



# CERTIFICATE OF ANALYSIS

Name **CARDALIS M**  
Presentation **30 tablets**  
Code list **C63520B**

Batch N° **12B4**  
Manufacturing date **6-MAR-2014**  
Expiry date **6-MAR-2016**

Tests	Specifications	Results
<b>TESTS</b>		
-Mean of Benazepril Hcl dissolved in 30 min	$\geq 75$ %	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	$\leq 1.0$ %	0.1
Unknown (each)	$< 1.0$ %	0.0
Total	$\leq 1.0$ %	0.1
- 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	NA
- Total combined Yeast/ Mould Count (TYMC)	$\leq 100$ CFU/g	NA

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

~~COMPLIES / NOT COMPLIES~~

Batch Release number **352638**

Checked by : **Cath. GOOSSAERT**

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  
 Presentation: 30 tablets  
 Code list: C63520B

Batch N°: 12B4  
 Manufacturing date: 6-MAR-2014  
 Expiry date: 6-MAR-2016

Tests	Specifications	Results
CHARACTERS	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
IDENTIFICATIONS		
Spironolactone; (HPLC/UV diode array)	Rt of test substance concordant with the reference substance and UV spectra superimposable	COMPLIES
Benzapril; (HPLC/UV diode array)	Rt of test substance concordant with the reference substance and UV spectra superimposable	COMPLIES
TESTS		
Uniformity of dosage units :	Complies to Ph. Eur. 2.9.40	COMPLIES
Subdivision of tablets :	Complies to Ph. Eur. 0478	COMPLIES
Water content (KF):	<=3,0 %	1,9
Dissolution test :	Complies to Ph. Eur. 2.9.3.1 (With Q<=75%)	
Mean of Spironolactone dissolved in 45 min	>=75 %	98

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

COMPLIES / NOT-COMPLIES-

Batch Release number: 352636  
 Batch Release date: 23-JUN-2014  
 Checked by: Cath. GOSSAERT  
 Laurent MAGNIES  
 Qualified Person

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