5%	N,D
Assay (titration)	99.0%~101.0%(calculated on anhydrous substance)	99.70%
Conclusion: The results conform with the USP35 standard.		

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