



TECHNICAL DATA SHEET

002407-TDS-ENG-2024

FENTOLAMINA MESILATO (EUR. PH.)		
DESCRIPTION DCI: PHENTOLAMINE MESYLATE		DESCRIPTION DOE: FENTOLAMINA MESILATO
CAS N°: 65-28-1	EC N°: 200-604-6	AEMPS CODE: 2760MB
MOL. WEIGHT: 377,47	MOL. FORMULA: C ₁₇ H ₁₉ N ₃ O · CH ₃ SO ₃ H	ARTICLE CODE: 002407

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

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".

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.