

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 12.12.2018

ORIGINAL

Material

S607001-006994-01 NEOPEN L.A. 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4003172 / Manufacturing Date 10.2018 Expiry date 10.2020

Inspection lot 40000038870 from 10.2018

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

Aspect: homogeneous white to yellow suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	100,14	98,00	102,00
pH		6,57	6,00	7,00
Relative density		1,163	1,160	1,185
Viscosity	mPa.s	153	30	200
Needling time	s	21		30
Id: Benzylpenicillin		Complies		
Id: Procaine		Complies		
Id: Benzathine		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Benzylpenicillin	%	103,39	95,00	105,00
Assay: Methyl p-hydroxybenz	%	96,98	90,00	105,00
Sterility		Complies		



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Qualified Person

Conclusion:
Quality test complied