



## CERTIFICATE OF ANALYSIS

Name	CARDALIS M	Batch N°	9B1
Presentation	30 tablets	Manufacturing date	30-JAN-2013
Code list	C63520B	Expiry date	30-JAN-2015

Tests	Specifications	Results
<b>CHARACTERS</b>		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	286.9 - 317.1 mg	303.9
Sizes :		
- Length	13.0 - 14.0 mm	13.6
- Width	5.2 - 6.2 mm	5.7
<b>IDENTIFICATIONS</b>		
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
<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):	<=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 %	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 345168

Batch Release date 18-FEB-2014

ACCEPTED by

Olivier DENIAU  
Qualified Person

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

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