



TECHNICAL DATA SHEET

0161-TDS-ENG-2021

AMITRIPTILINA HCL (Ph.Eur)		
DESCRIPTION DCI: AMITRIPTYLINE HYDROCHLORIDE		DESCRIPTION DOE: AMITRIPTILINA HIDROCLORURO
CAS N°: 549-18-8	EC N°: 208-964-6	AEMPS CODE: 395CH
MOL. WEIGHT: 313.87	MOL. FORMULA: C ₂₀ H ₂₃ N·HCl	ARTICLE CODE: 0161

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder or colourless crystals
Solubility	Freely soluble in water, in ethanol (96 %) and in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B7
Acidity or alkalinity	Complies
Related substances	
Impurity B	= < 0.1 %
Impurity A	= < 0.05 %
Any unspecified impurities	= < 0.10 %
Total impurities	= < 0.3 %
Loss on drying	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %
Residual solvents	
Methanol	= < 500 ppm
Acetone	= < 500 ppm
Tetrahydrofuran	= < 500 ppm
Toluene	= < 500 ppm

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

REMARKS

Amitriptyline Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.