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RPR Turnhout

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, 25.10.2016

Material

L071029-006994-01 KELAPRIL 5 MG FILMTABLETTEN 28 TABS

Pharmaceutical Form:

Non sterile tablet coated

Batch 25889A / Manufacturing Date 08.2016 Expiry date 02.2019

Inspection lot 40000015433 from 09.2016

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: BenazeprilHCl 5 mg - excipients q.s. ad one coated oval tablet (192 mg)

Aspect: yellow, oval divisible film-coated tablet scored on both sides

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average length	mm	11,0	11,0	11,4
Average width	mm	5,6	5,4	5,8
Average mass	%	100,53	95,00	105,00
Uniformity of mass		Complies		
Unif. dosage units (cu): AV		4,8		15,0
Hardness	N	131	140	
Water content	%	5,00		6,00
Disintegration time	min	3		10
Id: Benazepril HCl		Complies		
Assay: Benazepril HCl	%	95,40	95,00	105,00

DEV 15-0056

Dig. Sign.: Van Buggenhout Kris  
06.10.2016 14:12:03

Qualified Person

Conclusion:  
Quality test complied



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