

**KELA N.V.**

St.-Lenaartseweg 48  
B-2320 Hoogstraten/Belgium  
RPR Turnhout  
BTW BE 0403.835.645

T. +32 3 340 04 11  
F. +32 3 340 04 23  
info@kela.be  
www.kela.be

Established in 1941

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

Produkt - Produit - Product		NEWCOPHARM HUNGARIA LTD. 142-146. RAKOCZI U. SZEKSZARD 7100 HUNGARY Z.Hd: Dr. Varga
NEOPEN 12 X 100 ML		
Farm. Vorm - Pharm. Form		
STERILE SUSPENSION		
Art. No.		Hoogstraten, 23.11.15
F871X12		
Batch Nr.	MAN: EXP	
23581.14	08-2015 08-2018	

**Formula :**

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

Tests Performed	Specifications	Results
Appearance	white to yellowish white suspension	white to yellowish white suspension
Theoretical volume	50 ml 100 ml 250 ml	100 ml
Average volume	98% - 102%	101,5 %
pH	5,00 - 7,00	6,64
Specific gravity(s.g.)	1,050 - 1,100 g/ml	1,070
Needling time	10 ml 19G needle < 30s	10 sec
Resuspendability	10 x = homogeneous	3 x
<b>Identifications</b>		
procain	positive	positive
benzylpenicillin	positive	positive
sodiummeth	positive	positive
ylhydroxybenzoate	positive	positive
<b>Assays</b>		
benzylpenicillin	95 - 105%	101,3 %
sodiummeth	90 - 110%	103,1 %
ylhydroxybenzoate		
<b>Special Tests</b>		
sterility	passes test	passes test
<b>Conclusion</b>		
CONFORM		

**BATCH RELEASE CERTIFICATE :**

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.

**KELA N.V.**  
N. VAN EEGHEM  
Qualified Person