

KELA N.V.

St.-Lenaartseweg 48
B-2320 Hoogstraten/Belgium
RPR Turnhout
BTW BE 0403.835.645

T. +32 3 340 04 11
F. +32 3 340 04 23
info@kela.be
www.kela.be

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
Farm. Vorm - Pharm. Form			
Art. No.			
Batch Nr.	MAN:	EXP	
23239	09-2015	09-2018	Hoogstraten, 23.11.15

Formula :

Prednisolone 5 mg- excipients q.s. ad one tablet

Tests Performed	Specifications	Results
Appearance	white round biconvex tablet scored on one side	white round biconvex tablet scored on one side
Theoretical mass	200 mg	200 mg
Average mass	95 - 105 %	100,3 %
Diameter	8,3 - 8,7 mm	8,5 mm
Hardness	>20 N	79 N
Disintegration time in water 37gr C	max 15 min	5 min 14 sec
Identifications		
prednisolone	HPLC : positive	Positive
Assays		
prednisolone	95 - 105 %	100,4 %
Special Tests		
mass variation	AV < or equal to 15	1,78
Conclusion		
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