

QUALITY CERTIFICATE No. 24-008169/04
Oxytocin complies with CEPBatch No. 100624
Mfr. date: 19-06-2024
Retest date: 06-2027Item No. 10-01202
Analysis date: 22-07-2024
Batch size: 271.8 g

Analysis performed according to SpecAPI00026717-en

Characters: 1 mg of Oxytocin peptide ($C_{42}H_{64}N_{12}O_{12}S_2$) 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: ¹		
A. HPLC	Passes test	Passes test
B. NMR	Passes test	Not determine
C. Amino acids	Passes test	Passes test
pH	3.0 to 6.0	4.9
Related substances:		
- impurity B (Ph.Eur.) ²	NMT 1.0 per cent	0.20 per cent
- sum of "Carbamido-oxytocin" and Impurity I (Ph.Eur.) ^{3,4}	NMT 1.0 per cent	0.61 per cent
- sum of Impurity E (Ph.Eur.) and impurity F (Ph.Eur.) ⁵	NMT 1.5 per cent	0.10 per cent
- any other impurity	NMT 0.5 per cent	0.19 per cent
- sum	NMT 5.0 per cent	1.2 per cent
Water	NMT 5.0 per cent	2.9 per cent
Acetic acid	6.0 per cent to 10.0 per cent	7.7 per cent
Ethanol	NMT 5000 ppm	Less than 160 ppm
Bacterial endotoxins	NMT 300 IU/mg	Less than 0.25 IU/mg
Assay:		
- on anhydrous and acetic acid free substance	93.0 per cent to 102.0 per cent	94.6 per cent
- on powder ⁷	NLT 80.0 per cent NLT 480 IU/mg	84.5 per cent 507 IU/mg

CEP - Certificate of Suitability of the European Pharmacopoeia

¹Perform two out of three identification tests: A and B or A and C²S3.1, S3.6: S3.6, S3.1-Cyclo[bis(L-cysteinyl-L-tyrosyl-L-isoleucyl-L-glutamyl-L-asparagyl-L-cysteinyl-L-prolyl-L-leucylglycinamide), "β-Oxytocin dimer", Oxytocin antiparallel dimer³S3.1, S3.6-Cyclo(L-cysteinyl-L-tyrosyl-NH-CH(sec-butyl)-NH-CO-L-glutamyl-L-asparagyl-L-cysteinyl-L-prolyl-L-leucylglycinamide)⁴S3.1, S3.6-Cyclo(L-cysteinyl-L-tyrosyl-L-isoleucyl-L-glutamyl-L-asparagyl-L-cysteinyl-L-prolyl-L-leucylglycinamide), [5-aspartic acid]oxytocin⁵S3.1, S3.6-Cyclo(N2,1-acetyl-L-cysteinyl-L-tyrosyl-L-isoleucyl-L-glutamyl-L-asparagyl-L-cysteinyl-L-prolyl-L-leucylglycinamide), "Acetyloxytocin", N2,1-acetyloxytocin⁶S3.1, S3.6-Cyclo(L-cysteinyl-L-tyrosyl-L-isoleucyl-L-glutamyl-L-(3-cyanoalanine)-L-cysteinyl-L-prolyl-L-leucylglycinamide), [5-(3-cyanoalanine)] oxytocin⁷In-house additional requirement, is not included in pharmacopoeias

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Analysis date: 22-07-2024
Batch size: 271.8 gConclusion: Complies with requirements of Quality specification SpecAPI000267/7-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:

Elna Mislina Jubele	Head of Quality Division/ Qualified	
(name/ surname)	Person	12-08-2024 16:06:22+03:00 GMT
	(position)	(date)

Released by:

Anda Ancane	API Responsible Person/ Qualified	
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