



## CERTIFICATE OF ANALYSIS

Name	CARDALIS S	Batch N°	11A2
Presentation	30 tablets	Manufacturing date	2-DEC-2013
Code list	C63510B	Expiry date	2-DEC-2015

Tests	Specifications	Results
<b>CHARACTERS</b>		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	139.7 - 162.3 mg	151.5
Sizes :		
- Length	9.5 - 11.2 mm	10.7
- Width	4.2 - 4.7 mm	4.5
<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):	$\leq 3.0$ %	1.9
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With Q $\geq$ 75%)	
-Mean of Spironolactone dissolved in 45 min	$\geq 75$ %	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~~

Batch Release number 345956  
Batch Release date 4-MAR-2014

Checked by : Cath. GOOSSAERT

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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