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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

S806992-006994-01 OXYTETRACYCLINE 80% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 4000819 / Manufacturing Date 02.2018 Expiry date 02.2021

Inspection lot 40000031961 from 02.2018

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: oxytetracycline hydrochloride eq. with oxytetracycline 800 mg - excipients q.s. ad 1g

Aspect: yellow, homogeneous powder free from conglomerates

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass (1000 g)	%	99,91	95,00	105,00
pH of solution		2,07	1,50	3,00
Water content	%	1,62		4,00
Id: Oxytetracycline HCl		Complies		
Assay: Oxytetracycline	%	99,61	95,00	105,00

 KELA N.V.
SINT LENAARTSEWEG 48
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BELGIUM

Dig. Sign.: Van Buggenhout Kris
28.05.2018 11:26:10

Qualified Person

Conclusion:
Quality test complied