



CERTIFICATE OF ANALYSIS

Name	CARDALIS M	Batch N°	21B2
Presentation	30 tablets	Manufacturing date	31-MAR-2015
Code list	C63520B	Expiry date	31-MAR-2017

Tests	Specifications	Results
CHARACTERS		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	286.9 - 317.1 mg	302.0
Sizes :		
- Length	13.0 - 14.0 mm	10.7
- Width	5.2 - 6.2 mm	4.6
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 %	2.2
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With Q \geq 75%)	
-Mean of Spironolactone dissolved in 45 min	≥ 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 373773

Batch Release date 11-JUN-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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Tests	Specifications	Results
TESTS		
-Mean of Benazepril Hcl dissolved in 30 min	≥ 75 %	97
ASSAYS		
Spironolactone :	38.0 - 42.0 mg/ cp	40.1
Benazepril Hcl :	4.75 - 5.25 mg/ cp	4.91
DEGRADATION PRODUCTS (HPLC)		
-Degradation products of Spironolactone :		
Canrenone	≤ 1.0 %	0.4
Unknown (each)	< 1.0 %	0.0
Total	≤ 1.0 %	0.4
- 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	<u>NA</u>
- Total combined Yeast/ Mould Count (TYMC)	≤ 100 CFU/g	<u>NA</u>

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ASSAYS		
- Escherichia coli	Absent	NA

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