Joint Stock Company Grindeks
53 Krustpils Street, Riga, LV-1057, Latvia
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E-mail grindeks@grindeks.lv, www.grindeks.eu
Unified registration No. 40003034935

Grindex

QUALITY CERTIFICATE No. 10D-20

OXYTOCIN complies with CEP

Batch No. 100320
Mfr. date March 2020
Retest date March 2023

Analysis date: April 16, 2020
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. HPLC 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 %	0.15 %
- 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 %	0.07 %
- β - Oxytocin dimer (RRT1.4-1.6)	NMT 1.5 %	Less than 0.1 %
- Acetyloxytocin (RRT 1.5 – 1.7)	NMT 1.5 %	0.16 %
- Unidentified related substance ("Impurity A" RRT 1.0-1.2)	NMT 0.5 %	Less than 0.1 %
- Unidentified related substance ("Impurity B" RRT 1.7-1.8)	NMT 0.2 %	Less than 0.1 %
- Any other detectable impurity	NMT 0.5 %	0.06 %
- sum	NMT 5.0 %	0.43 %
Water	NMT 5.0 %	1.4 %
Acetic acid	6.0 – 10.0 %	8.0 %
Ethanol	NMT 5000 ppm	166 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 – 102.0 %	97.4 %
- on powder [3]	NLT 80.0 %	86.5 %
	NLT 480 IU/mg	519 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 J. Kudrjavceva

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

17 -04- 2020

API Responsible Person E. Misina-Jubele

27.04.2020

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Specifications	Requirements	Results
Amino acids	**Asp** 0.90 – 1.10	1.01
	Glu 0.90 – 1.10	1.01
	Pro 0.90 – 1.10	1.03
	Gly 0.90 – 1.10	1.01
	Leu 0.90 – 1.10	0.98
	Ile 0.90 – 1.10	0.98
	Tyr 0.70– 1.05	0.97
	half Cys 1.40– 2.10	1.90
	other - traces	traces

Head of Quality Control Laboratory J. Jekabsons

17 -04- 2020