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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

F872100-006994-01 NEOPEN 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4003341 / Manufacturing Date 09.2018 Expiry date 09.2021

Inspection lot 40000038214 from 09.2018

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: Penicilline G Procaine 1 aqua 300.000 IU -excipients q.s. ad 1 ml

Aspect: white to yellow-white suspension with a penicillin odour

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	100,30	98,00	102,00
pH		6,60	5,00	7,00
Relative density		1,072	1,050	1,100
Resuspendability	ROT	6		10
Needling time	s	10		30
Id: Benzylpenicillin procaine		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Benzylpenicillin	%	98,74	95,00	105,00
Assay: Na methyl p-hydroxybenz	%	99,80	90,00	110,00
Sterility		Complies		

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Dig. Sign.: Van Buggenhout Kris  
09.11.2018 15:41:30

Qualified Person

Conclusion:  
Quality test complied