



KELA N.V.
St-Lenaartseweg 48
B-2320 Hoogstraten
Belgium

T. +32 3 340 04 11
F. +32 3 340 04 23
E-mail: info@kela.be
BTW BE 0403.835.645
RPR Turnhout

SOP 426
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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 01.06.2018

ORIGINAL

Material

S888998-006994-01 AMOXYCILLINE 70% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 4000885 / Manufacturing Date 04.2018 Expiry date 04.2021

Inspection lot 40000033664 from 04.2018

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: Amoxicillinetrihydrate equivalent with 700 mg Amoxicilline - excipients q.s. ad 1 g

Aspect: white to almost white powder free from conglomerates

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass (1 kg)	%	100,17	95,00	105,00
pH of solution		7,70	7,00	8,00
Water content (between)	%	11,31	11,00	15,50
Id: Amoxicillin		Complies		
Assay: Amoxicillin	%	101,58	95,00	105,00

 KELA N.V.
SINT LENAARTSEWEG 48
2320 HOOGSTRATEN
BELGIUM

Dig. Sign.: Van Buggenhout Kris
08.05.2018 17:03:53

Qualified Person

Conclusion:
Quality test complied