

CERTIFICATE OF ANALYSIS

Product: Galanthamine HBr
Batch №: 30211118
MFD: March 2018

Analysis standard: Eu. Ph. "8" edition.
Quantity: 10,400 kg
Re-taste: Date: March 2022

Item	Analysis standard	Results
1. APPEARANCE	Fine crystalline powder	correspond
2. COLOR	White or almost white	correspond
3. IDENTIFICATION	Color reaction	correspond
4. SOLUBILITY		
- in water	Sparingly soluble	correspond
- in 95% ethanol and chloroform, ether	Practically insoluble	correspond
5. ACIDITY OR ALKALINITY	According to the specification	correspond
6. COLOR SOLUTION (1%)	ref. standard	correspond
7. SULPHATE ASH	NMT 0.1%	0.07%
8. SULPHATED	NMT 0.1%	correspond
9. SPECIFIC OPTICAL ROTATION (2% in water)	- 90.0° to - 100.0°	-92.5°
10. HEAVY METALS	NMT 20 ppm	correspond
11. LOSS ON DRYING	NMT 1.0%	0.35%
12. ASSAY OF GALANTHAMINE HBr	from 98.0% to 102.0%	99.94%
13. RELATED SUBSTANCE by HPLC		
- Impurity A (Narwedine)	NMT 0.15%	0.01%
- Impurity E (N-desmethygalanthamine)	NMT 0,60%	0.15%
- Unspecified impurity	NMT 0.10	0.00
- Total impurity	NMT 0.80%	0.16%
14. Residual solvents		
- Methanol	NMT 3000ppm	1.0 ppm
- Ethanol	NMT 5000ppm	2.5 ppm
- Chloroform	NMT 60ppm	0 ppm
15. MICROBIAL CONTENT		
- Bacteria, CFU/g	NMT 10 ⁴	<10 ⁴
- Mould and barm, CFU/g	NMT 10 ²	<10 ²
- Enterobacteriaceae	NMT 10 ²	<10 ²
- E. coli, Salmonella, St. aureus, Ps. Aeruginosa	not allowed	correspond

Conclusion:

The analyzed batch No. 30211118 of GALANTHAMINE HBr, has been tested according to the approved analytical methods and conforms to Eu. Ph. 8th edition

Analyst:

Mag. Chem. V. Ivanova

4155 Zelenikovo village, Brezovo municipality, Plovdiv region, Bulgaria
tel.: +359-2-9583034, fax: +359-2-9583134, e-mail: info@galen-n.com
www.galen-n.com