

Certificate of analysis

Manufacturing site

Stab. Baranzate
Via Bissone 5
20021 Baranzate MI
Italy
+39 02 382281

Issued QP
12.01.2018

Code
500286

Ref. DDT.
80005793

Ref. Order
BI171873

Batch Nr. 1712930
Mfg. date 03.10.2017
Retest date 02.10.2022
Analysis nr. 40000022518

Buyer 20077

FAGRON SERVICES NL
Molenwerf 13
1911 DB UITGEEST
Netherlands

End User 20077

FAGRON SERVICES NL

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, no more colored B7	EP	clear, no more colored B7
Acidity/Alcalinity	-	Conform	EP	Conform
pH(soluz. 1%)		5,0 - 6,0	USP	5,3
Loss on dry	%	max 0,5	EP	0,1
Sulphated Ash	%	max 0,1	EP	0,0
Heavy metals	%	max 0,001	USP	< 0,001
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	< 0,01
Totals impurity (HPLC)	%	max 0,3	EP	< 0,0
Assay (potentiometric)	%	99,0 - 100,5	Company	99,3
Acetone (GC)	µg/g	max 500	Company	78
Tetrahydrofuran (GC)	µg/g	max 500	Company	28
Toluene (GC)	µg/g	max 500	Company	83

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TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Residual Solvents (as per USP 467): We can certify that there is no potential for specific toxic solvents (class 1) to be present and that material, if tested, will comply with established standards. Residual Solvents (as per USP 467): We can certify that there is no potential for specific toxic solvents (class 1) to be present and that material, if tested, will comply with established standards.				
FAGRON IBÉRICA, S.A.U Corresponde al lote de Fagron: <i>ISA 16-BOF</i> <i>[Signature]</i> Director Técnico				

Name and Surname: Roberta Pancera
 Title: Quality Control
 Approved
 Date: 20.10.2017 16:06:29

Name and Surname: Marina Ariu
 Title: Quality Assurance
 Approved
 Date: 23.10.2017 10:43:42