



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

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

Hoogstraten, 27/04/2016

Material:

L071029-006694-01 KELAPRIL 5MG FILMTABLETTEN 28 TABS

Pharmaceutical form:

Non sterile tablet coated

Batch: 25217A

Manufacturing date: 02.2016

Expiry date: 08.2018

Inspection lot: 40000007518 **From:** 04.2016

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

Test parameters	Specifications	Results
Aspect	Yellow, oval divisible film-coated tablet scored on both sides	Complies
Average length	11.0-11.4mm	11.2mm
Average width	5.4-5.8mm	5.7mm
Average mass	95.00-105.00%	100.54%
Uniformity of mass	Complies	Complies
Unif of dosage units (cu): AV	≤15.0	7.1
Hardness (DEV 16-0017)	≥140N	111N
Water content	≤6.00%	4.53%
Disintegration time	<10min	<10min
Id: Benazepril HCl	Complies	Complies
Assay: Benazepril HCl	95,00-105,00%	100.01%

Conclusion:

Quality test complied

Qualified person:

Kris Van Buggenhout

to

Robin Vriends
Industrial Pharmacist
Cert. Nr. 2299