

QUALITY CERTIFICATE No. 11F-19
OXYTOCIN complies with CEP

Batch No. 110519
Mfr. date May 2019
Retest date May 2022

Analysis date: June 30, 2019

Analyses performed according to SpecAPI000267/4-en

Specifications	Requirements	Results
Characteristic ¹	1 mg of Oxytocin peptide ($C_{43}H_{66}N_{12}O_{12}S_2$) is equivalent to 600 IU. Very soluble in water, soluble in ethanol and diluted solutions of acetic acid (from 11.5 % to 12.5 %)	-
Description	White or almost white powder. It is hygroscopic	White powder. Hygroscopic
Identification	Passes tests A and B A. IPLC B. Amino acids ²	Passes tests A, B
pH	3.0 – 6.0	4.9
Related peptides:		
- Carbamido-oxytocin (RRT 0.8-0.9)	NMT 1.5 %	0.2 %
- Imine-oxytocin (RRT 0.85-0.95)	NMT 0.8 %	Less than 0.1 %
- α - Oxytocin dimer (RRT 1.3-1.4)	NMT 0.5 %	0.1 %
- β - Oxytocin dimer (RRT 1.4-1.6)	NMT 1.5 %	0.1 %
- Acetyloxytocin (RRT 1.5 – 1.7)	NMT 1.5 %	0.1 %
- Unidentified related substance ("Impurity A" RRT 1.0-1.2)	NMT 0.5 %	0.1 %
- Unidentified related substance ("Impurity B" RRT 1.7-1.8)	NMT 0.2 %	0.1 %
- Any other detectable impurity	NMT 0.5 %	Less than 0.1 %
- sum	NMT 5.0 %	0.8 %
Water	NMT 5.0 %	2.8 %
Acetic acid	6.0 – 10.0 %	8.1 %
Ethanol	NMT 5000 ppm	Under LOD
Bacterial endotoxins	NMT 300 IU of endotoxin/mg of Oxytocin	Less than 0.25 IU/mg
Assay:		
- calculated with reference to anhydrous, acetic acid-free substance	93.0 – 102.0 %	100.8 %
- on powder ³	NLT 80.0 % NLT 480 IU/mg	89.4 % 536 IU/mg
Storage conditions	In an airtight containers at a temperature between 2 °C and 8 °C, protected from light	

CEP - Certificate of Suitability of the European Pharmacopoeia

¹ Not tested, for information only

² Determine by the request of Quality Director

³ In-house additional requirement, is not included in pharmacopoeias

LOD – limit of detection for ethanol 30 ppm

LOQ – limit of quantitation for ethanol 100 ppm

Chemist of Quality Control Laboratory A. Kozlovs

The batch has been manufactured and controlled in compliance with API GMP requirements
Eudralex, Volume 4, Part II (ICH Q7).

Head of Quality Control Laboratory J. Jekabsons

API Responsible Person E. Misina-Jubele



01-07-2019

02.07.2019

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Amino acids	Asp 0.90 – 1.10	1.02
	Glu 0.90 – 1.10	1.03
	Pro 0.90 – 1.10	0.99
	Gly 0.90 – 1.10	0.98
	Leu 0.90 – 1.10	0.99
	Ile 0.90 – 1.10	1.00
	Tyr 0.70– 1.05	0.94
	half Cys 1.40– 2.10	1.83
	other - traces	traces

Head of Quality Control Laboratory J. Jekabsons



01-07-2019