



## CERTIFICATE OF ANALYSIS

Name	CARDALIS M	Batch N°	12B4
Presentation	30 tablets	Manufacturing date	6-MAR-2014
Code list	C63520B	Expiry date	6-MAR-2016

Tests	Specifications	Results
<b>CHARACTERS</b>		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	286.9 - 317.1 mg	302.3
Sizes :		
- Length	13.0 - 14.0 mm	13.6
- Width	5.2 - 6.2 mm	5.7
<b>IDENTIFICATIONS</b>		
Spirinolactone: (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):	$\leq 3.0$ %	1.9
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 : Cath. GOOSSAERT

Batch Release number 352636

Batch Release date 23-JUN-2014

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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## CERTIFICATE OF ANALYSIS

Name	CARDALIS M	Batch N°	12B4
Presentation	30 tablets	Manufacturing date	6-MAR-2014
Code list	C63520B	Expiry date	6-MAR-2016

Tests	Specifications	Results
<b>TESTS</b>		
-Mean of Benazepril Hcl dissolved in 30 min	>=75 %	97
<b>ASSAYS</b>		
Spirolactone :	38.0 - 42.0 mg/ cp	39.8
Benazepril Hcl :	4.75 - 5.25 mg/ cp	5.00
<b>DEGRADATION PRODUCTS (HPLC)</b>		
-Degradation products of Spirolactone :		
Canrenone	<=1.0 %	0.1
Unknown (each)	<1.0 %	0.0
Total	<=1.0 %	0.1
- 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	NA
- Total combined Yeast/ Mould Count (TYMC)	<= 100 CFU/g	NA

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