



TECHNICAL DATA SHEET

002321-TDS-ENG-2024

ATENOLOL (EUR. PH.)		
DESCRIPTION DCI: ATENOLOL		DESCRIPTION DOE: ATENOLOL
CAS Nº: 29122-68-7	EC Nº: 249-451-7	AEMPS CODE: 356A
MOL. WEIGHT: 266,3	MOL. FORMULA: C ₁₄ H ₂₂ N ₂ O ₃	ARTICLE CODE: 002321

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Sparingly soluble in water, soluble in anhydrous ethanol, slightly soluble in methylene chloride
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. grade 6
Optical rotation	+0.10° / -0.10°
Related substances	
Impurity B	=< 0.2 %
Impurity F	=< 0.15 %
Impurity G	=< 0.15 %
Impurity I	=< 0.15 %
Impurity J	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Chlorides	=< 0.1 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep locked up. Keep away from heat or from sources of ignition.

REMARKS

Atenolol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.