

Certificate of analysis

Manufacturing site
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QA Approved
20.02.2019

Code
500286

Ref. DDT.

Ref. Order

Batch Nr. 1901746
Mfg. date 12.02.2019
Retest date 11.02.2024
Analysis nr. 40000033126

Product

AMITRIPTYLINE HYDROCHLORIDE

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Description	-	White or almost white crystalline powder or small crystals.	EP/USP	Conform to description
Identification: Spectrum IR	-	Positive	EP/USP	Positive
Identification: Chlorides	-	Positive	EP/USP	Positive
Melting range (lower limit)	°C	min 195	USP	196
Melting range (upper limit)	°C	max 199	USP	198
Appearance of solution	-	Clear, not more colored than B7	EP	clear, no more colored B7
Acidity/Alcalinity	-	Conform	EP	Conform
pH(soluz.1%)		5,0 - 6,0	USP	5,3
Loss on drying	%	max 0,5	EP	0,0
Sulphated Ash	%	max 0,1	EP	0,1
Dibenzosuberone (HPLC)	%	max 0,05	EP	< 0,01
Cyclobenzaprine (HPLC)	%	max 0,1	EP	0,0
Carbinol (HPLC)	%	max 0,15	EP	< 0,01
Each other impurity (HPLC)	%	max 0,10	EP	0,02
Total impurities (HPLC)	%	max 0,3	EP	0,0
Assay (potentiometric)	%	99,0 - 100,5	Company	100,4
Acetone (GC)	µg/g	max 500	Company	80
Tetrahydrofuran (GC)	µg/g	max 500	Company	14
Toluene (GC)	µg/g	max 500	Company	67
Elemental impurities: none of the elemental impurity reported in ICHQ3D is likely to be present				

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Title: Quality Control
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Date: 19.02.2019 18:34:52

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