

ATENOLOL (EUR. PH.)			
PRODUCT CODE: 002321		CAS Nº: 29122-68-7	ANALYSIS Nº: 093/25
MANUFACTURER BATCH:	ALU/P2502001	CERTIFICATE ID:	45.899
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/02/2025
METAPH BATCH:	0100425	EXPIRY DATE:	30/01/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Sparingly soluble in water, soluble in anhydrous ethanol, slightly soluble in methylene chloride	Complies (*)
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. grade 6	Complies
Optical rotation	+0.10° / -0.10°	+0.00°
Related substances		
Impurity B	=< 0.2 %	< 0.05 %
Impurity F	=< 0.15 %	Not Detected
Impurity G	=< 0.15 %	Not Detected
Impurity I	=< 0.15 %	< 0.05 %
Impurity J	=< 0.15 %	0.07 %
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 0.5 %	0.07 %
Chlorides	=< 0.1 %	< 0.1 %
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	99.0 - 101.0 %	99.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 21/05/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000375
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