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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, 22.11.2017

**Material**

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

Pharmaceutical Form:

Sterile solution

Batch 27589B13 / Manufacturing Date 09.2017 Expiry date 09.2020

Inspection lot 40000028764 from 09.2017

**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) | %    | 101,16   | 96,00       | 104,00      |
| Relative density        |      | 1,006    | 1,003       | 1,012       |
| Refractive index        |      | 1,335    | 1,320       | 1,350       |
| pH                      |      | 4,15     | 3,50        | 5,00        |
| Id: Oxytocin            |      | Complies |             |             |
| Id: Phenol              |      | Complies |             |             |
| Assay: Oxytocin         | %    | 98,07    | 95,00       | 105,00      |
| Assay: Phenol           | %    | 100,29   | 90,00       | 105,00      |
| Sterility               |      | Complies |             |             |

Dig. Sign.: Van Buggenhout Kris  
27.10.2017 08:06:39

Qualified Person

Conclusion:  
Quality test complied