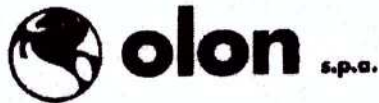


Stabilimento di Garbagnate
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Olon S.p.A.
Sede Legale
Strada Rivoltana km 6/7
Rodano (MI)



Certificate of analysis

Product **MEMANTINE HCl USP Current Edition** Code N° **2611190** Batch N° **1510000578**

Manufacturing date **MAR 2015** Retest date (where applicable) **FEB 2020**

Analysis Number **P1PF032101** Bulletin **4P1521906**

Test	References	Result	M.U.	Limits
Description		White crystalline powder	--	White crystalline powder
IR	EP 2.2.24, USP <197K>	Conforms to Standard	--	Conforms to Standard
Chlorides	EP 2.3.1	Conforms	--	Conforms
Rt GC		Conforms to Standard		Conforms to Standard
Loss on drying	EP 2.2.32	0,2	%	≤ 0,5
Sulphated Ash	EP 2.4.14, USP <281>	0,0	%	≤ 0,1
Chloride content	Internal method	98,2	% dried	98,0 + 102,0
Heavy metals	USP <231> Method II	< 10	ppm	≤ 10
Any specified impurity	USP Method	< 0,01	%	≤ 0,10
Any individual unspecified impurity	USP Method	0,01	%	≤ 0,10
Total impurities	USP Method	0,01	%	≤ 0,50
Assay (GC)	USP Method	99,6	% db	98,0 + 102,0
Water content (K.F.)	USP <921>	0,2	%	≤ 1,0
Ethanol	Internal method	< 150	ppm	≤ 3000
Acetone	Internal method	58	ppm	≤ 3000
Nickel (Ni)		0,0	ppm	≤ 2,5
Packaging and storage		Store in tight containers , in a dry place, protect from light	--	Store in tight containers , in a dry place, protect from light

Analysis Date
04/09/2015

QC Manager
09 APR. 2015

Reviewed by Qualified Person

Notes:
This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A).
Manufacturing site of the Active Pharmaceutical Ingredient: Stabilimento di Garbagnate

Capitale Sociale € 40.000.000 I.v. - R.I. Milano, Cod. Fisc. e P. IVA n. 08101100157 - R.E.A. Milano n. 1201640
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Strada Rivoltana km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 I.v. - C.F. e P.I. 00651030181