

OXITOCINA (EUR. PH.)

PRODUCT CODE: 009654	CAS Nº: 50-56-6	ANALYSIS Nº: 178/25
MANUFACTURER BATCH: 2503009	CERTIFICATE ID: 46.894	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 19/04/2025	
METAPH BATCH: 0130625	EXPIRY DATE: 18/04/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, hygroscopic powder	White hygroscopic powder
Identification A	Complies	Complies
Identification B	Complies	Complies
pH	3.0 - 6.0	5.2
Related substances		
Sum of impurities E and F	=< 1.5 %	0.2 %
Impurity B	=< 1.0 %	0.1 %
Impurity I	=< 1.0 %	< 0.1 %
Any other impurity	=< 1.0 %	0.1 % (RT=6.45min)
Total impurities	=< 5.0 %	0.4 %
Acetic acid	6.0 - 10.0 %	6.8 % (*)
Water	=< 5.0 %	1.6 %
Bacterial endotoxines	< 300 IU/mg	< 0.01 IU/mg
Assay	93.0 - 102.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.2

REMARKS

The potency value obtained is 548 IU/mg.

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

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".

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

Analysis date: 29/08/2025
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001561
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