



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
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

NEWCO PHARM HUNGARIA KFT
RÁKÓCZI U. 142 - 146.
7100 SZEKSZÁRD
HUNGARY

Hoogstraten, 15.02.2016

Material

F871X22-006994-01 NEOPEN 12 X 250 ML

Pharmaceutical Form:

Sterile suspension

Batch 25105A11 / Manufacturing Date 01.2016 Expiry date 01.2019

Inspection lot 40000000527 from 01.2016

We declare that this batch has been manufactured and packed according to current GMP rules and has been released according to the relevant Marketing Authorization.

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

Aspect: white to yellow-white suspension with penicilline odorur

Characteristic	Unit	Value	Lower Limit	Upper Limit
Average volume (250 ml)	‰	100,45	98,00	102,00
Aspect		Complies		
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		

Conclusion:
Quality test complied

Dig. Signature: Van Buggenhout Kris
08.02.2016 09:13:53