



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, 04.10.2017

Material

F872100-006994-01 NEOPEN 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 27646A11 / Manufacturing Date 07.2017 Expiry date 07.2020

Inspection lot 40000028183 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: 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)	%	101,42	98,00	102,00
pH		6,68	5,00	7,00
Relative density		1,074	1,050	1,100
Resuspendability	ROT	5		10
Needling time	s	7		30
Id: Benzylpenicillin procaine		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Benzylpenicillin	%	101,14	95,00	105,00
Assay: Na methyl p-hydroxybenz	%	102,08	90,00	110,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
02.10.2017 11:21:24

Qualified Person

Conclusion:
Quality test complied