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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, 01.06.2016

Material

D068009-006994-01 OXYTOCINE NCP 10 NE/ML 50ML

Pharmaceutical Form:

Sterile solution

Batch 25347B20 / Manufacturing Date 03.2016 Expiry date 03.2019

Inspection lot 40000010785 from 05.2016

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)	%	102,83	96,00	104,00
Relative density		1,005	1,003	1,012
Refractive index		1,335	1,320	1,350
pH		4,14	3,50	4,50
Id: Oxytocin		Complies		
Id: Phenol		Complies		
Assay: Oxytocin	%	102,45	95,00	105,00
Assay: Phenol	%	99,53	90,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
26.05.2016 08:26:16

Qualified Person

Conclusion:  
Quality test complied



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

Hoogstraten, 01.06.2016

Material

D068009-006994-01 OXYTOCINE NCP 10 NE/ML 50ML

Pharmaceutical Form:

Sterile solution

Batch 25734B15 / Manufacturing Date 04.2016 Expiry date 04.2019

Inspection lot 40000010837 from 05.2016

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)	%	99,84	96,00	104,00
Relative density		1,005	1,003	1,012
Refractive index		1,335	1,320	1,350
pH		4,09	3,50	4,50
Id: Oxytocin		Complies		
Id: Phenol		Complies		
Assay: Oxytocin	%	95,78	95,00	105,00
Assay: Phenol	%	100,71	90,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
26.05.2016 17:08:43

Qualified Person

Conclusion:  
Quality test complied