

QUALITY CERTIFICATE No. 23-014827/04
Oxytocin complies with CEPBatch No. 040723
Mfr. date: 06-07-2023
Retest date: 07-2026Item No. 10-01202
Analysis date: 31-08-2023
Batch size: 359 g

Analysis performed according to SpecAPI000267/6-en

Characters: 1 mg of Oxytocin peptide ($C_{107}H_{164}N_{12}O_{12}S_2$) is equivalent to 600 IU. Very soluble in water, soluble in ethanol and diluted solutions of acetic acid (from 11.5 per cent to 12.5 per cent). It is hygroscopic.

Specification	Requirements	Results
Description	White or almost white powder	White powder
Identification		
A. HPLC	Passes test	Passes test
B. Amino acids ¹	Passes test	Passes test
pH	3.0 to 6.0	4.9
Related peptides:		
- Carbamido-oxytocin (RRT 0.8-0.9)	NMT 1.5 per cent	0.34 per cent
- alfa-Oxytocin dimer (RRT 1.3-1.4)	NMT 0.5 per cent	0.09 per cent
- beta-Oxytocin dimer (RRT 1.4-1.6)	NMT 1.5 per cent	Less than 0.10 per cent
- Acetyloxytocin (RRT 1.5-1.7)	NMT 1.5 per cent	0.12 per cent
- Unidentified related substance ("Impurity A" RRT 1.0-1.2)	NMT 0.5 per cent	0.08 per cent
- Unidentified related substance ("Impurity B" RRT 1.7-1.8)	NMT 0.2 per cent	Less than 0.10 per cent
- Any other detectable impurity	NMT 0.5 per cent	0.10 per cent
- sum	NMT 5.0 per cent	1.1 per cent
Water	NMT 5.0 per cent	2.3 per cent
Acetic acid	6.0 per cent to 10.0 per cent	7.9 per cent
Ethanol	NMT 5000 ppm	Less than 160 ppm
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 per cent to 102.0 per cent	98.0 per cent
- on powder ²	NLT 80.0 per cent	86.9 per cent
	NLT 480 IU/mg	521 IU/mg

CEP - Certificate of Suitability of the European Pharmacopoeia

¹Determine by the request of Head of Quality Department²In-house additional requirement, is not included in pharmacopoeias

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Batch size: 359 g**Conclusion:** Complies with requirements of Quality specification SpecAPI000267/6-en**Storage conditions:** In an airtight containers at a temperature between 2 °C and 8 °C, protected from light**Comments:** N/A*The batch has been manufactured and controlled in compliance with API GMP requirements
Eudralex, Volume 4, Part II (ICH Q7).*

Approved by:

	Head of Quality Division/ Qualified	
	Person	
Elina Misina Jubele		06-09-2023 11:08:25 +03:00 GMT
(name/ surname)	(position)	(date)

Released by:

	API Responsible Person	
Rudite Vabule		06-09-2023 15:12:15 +03:00 GMT
(name/ surname)	(position)	(date)

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Addendum

Specification	Requirements	Results
Amino acids:		
- aspartic acid	0.90 to 1.10	1.00
- glutamic acid	0.90 to 1.10	1.00
- proline	0.90 to 1.10	1.00
- glycine	0.90 to 1.10	1.00
- leucine	0.90 to 1.10	1.00
- isoleucine	0.90 to 1.10	1.00
- tyrosine	0.70 to 1.05	0.90
- half-cistine	1.40 to 2.10	2.00
- other traces	traces	traces

