



TECHNICAL DATA SHEET

009654-TDS-ENG-2025

OXITOCINA (EUR. PH.)		
DESCRIPTION DCI: SYNTHETIC OXYTOCIN		DESCRIPTION DOE: OXITOCINA SINTÉTICA
CAS Nº: 50-56-6	EC Nº: 200-048-4	AEMPS CODE: 90086A
MOL. WEIGHT: 1007	MOL. FORMULA: C43H66N12O12S2	ARTICLE CODE: 009654

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, hygroscopic powder
Solubility	Very soluble in water. It dissolves in dilute solutions of acetic acid and of ethanol (96 %)
Identification A	Complies
Identification B	Complies
pH	3.0 - 6.0
Related substances	
Sum of impurities E and F	=< 1,5 %
Impurity B	=< 1,0 %
Impurity I	=< 1,0 %
Any other impurity	=< 1,0 %
Total impurities	=< 5,0 %
Acetic acid	6.0 - 10.0 %
Water	=< 5,0 %
Bacterial endotoxines	< 300 IU/mg
Assay	93.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.2

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Oxytocin 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.