



CERTIFICATE OF ANALYSIS

Name	CARDALIS S	Batch N°	8A5
Presentation	30 tablets	Manufacturing date	28-JAN-2013
Code list	C63510B	Expiry date	28-JAN-2015

Tests	Specifications	Results
CHARACTERS		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	139.7 - 162.3 mg	151.5
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 %	2.5
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With Q \geq 75%)	
- Mean of Spironolactone dissolved in 45 min	≥ 75 %	92

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 343883
Batch Release date 29-JAN-2014

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.

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