

**FENTOLAMINA MESILATO (EUR. PH.)**

PRODUCT CODE: 002407	CAS Nº: 65-28-1	ANALYSIS Nº: 226/24
MANUFACTURER BATCH: PR241212	CERTIFICATE ID: 43.445	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2024	
METAPH BATCH: 0090924	RETEST DATE: 31/05/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, slightly hygroscopic, crystalline powder	Almost white, slightly hygroscopic, crystalline powder
Solubility	Freely soluble in water and in ethanol (96 per cent), practically insoluble in methylene chloride	Complies (*)
Identification C	Complies	Complies
Identification E	Complies	Complies
Acidity	=< 0.05 mL of 0.1 M NaOH	0.02 mL of 0.1 M NaOH
Related substances		
Impurity A	=< 0.2 %	0.08 %
Unspecified impurities	=< 0.1 %	< 0.05 %
Total impurities	=< 0.5 %	0.08 %
Loss on drying	=< 0.5 %	0.1 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	98.0 - 101.0 %	100.2 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

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

Phentolamine Mesylate 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".

(\*) 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 tightly closed, in a dry and cool place and protected from the light.

Analysis date: 02/10/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40001115