



KELA N.V.
St-Lenaartseweg 48
B-2320 Hoogstraten
Belgium

T. +32 3 340 04 11
F. +32 3 340 04 23
E-mail: info@kela.be
BTW BE 0403.835.645
RPR Turnhout

SOP 426
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 30.08.2017

Material

D068100-006994-01 OXYTOCINE NCP 10 NE/ML 100 ML

Pharmaceutical Form:

Sterile solution

Batch 26763B11 / Manufacturing Date 06.2017 Expiry date 06.2020

Inspection lot 40000024767 from 06.2017

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 (100 ml)	%	100,80	96,00	104,00
Relative density		1,006	1,003	1,012
Refractive index		1,335	1,320	1,350
pH		4,13	3,50	4,50
Id: Oxytocin		Complies		
Id: Phenol		Complies		
Assay: Oxytocin	%	95,05	95,00	105,00
Assay: Phenol	%	99,80	90,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
27.07.2017 07:58:51

Qualified Person

Conclusion:
Quality test complied