

**KELA N.V.**

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Established in 1941

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

Produkt - Produit - Product			NEWCOPHARM HUNGARIA LTD. 142-146. RAKOCZI U. SZEKSZARD 7100 HUNGARY Z.Hd: Dr. Varga
NEOCYCLIN TABS 100 PCS/BOX			
Farm. Vorm - Pharm. Form			
OBLONG TABLETS (OBLETS)			
Art. No.			Hoogstraten, 23.11.15
L661120			
Batch Nr.	MAN:	EXP	
23715	09-2015	09-2018	

**Formula :**

Chlortetracycline Hydrochloride 1000 mg , excipients q.s.

Tests Performed	Specifications	Results
Appearance	pale yellow oblong tablet	pale yellow oblong tablet
Theoretical mass	9,75 g	9,75 g
Average mass	98 - 102 % of th. mass	100,1 %
Uniformity of mass	meets Ph.Eur.requirements	meets Ph.Eur.requirements
Length	59 - 61 mm	60,4 mm
Breadth	21 - 23 mm	22,2 mm
Hardness	> 160 N	444 N
Disintegration time in water 37gr C	<15 min	0 min 53 sec
<b>Identifications</b>		
Chlortetracyclin HCl	positive	positive
<b>Assays</b>		
Chlortetracyclin	95 % - 105 %	98,9 %
<b>Special Tests</b>		
Microb. contamination	TAMC: max. 1000 CFU/g TYMC: max. 100 CFU/g E. coli: absent	passes test passes test absent
<b>Conclusion</b>		
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