CERTIFICATE OF ANALYSIS

Name	CARDALIS L	Batch N°	11C1
Presentation	30 tablets		
Code list	C63530B	Manufacturing date	2-DEC-2013
		Expiry date	2-DEC-2016

Tests	Specifications	Results
CHARACTERS		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	573.8 - 634.2 mg	602.1
Sizes :		
- Length	16.5 - 17.5 mm	17.0
- Width	6.7 - 7.8 mm	7.2
IDENTIFICATIONS		
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
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 %	97

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 349420

Batch Release date **24-APR-2014** **ACCEPTED by** Valérie AUGELLO
Qualified Person

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

Ceva Santé Animale
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SA au capital de 40 331 892 Euros - RCS Libourne B 301 763 405

CERTIFICATE OF ANALYSIS

Name	CARDALIS L	Batch N°	11C1
Presentation	30 tablets		
Code list	C63530B	Manufacturing date	2-DEC-2013
		Expiry date	2-DEC-2015

Tests	Specifications	Results
TESTS		
-Mean of Benazepril Hcl dissolved in 30 min	>=75 %	97
ASSAYS		
Spironolactone :	76.0 - 84.0 mg/ cp	79.3
Benazepril Hcl :	9.50 - 10.50 mg/ cp	9.78
DEGRADATION PRODUCTS (HPLC)		
-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 %	0.2
Benazepril Hcl impurity E	<=1.0 %	0.1
Unknown (each)	<1.0 %	0.3
Total (including impurity C)	<=1.0 %	0.7
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

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 349420

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