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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, 26.08.2016

Material

L661120-006994-01 NEOCYCLIN TABS 100 PCS/BOX

Pharmaceutical Form:

Non sterile oblong tablets (oblets)

Batch 25885 / Manufacturing Date 07.2016 Expiry date 07.2019

Inspection lot 40000013084 from 07.2016

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: Chlortetracycline Hydrochloride 1000 mg ,excipients q.s. ad one tablet (9.75 g)

Aspect: pale yellow oblong tablet

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average length	mm	60,4	59,0	61,0
Average width	mm	22,2	21,0	23,0
Average mass	%	100,21	98,00	102,00
Uniformity of mass		Complies		
Disintegration time	min	1		15
Hardness	N	322	160	
Id: Chlortetracycline HCl		Complies		
Assay: Chlortetracycline base	mg	879,36	774,25	975,45
Micr.qual: TAMC	CFU/G	0		1000
Micr.qual: TYMC	CFU/G	0		100
Micr.qual: E.coli		Absent		

Dig. Sign.: Van Buggenhout Kris  
25.08.2016 11:59:51

Qualified Person

Conclusion:  
Quality test complied