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RPR Turnhout

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

NEWCO PHARM HUNGARIA KFT
RÁKÓCZI U. 142 - 146.
7100 SZEKSZÁRD
HUNGARY

Hoogstraten, 29.08.2016

Material
S808031-006994-01 PREDNITAB 5MG 3X10 TABLETTA
Pharmaceutical Form:
Non sterile tablet uncoated
Batch 25502 / Manufacturing Date 05.2016 Expiry date 05.2019

Inspection lot 40000009708 from 05.2016

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: Prednisolone 5 mg- excipiens 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	%	100,08	95,00	105,00
Unif. dosage units (mv): AV		1,3		15,0
Dissolution (S1)	%	98,81	75,00	
Dissolution (S2a)	%		70,00	
Dissolution (S2b)				
Dissolution (S3a)	%		70,00	
Dissolution (S3b)				
Hardness	N	82	20	
Friability	%	0,38		1,00
Breakability		Complies		
Id: Prednisolone		Complies		
Assay: Prednisolone	%	100,35	95,00	105,00

Dig. Sign.: Van Buggenhout Kris
26.08.2016 15:33:34

Qualified Person

Conclusion:
Quality test complied