

BE 0103/13

LABIANA Life Sciences, S.A.



CERTIFICATE OF RELEASE

A) BASIC DATA

PRODUCT: BUSCOPAN COMP. 100 ML
 COUNTRY: HUNGARY
 PRODUCT CODE LABIANA: 54144
 MANUFACTURING SPECIFICATION N°: C 0380-01-06
 TESTING SPECIFICATION N°: 1011243-A18R-01
 LABIANA BATCH N°: F13617-16
 SPECIFIC BATCH N°: F13617-16
 ANALYSIS N°: 48720
 MANUFACTURING DATE: 23-07-2013
 EXPIRY DATE: 07-2017
 UNITS RELEASED: 1238
 COMMENTS:

B) RAW MATERIALS

We herewith certify that all raw materials have been tested and are in compliance with the requirements of the testing specifications

C) MANUFACTURING / PACKAGING

The manufacturing and packaging documentation for the above mentioned product have been reviewed and it was determined that this lot number was manufactured and packaged according to the requirements of the manufacturing specifications and master production documents.

D) QUALITY ASSURANCE

All documentation has been found to be in compliance with the requirements of the above mentioned manufacturing specifications and master production documents. Explanations for deviations, if any are attached. This lot has been tested to the requirements of the above mentioned testing specification and the certificate of analysis is attached. All batch documentation is available upon request.

E) QUALIFIED PERSON RELEASE

The pharmaceutical product has been tested and complies with the requirements of the testing specifications and the relevant marketing authorisation and European cGMP requirements. The pharmaceutical product is released by a Qualified Person (75/319/EEC or 81/851/EEC).

Reviewed by:

In-process Control (QA)

Released by:

Qualified Person (QP)

13/07/13

Date: 13/07/13

Dr. Bányai Lászlóné
 minőségbiztosító gyógyszerész
 Boehringer Ingelheim RCV Fióktelep

