



## CERTIFICATE OF ANALYSIS

Name	<b>CARDALIS L</b>	Batch N°	<b>19C6</b>
Presentation	30 tablets	Manufacturing date	15-DEC-2014
Code list	<b>C63530B</b>	Expiry date	15-DEC-2016

Tests	Specifications	Results
<b>CHARACTERS</b>		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	573.8 - 634.2 mg	606.8
Sizes :		
- Length	16.5 - 17.5 mm	16.8
- Width	6.7 - 7.8 mm	7.1
<b>IDENTIFICATIONS</b>		
Spirolactone: (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
Benazepril: (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
<b>TESTS</b>		
Uniformity of dosage units :	Complies to Ph.Eur. 2.9.40	COMPLIES
Subdivision of tablets :	Complies to Ph. Eur. 0478	COMPLIES
Water content (KF):	$\leq 3.0$ %	2.1
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With Q $\geq$ 75%)	
-Mean of Spirolactone dissolved in 45 min	$\geq 75$ %	94

This batch has been tested in reference to the dossier in force and has been found to meet the specification requirements

**COMPLIES / NOT COMPLIES**

Checked by : Cath. GOOSSAERT

Batch Release number 372207  
Batch Release date 19-MAY-2015

**ACCEPTED by**

Laurent MAGNIES  
Qualified Person

The undersigned certifies this is a true copy of the results of tests and assays.



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Tests	Specifications	Results
<b>TESTS</b>		
-Mean of Benazepril Hcl dissolved in 30 min	>=75 %	96
<b>ASSAYS</b>		
Spironolactone :	76.0 - 84.0 mg/ cp	79.5
Benazepril Hcl :	9.50 - 10.50 mg/ cp	9.72
<b>DEGRADATION PRODUCTS (HPLC)</b>		
-Degradation products of Spironolactone :		
Canrenone	<=1.0 %	0.0
Unknown (each)	<1.0 %	0.0
Total	<=1.0 %	0.0
- Degradation products of Benazepril Hcl :		
Benazepril Hcl impurity C	<=1.0 %	0.0
Benazepril Hcl impurity E	<=1.0 %	0.0
Unknown (each)	<1.0 %	0.0
Total (including impurity C)	<=1.0 %	0.0
Microbial contamination :		
Test performed on one batch every ten		
- Total Aerobic Microbial Count (TAMC)	<= 1000 CFU/g	<u>NA</u>
- Total combined Yeast/ Mould Count (TYMC)	<= 100 CFU/g	<u>NA</u>

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Code list **C63530B** Manufacturing date **15-DEC-2014**  
Expiry date **15-DEC-2016**

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<b>ASSAYS</b>		
- Escherichia coli	Absent	<u>NA</u>

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