

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 <i>NEOPEN L.A. 12 X 100 ML</i>			NEWCOPHARM HUNGARIA LTD. 142-146. RAKOCZI U. SZEKSZARD 7100 HUNGARY Z.Hd: Dr. Varga
Farm. Vorm - Pharm. Form <i>STERILE SUSPENSION</i>			
Art. No. S607X12			
Batch Nr.	MAN:	EXP	
23741.14	11-2015	11-2017	Hoogstraten, 14.12.15

Formula :

Penicillin G benzathine 150.000 i.u.
Penicillin g procaine 150.000 i.u.
excipients q.s.ad 1 ml

Tests Performed	Specifications	Results
Appearance	white to yellowish white suspension	white to yellowish white suspension
Theoretical volume	50ml - 100ml - 250ml	100 ml
Average volume	98 - 102%	101,2 %
pH	6,00-7,00	6,60
Specific gravity(s.g.)	1,160 - 1,185	1,160
viscosity	30 - 200 mPas	82 mPas
Needling time	10 ml needle 19 G max 30s	16 sec

Identifications		
Procaine HCl	positive	positive
Benzathine	positive	positive
Benzylpenicillin	positive	positive

Assays		
Total Benzylpenicillin	95 - 105 %	99,9 %
Preservative	90 - 105 %	98,1 %

Special Tests		
Sterility	passes test	passes test

Conclusion

CONFORM

BATCH RELEASE CERTIFICATE :

We declare that this batch has been manufactured and packed according to current GMP rules and has been re-leased according to the relevant Marketing authorization.

KELA N.V.
N. VAN BUGHEN
Industrial Pharmacist
Cert. Nr. 1562
Qualified Person