

KELA N.V.

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Established in 1941

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

Produkt - Produit - Product <i>OXYTOCINE NCP 10 NE/ML 12 X 100 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. D068X12	
Batch Nr. MAN: EXP 23973.10 11-2015 11-2018	
Hoogstraten, 9.02.16	

Formula :

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

Tests Performed	Specifications	Results
Appearance	clear colourless solution to lightyellow solution	clear colourless solution to lightyellow solution
Theoretical volume	50 ml, 100 ml	50 ml, 100 ml
Average volume	96 - 104 %	100,3 %
pH	3,50-4,50	4,21
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 %	98,9 %
Preservative	90 - 105 %	98,3 %
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 according to the relevant Marketing authorization.

KELA N.V.
N. VAN EEGHEM
Qualified Person