CERTIFICATE OF ANALYSIS

Name	CARDALIS S	Batch N°	13A1
Presentation	30 tablets		
Code list	C63510B	Manufacturing date	9-JUN-2014
		Expiry date	9-JUN-2016

Tests	Specifications	Results
CHARACTERS		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	139.7 - 162.3 mg	150.3
Sizes :		
- Length	9.5 - 11.2 mm	10.8
- Width	4.2 - 4.7 mm	4.5
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 %	2.0
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With Q>=75%)	
-Mean of Spironolactone dissolved in 45 min	>=75 %	90

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 356072

Batch Release date 26-AUG-2014 ACCEPTED by Laurent MAGNIES
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 S	Batch N°	13A1
Presentation	30 tablets		
Code list	C63510B	Manufacturing date	9-JUN-2014
		Expiry date	9-JUN-2016

Tests	Specifications	Results
TESTS		
-Mean of Benazepril Hcl dissolved in 30 min	>=75 %	94
ASSAYS		
Spironolactone :	19.0 - 21.0 mg/ cp	19.4
Benazepril Hcl :	2.38 - 2.63 mg/ cp	2.40
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 %	0.0
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

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

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