



KELA N.V.
St-Lenaartseweg 48
B-2320 Hoogstraten
Belgium

T. +32 3 340 04 11
F. +32 3 340 04 23
E-mail: info@kela.be
BTW BE 0403.835.645
RPR Turnhout

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, 13.08.2018

ORIGINAL

Material

S808031-006994-01 PREDNITAB 5MG 3X10 TABLETTA

Pharmaceutical Form:

Non sterile tablet uncoated

Batch 28022 / Manufacturing Date 04.2018 Expiry date 04.2021

Inspection lot 40000034306 from 04.2018

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: Prednisolone 5 mg- excipients q.s. ad one tablet (200 mg)

Aspect: white, round, biconvex tablet with division mark on one side

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Diameter	mm	8,5	8,3	8,7
Average mass	%	100,24	95,00	105,00
Unif. dosage units (mv): AV		1,6		15,0
Dissolution (S1)	%	98,05	75,00	
Dissolution (S2a)	%		70,00	
Dissolution (S2b)				
Dissolution (S3a)	%		70,00	
Dissolution (S3b)				
Hardness	N	81	20	
Friability	%	0,13		1,00
Breakability		Complies		
Id: Prednisolone		Complies		
Assay: Prednisolone	%	100,53	95,00	105,00



Dig. Sign.: Van Buggenhout Kris
10.07.2018 14:24:12

Qualified Person

Conclusion:
Quality test complied