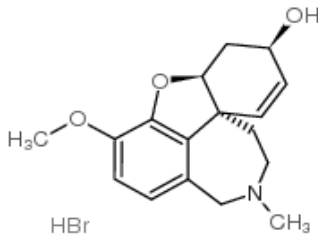




CERTIFICATE OF ANALYSIS

Product Name	Galanthamine Hydrobromide [4as,6R,8as]-4a,5,9,10,11,12-Hexahydro-3-Methoxy-11-Methyl-6H-Benzofuro [3a,3,2-ef][2] Benzazepin-6-OL Hydrobromide	 HBr	
Molecular Formula	C ₁₇ H ₂₂ BrNO ₃		
Cas No.	1953-04-4	Quantity	21.3 kg
MFG. Date	2022.01.07	Batch No	MLP-GT-20220107
Report Date	2022.01.11	Retest. Date	2024.01.06

Testing Items	Specifications	Results
Description	White to almost white powder	Conforms
Solubility	Soluble in 0.1N sodium hydroxide, sparingly soluble in water, very slightly soluble in alcohol, insoluble in n-propanol.	Conforms
Identification		
By 1HNMR	Conforms to structure	Conforms
By HPLC	The retention time of the major peak as obtained in the "Limit of Galanthamine enantiomer[(+)-Galanthamine]test" of the sample solution should correspond to that of the Galanthamine peak in the system suitability solution.	Conforms
Test for Bromide	A yellow precipitate is formed indicating the presence of bromide ions.	Conforms
Loss on Drying (%w/w, determined on 1.0g at 105°C for 4h)	Not more than 0.5%	0.14%
Residue on Ignition (%w/w, determined on 1.0g)	Not more than 0.1%	0.03%
Heavy Metals	Not more than 20 PPM	Less than 10 PPM

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苏州麦轮生物科技有限公司
Suzhou MyLand Pharm & Nutrition Inc.

地址: 苏州工业园区致和医药大厦 电话: 86 512 66706057
Add: ZhiHe Pharmaceutical Tower, SIP, Suzhou, CN.

info@mylandpharm.com
www.mylandpharm.com

Limit Of Galanthamine Enantiomer (+)-Galanthamine] (By HPLC,%w/w)	Not more than 0.01%	Not detected
Related Substances (By HPLC, % w/w)		
Norgalanthamine[USP: N-Desmethylgalantamine]	Not more than 0.20%	Not detected
Lycoramine [USP: Dihydrogalantamine]	Not more than 0.35%	0.17%
Glanthamine N-oxide [USP: Glanthamine N-Oxide]	Not more than 0.20%	Not detected
Epigalanthamine[USP: 6S-Galantamine]	Not more than 0.20%	0.04%
Dehydroxygalanthamine [USP: Didehydrodeoxygalantamine]	Not more than 0.40%	0.05%
O-Desmethylgalanthamine	Not more than 0.20%	Not detected
Narwedine	Not more than 0.15%	Not detected
Any other	Not more than 0.10%	0.02%
Total	Not more than 1.0%	0.32%
Assay (By HPLC, %w/w, as C ₁₇ H ₂₂ BrNO ₃ , on dried basis)	Not less than 98.0% and Not more than 102.0%	99.68%
Residual Solvents (By GC, µg/g)		
Toluene	Not more than 890	Not detected
Ethanol	Not more than 5000	254
Tetrahydrofuran	Not more than 500	Not detected
Bromide Content (By Titrimetry, %w/w, on as is basis)	Between 20.6 % and 22.8%	21.5%
Particle Size (By Malvern Particle size analyzer, µm)		
D(v,0.1)	Report results	22
D(v,0.5)		87
D(v,0.9)		164
Conclusion	This product conforms to USP30 standard	

Remark: The material complies as per the above specification of USP30

ANALYST:

检1

CHECKER:

检2

QC DIRECTOR:



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