

QUALITY CERTIFICATE No. 22-004723/03
Oxytocin complies with CEPBatch No. 050422
Mfr. date: 06-04-2022
Retest date: 04-2025Item No. 10-01202
Analysis date: 08-06-2022
Batch size: 356 g

Analysis performed according to SpecAPI000267/6-en

Characters: 1 mg of Oxytocin peptide ($C_{45}H_{64}N_{12}O_{12}S_2$) 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	5.0
Related peptides:		
- Carbamido-oxytocin (RRT 0.8-0.9)	NMT 1.5 per cent	0.32 per cent
- alfa-Oxytocin dimer (RRT 1.3-1.4)	NMT 0.5 per cent	0.20 per cent
- beta-Oxytocin dimer (RRT 1.4-1.6)	NMT 1.5 per cent	0.19 per cent
- Acetyloxytocin (RRT 1.5-1.7)	NMT 1.5 per cent	0.20 per cent
- Unidentified related substance	NMT 0.5 per cent	0.06 per cent
("Impurity A" RRT 1.0-1.2)		
- Unidentified related substance	NMT 0.2 per cent	0.10 per cent
("Impurity B" RRT 1.7-1.8)		
- Any other detectable impurity	NMT 0.5 per cent	0.10 per cent
- sum	NMT 5.0 per cent	1.5 per cent
Water	NMT 5.0 per cent	1.3 per cent
Acetic acid	6.0 per cent to 10.0 per cent	7.9 per cent
Ethanol	NMT 5000 ppm	106 ppm
Bacterial endotoxins	NMT 300 IU of endotoxin/mg of Oxytocin	Less than 5.0 IU/mg
Assay:		
- calculated with reference to	93.0 per cent to 102.0 per cent	97.8 per cent
anhydrous, acetic acid-free substance		
- on powder ²	NLT 80.0 per cent	86.3 per cent
	NLT 480 IU/mg	518 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: 356 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:

Sinta Antonovica	Head of Quality Control Laboratory	10-06-2022 14:11:55 +02:00 GMT
(name/ surname)	(position)	(date)

Released by:

Rudite Vabule	API Responsible Person	27-06-2022 12:25:09 +02:00 GMT
(name/ surname)	(position)	(date)

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Addendum

Specification	Requirements	Results
Amino acids:		
- aspartic acid	0.90 to 1.10	1.01
- glutamic acid	0.90 to 1.10	1.02
- proline	0.90 to 1.10	1.01
- glycine	0.90 to 1.10	1.03
- leucine	0.90 to 1.10	0.98
- isoleucine	0.90 to 1.10	0.97
- tyrosine	0.70 to 1.05	0.92
- half-cistine	1.40 to 2.10	1.91
- other traces	traces	traces

