



CERTIFICATE OF ANALYSIS

Name	CARDALIS M	Batch N°	7B2
Presentation	30 tablets	Manufacturing date	18-DEC-2012
Code list	C63520B	Expiry date	18-DEC-2014

Tests	Specifications	Results
CHARACTERS		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	286.9 - 317.1 mg	302.9
Sizes :		
- Length	13.0 - 14.0 mm	13.6
- Width	5.2 - 6.2 mm	5.8
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 \geq 75%)	
-Mean of Spironolactone dissolved in 45 min	≥ 75 %	98

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 342000
Batch Release date 23-DEC-2013

Checked by : Cath. GOOSSAERT

ACCEPTED by Valérie AUGELLO
Qualified Person

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

Page 1 sur 3

