



Certificate of Analysis

Product name **AMITRIPTYLINE HYDROCHLORIDE**

Product Code C3200
Batch Number 2050000969
Batch Size 719,000 KG

Manufacturing date 10/04/2020
Re-test date 08/04/2025
Certificate Nr. 040000020478

<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
DESCRIPTION: white or almost white crystalline powder	complies		complies
IDENTIFICATION (IR)	complies		complies
IDENTIFICATION (HPLC retention time)	complies		complies
IDENTIFICATION (chlorides)	complies		complies
MELTING RANGE	195°-199°C		195°-196°C
pH 1.0% solution	5,0 - 6,0		5,5
pH (5.0% solution)	4,0 - 5,0		4,4
ACIDITY OR ALKALINITY (2.0% solution)	complies to Ph.Eur.		complies
APPEARANCE OF SOLUTION: a 5.0% solution in water is clear and not more intensely coloured than reference solution B ₉	complies		complies
LOSS ON DRYING	<= 0,5	%	0,19
SULPHATED ASH	<= 0,1	%	0,00
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	< LOQ (50)
-Ethyl acetate (GC)	<= 500	ppm	127
Impurity A (rel. sub. USP)	<= 0,05	%	< LOQ (0,006)
Impurity B (rel. sub. HPLC USP)	<= 0,10	%	< LOQ (0,003)
Cyclobenzaprine (rel. sub. HPLC USP)	<= 0,10	%	0,03
Nortipityline (rel. sub. HPLC USP)	<= 0,10	%	< LOQ (0,003)
Any other Impurity (rel. sub. HPLC USP)	<= 0,10	%	< LOQ (0,08)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,03
Impurity A (rel. sub. HPLC Ph.Eur.)	<= 0,05	%	< 0,05
Impurity B (rel. sub. HPLC Ph.Eur.)	<= 0,10	%	< 0,05
Any other Impurity (rel. sub. HPLC Ph.Eur.)	<= 0,10	%	< 0,05
Sum of all Impurities (rel. sub. HPLC Ph.Eur.)	<= 0,30	%	< 0,30
ASSAY A (HPLC) (calculated on the dried basis)	98,0 - 102,0	%	100,2

Andrea Rebora
QC Manager
Approved April 22, 2020

Agnese Messina
Qualified Person
Released April 22, 2020



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ASSAY B (pot.) (calculated on the dried basis)	99,0 - 101,0	%	100,6

Solubility: Freely soluble in water, in methanol, in ethanol ,in methylene chloride and in chloroform.

Complies with: EP BP USP JP IP

This material has been prepared following the current Good Manufacturing Practice (cGMP).

Andrea Rebora
QC Manager
Approved April 22, 2020

Agnese Messina
Qualified Person
Released April 22, 2020

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - R.E.A. Milano n. 1201640
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Società con Socio unico - Strada Rivoltana km. 6/7 - 20090 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v.- C.F. e P.IVA 11155530964