

Grindex

Joint Stock Company "Grindex"
53 Krustpils Street, Riga LV-1057, Latvia
Phone: +371 67063205, +371 67063500

E-mail: grindex@grindex.lv
www.grindex.lv
Unified registration No. 40003034935

QUALITY CERTIFICATE No. 23-014827/04
Oxytocin complies with CEP



Batch No. 040723
Mfr. date: 06-07-2023
Retest date: 07-2026

Item 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 ($C_{43}H_{66}N_{12}O_{12}S_2$) is equivalent to 600 IU. Very soluble in water, soluble in ethanol and diluted solutions of acetic acid (from 11.5 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	4.0
Related peptides:		
- Carbamido-oxytocin (RRT 0.8-0.9)	NMT 1.5 per cent	0.34 per cent
- alpha-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 NLT 480 IU/mg	86.9 per cent 521 IU/mg

CEP - Certificate of Suitability of the European Pharmacopoeia

¹Determine by the request of Head of Quality Department

²In-house additional requirement, is not included in pharmacopoeias

This document is signed electronically

Report templateID version: GRX-API 9
Software: SampleManagerLIMS 12.1, SP 2
Record unique keyID version: 0E0E1285-319F-466D-AE2A-94D5F8A381EA/ 1

Generated by: Rudite Vabule
Generated at: 06-09-2023 12:16:38 +00:00 GMT
Controlled copy No.: 1

Page 1/3

DISTRIBUIDO POR
JACINTO CAMARERO
LUB. INDUSTRIAL S.L.



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

19 NOV 2024

[Signature]

Grindex

Joint Stock Company "Grindeks"
53 Krustpils Street Riga, LV-1057, Latvia
Phone: +371 67083205, +371 67083500

E-mail: grindeks@grindeks.lv
www.grindeks.eu
Unified registration No. 40003036935

QUALITY CERTIFICATE No. 23-014827/04
Oxytocin complies with CEP



Batch No. 040723
Mfr. date: 06-07-2023
Retest date: 07-2026

Item No. 10-01202
Analysis date: 31-08-2023
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:

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

This document is signed electronically

Report templateID/ version: GRX-API 9
Software: SampleManagerLIMS 12.1 SP 2
Record unique key/ version: 0E0E1285-319F-468D-AE2A-94D9F8A351EA/ 1

Generated by: Rudite Vabule
Generated at: 06-09-2023 12:16:36 +00:00 GMT
Controlled copy No.: 1

Page 2/3

DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

19 NOV 2024

Grindex

Joint Stock Company "Grindex"
53 Krustpils Street, Rīga, LV-1057, Latvia
Phone: +371 67083205, +371 67083500

E-mail: grindex@grindex.lv
www.grindex.eu
Unified registration No. 40003014935

QUALITY CERTIFICATE No. 23-014827/04
Oxytocin complies with CEP



Batch No. 040723
Mfr. date: 06-07-2023
Retest date: 07-2026

Item No. 10-01202
Analysis date: 31-08-2023
Batch size: 359 g

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-cystine	1.40 to 2.10	2.00
- other traces	traces	traces

Report templateID: version: GRX-API 9
Software - SampleManagerLIMS 12.1, SP.2
Record unique key: version: 0E0E1285-319F-466D-AE2A-94D5F8A381EA/1

This document is signed electronically

Generated by: Rudite Vabule
Generated at: 06-09-2023 12:16:38 +00:00 GMT
Controlled copy No: 1

Page 3/3



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

19 NOV 2024

DISTRIBUIDO POR
METAFARMACEUTICAL
INDUSTRIAL S.L.U.

13 NOV 2024

