



## CERTIFICATE OF ANALYSIS

Name	<b>CARDALIS L</b>	Batch N°	<b>17C3</b>
Presentation	30 tablets	Manufacturing date	5-NOV-2014
Code list	<b>C63530B</b>	Expiry date	5-NOV-2016

Tests	Specifications	Results
<b>CHARACTERS</b>		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	573.8 - 634.2 mg	604.7
Sizes :		
- Length	16.5 - 17.5 mm	17.0
- Width	6.7 - 7.8 mm	7.2
<b>IDENTIFICATIONS</b>		
Spironolactone: (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):	$\leq 3.0$ %	2.0
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With $Q \geq 75\%$ )	
-Mean of Spironolactone dissolved in 45 min	$\geq 75$ %	96

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 : Catherine WADE

Batch Release number 364497

Batch Release date **20-JAN-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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Expiry date **5-NOV-2016**

Tests	Specifications	Results
<b>TESTS</b>		
-Mean of Benazepril Hcl dissolved in 30 min	$\geq 75$ %	97
<b>ASSAYS</b>		
Spirolactone :	76.0 - 84.0 mg/ cp	80.2
Benazepril Hcl :	9.50 - 10.50 mg/ cp	9.91
<b>DEGRADATION PRODUCTS (HPLC)</b>		
-Degradation products of Spirolactone :		
Canrenone	$\leq 1.0$ %	0.2
Unknown (each)	$< 1.0$ %	0.0
Total	$\leq 1.0$ %	0.2
- Degradation products of Benazepril Hcl :		
Benazepril Hcl impurity C	$\leq 1.0$ %	0.0
Benazepril Hcl impurity E	$\leq 1.0$ %	0.0
Unknown (each)	$< 1.0$ %	0.0
Total (including impurity C)	$\leq 1.0$ %	0.0
Microbial contamination :	Test performed on one batch every ten	
- Total Aerobic Microbial Count (TAMC)	$\leq 1000$ CFU/g	<u>NA</u>
- Total combined Yeast/ Mould Count (TYMC)	$\leq 100$ CFU/g	<u>NA</u>

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

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