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SOP 426
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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

NEWCO PHARM HUNGARIA KFT
 RÁKÓCZI U. 142 - 146.
 7100 SZEKSZÁRD
 HUNGARY

Hoogstraten, 16.11.2018

ORIGINAL

Material
 D068009-006994-01 OXYTOCINE NCP 10 NE/ML 50ML
 Pharmaceutical Form:
 Sterile solution
 Batch 4003112 / Manufacturing Date 08.2018 Expiry date 08.2021

Inspection lot 40000038012 from 09.2018

CERTIFICATION STATEMENT: I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Formula: Oxytocine 10 i.u. - excipients q.s.ad 1 ml

Aspect: Clear, colourless to pale yellow solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (50 ml)	%	100,19	96,00	104,00
Relative density		1,006	1,003	1,012
Refractive index		1,335	1,320	1,350
pH		4,16	3,50	5,00
Id: Oxytocin		Complies		
Id: Phenol		Complies		
Assay: Oxytocin	%	98,03	95,00	105,00
Assay: Phenol	%	99,41	90,00	105,00
Sterility		Complies		



Dig. Sign.: Van Buggenhout Kris
 03.10.2018 15:36:04

Qualified Person

Conclusion:
 Quality test complied