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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, 16.11.2018

**ORIGINAL**

**Material**

P094101-006994-01 NEOGENT 5% 100 ML

Pharmaceutical Form:

Sterile solution

Batch 4003366 / Manufacturing Date 07.2017 Expiry date 07.2021

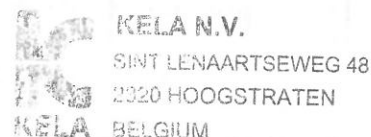
Inspection lot 40000038862 from 10.2018

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: Gentamycinesulfate equivalent with 50 mg base - excipients q.s. ad 1 ml

Aspect: clear, almost colourless solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	99,70	96,00	104,00
pH		5,80	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	%	101,70	90,00	110,00
Assay: Methyl p-hydroxybenz	%	98,10	80,00	120,00
Assay: Propyl p-hydroxybenz	%	100,20	80,00	120,00
Sterility		Complies		



Dig. Sign.: Van Buggenhout Kris  
13.11.2018 13:21:50

Qualified Person

Conclusion:  
Quality test complied