



KELA N.V.  
St-Lenaartseweg 48  
B-2320 Hoogstraten  
Belgium

T. +32 3 340 04 11  
F. +32 3 340 04 23  
E-mail: info@kela.be  
BTW BE 0403.835.645  
RPR Turnhout

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, 29.07.2016

Material

F871250-006994-01 NEOPEN 250 ML

Pharmaceutical Form:

Sterile suspension

Batch 25105A14 / Manufacturing Date 02.2016 Expiry date 02.2019

Inspection lot 40000011934 from 06.2016

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: 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 (250 ml)	%	100,45	98,00	102,00
pH		6,65	5,00	7,00
Relative density		1,072	1,050	1,100
Resuspendability	ROT	3		10
Needling time	s	3		30
Id: Benzylpenicillin procaine		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Benzylpenicillin	%	99,50	95,00	105,00
Assay: Na methyl p-hydroxybenz	%	101,75	90,00	110,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
25.07.2016 08:31:30

Qualified Person

Conclusion:  
Quality test complied