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SOP 426
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 22.11.2017

Material

S888998-006994-01 AMOXYCILLINE 70% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 27722B10 / Manufacturing Date 10.2017 Expiry date 10.2020

Inspection lot 40000029270 from 10.2017

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)	%	99,48	95,00	105,00
pH of solution		7,88	7,00	8,00
Water content (between)	%	12,71	11,00	15,50
Id: Amoxicillin		Complies		
Assay: Amoxicillin	%	99,62	95,00	105,00

Dig. Sign.: Van Buggenhout Kris
07.11.2017 14:10:05

Qualified Person

Conclusion:
Quality test complied