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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 15.02.2016

Material

L070029-006994-01 KELAPRIL 2,5 MG FILMTABLETTEN 28 TABS

Pharmaceutical Form:

Non sterile tablet coated

Batch 23632B / Manufacturing Date 11.2015 Expiry date 11.2017

Inspection lot 40000001797 from 02.2016

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.

Formula: Benazepril HCl 2.5 mg - excipients q.s. ad one coated oval tablet (192 mg)

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

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average length	mm	11,2	11,0	11,4
Average width	mm	5,6	5,4	5,8
Average mass	%	100,00	95,00	105,00
Uniformity of mass		Complies		
Unif. dosage units (cu): AV		1,6		15,0
Hardness	N	143	140	
Water content	%	4,09		6,00
Disintegration time	min	4		10
Id: Benazepril HCl		Complies		
Assay: Benazepril HCl	%	104,70	95,00	105,00

Conclusion:  
Quality test complied

Dig. Signature: Van Buggenhout Kris  
11.02.2016 09:36:45



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