



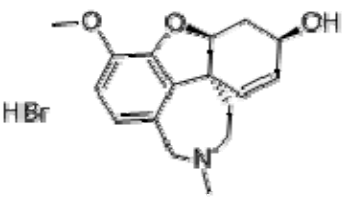
HANGZHOU DINGYAN CHEM CO.,LTD

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E-Mail:sales@dingyanchem.com,Web: www.dingyanchem.com

## CERTIFICATE OF ANALYSIS

NO: **DYC101607054**

Product name	Galanthamine hydrobromide(USP35)
CAS Number	1953-04-4
Molecule Structure	 HBr
Molecule Formula	C <sub>17</sub> H <sub>22</sub> BrNO <sub>3</sub>
Batch number	20160310
Manuf date	2016-03-10
Testing date	2016-03-11

Items	Standard	Result
Appearance	White to almost white powder	almost white powder
Solubility	Soluble in 0.1 N sodium hydroxide, Sparingly soluble in water, very slightly soluble in alcohol, insoluble in n-propanol	Soluble in 0.1 N sodium hydroxide, Sparingly soluble in water, very slightly soluble in alcohol, insoluble in n-propanol
Identification	<b>IR</b> Complices with the test in the test procedure. <b>HPLC</b> The retention time of the major peak of the sample solution corresponds to that of the system suitability solution, as obtained in the Assay <b>Bromide</b> Meet the requirements of the silver nitrate precipitate test.	Conforms
Heavy metals	≤20ppm	<20ppm
Loss on drying	≤0.5%	0.18%
Residue on ignition	≤0.1%	0.06%
Palladium	≤10ppm	<1ppm
Related substances(HPLC)		
N-Desmethylgalantamine	≤0.6%	≤0.05%
O- Desmethylgalantamine	≤0.20%	N.D
6 β -Hexahydrogalantamine	≤0.20%	≤0.05%

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6 $\beta$ -Octahydrogalantamine	$\leq$ 0.35%	$\leq$ 0.05%
6 $\alpha$ -Hexahydrogalantamine	$\leq$ 0.20%	0.09%
Tetrahydrogalantamine	$\leq$ 0.40%	$\leq$ 0.05%
Narwedine	$\leq$ 0.15%	$\leq$ 0.05%
Any unspecified impurity	$\leq$ 0.10%	$\leq$ 0.05%
Total impurities	$\leq$ 1.0%	0.09
Enantiomeric purity		
4R.8R stereoisomer	$\leq$ 0.1%	<0.01%
Assay	95.0%-102.0% calaulated on the dried dasia	99.3%
Conclusion	Complies with USP35	

Hangzhou Dingyan Chem Co., Ltd.  
QUALITY CONTROL: Freya  
Quality Control  
Signature(s)

CHECK: 姚仙娟

INSPECTOR: 刘清风