

**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	
23603.24	10-2015	10-2018	Hoogstraten, 23.11.15

**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	100 ml
Average volume	96 - 104 %	101,0 %
pH	3,50-4,50	4,15
Specific gravity (s.g.)	1,003 - 1,012	1,006
Refractive index	1,320 - 1,350	1,335
<b>Identifications</b>		
Oxytocine	positive	positive
Preservative	positive	positive
<b>Assays</b>		
Oxytocine	95 - 105 %	99,3 %
Preservative	90 - 105 %	97,4 %
<b>Special Tests</b>		
Sterility	passes test	passes test
<b>Conclusion</b>		
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