

KELA N.V.

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Established in 1941

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

Produkt - Produit - Product <i>NEOPEN 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. F871X12			
Batch Nr.	MAN:	EXP	
23581.12	08-2015	08-2018	Hoogstraten, 14.10.15

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
Identifications		
procain	positive	positive
benzylpenicillin	positive	positive
sodiummeth	positive	positive
ylhydroxybenzoate	positive	positive
Assays		
benzylpenicillin	95 - 105%	101,3 %
sodiummeth	90 - 110%	103,1 %
ylhydroxybenzoate		
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 released according to the relevant Marketing authorization.

KELA N.V.
N. VAN EEGHEM
Qualified Person