

KELA N.V.

St.-Lenaartseweg 48
B-2320 Hoogstraten/Belgium
RPR Turnhout
BTW BE 0403.835.645

T. +32 3 340 04 11
F. +32 3 340 04 23
info@kela.be
www.kela.be

Established in 1941

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

Produkt - Produit - Product <i>OXYTOCINE NCP 10 NE/ML 12 X 50 ML</i>			NEWCOPHARM HUNGARIA LTD. 142-146. RAKOCZI U. SZEKSZARD 7100 HUNGARY Z.Hd: Dr. Varga
Farm. Vorm - Pharm. Form <i>STERILE SOLUTION</i>			
Art. No. D068X13			
Batch Nr.	MAN:	EXP	
23232.17	06-2015	06-2018	Hoogstraten, 24.07.15

Formula :

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

Tests Performed	Specifications	Results
Appearance	clear colourless solution to light yellow solution	clear colourless solution to light yellow solution
Theoretical volume	50 ml, 100 ml	50 ml, 100 ml
Average volume	96 - 104 %	101,1 % 101,2 %
pH	3,50-4,50	4,22
Specific gravity (s.g.)	1,003 - 1,012	1,006
Refractive index	1,320 - 1,350	1,335

Identifications		
Oxytocine	positive	Positive
Preservative	positive	Positive

Assays		
Oxytocine	95 - 105 %	104,0 %
Preservative	90 - 105 %	100,3 %

Special Tests		
Sterility	passes test	passes test

Conclusion
CONFORM

BATCH RELEASE CERTIFICATE :

We declare that this batch has been manufactured and packed according to current GMP rules and has been released into the market.

KELA N.V.
N. VAN EEGHEM
Kris Van Bungenhout
Industrial Pharmacist
Qualified Person Cert. Nr. 1562