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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, 27.11.2017

**Material**

**F094100-006994-01 NEOGENT 5% 100 ML**

Pharmaceutical Form:

Sterile solution

Batch 27591A12 / Manufacturing Date 09.2017 Expiry date 09.2021

Inspection lot 40000027801 from 08.2017

**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: Gentamycin sulphate 50 000 IU - excipients q.s. ad 1 ml

Aspect: clear, almost colourless solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	100,77	96,00	104,00
pH		5,67	4,00	6,00
Relative density		1,043	1,000	1,100
Id: Gentamicin		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Id: Propyl p-hydroxybenzoate		Complies		
Assay (Micro): Gentamicin	%	104,60	90,00	110,00
Assay: Methyl p-hydroxybenz	%	99,88	80,00	120,00
Assay: Propyl p-hydroxybenz	%	98,07	80,00	120,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
27.10.2017 08:08:10

Qualified Person

Conclusion:  
Quality test complied