

KELA N.V.

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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	
22883.12	04-2015	04-2017	Hoogstraten, 21.10.15

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	50 ml 100 ml
Average volume	98 - 102%	101,7 % 100,5 %
pH	6,00-7,00	6,82
Specific gravity(s.g.)	1,160 - 1,185	1,164
Viscosity	30 - 200 mPas	87 mPas
Needling time	10 ml needle 19 G max 30s	23 sec
Identifications		
Procaine HCl	positive	positive
Benzathine	positive	positive
Benzylpenicillin	positive	positive
Assays		
Total Benzylpenicillin	95 - 105 %	101,1 %
Preservative	90 - 105 %	92,7 %
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 EEGHEM
Qualified Person