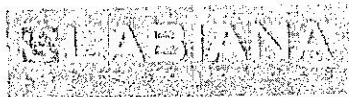


BE 0017/16

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°: H13610-22

SPECIFIC BATCH N°: H13610-22

ANALYSIS N°: 54174

MANUFACTURING DATE: 02-07-2015

EXPIRY DATE: 07-2019

UNITS RELEASED: 1735

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)

Date: 03/08/15

04108115  
minőségir  
Boehringer Ingelheim



**ANALYSIS CERTIFICATE**  
**Producto Acabado**

Producto/Product: BUSCOPAN COMPOSITUM		Código/Code : 45582 E	
Lote/Batch: H13610	Caducidad/Expiry: (*)	Cantidad/Amount: 2000L	
Fecha Fabricación/Manufac.Date: 02.07.15		Formato: 100ml	Reporte/Report: 721352
Recibido/Received : 07.07.15	Nº Análisis/Analysis : 54174	Fecha Análisis/Q Analysis Date/Q: 27.07.15	Fecha Análisis/M Analysis Date/M: 22.07.15
Prescripción análisis : TS nº 101243-561c-02 (08.10.2009)			Tipo Lote/Use of batch: Producción/Production

**ENSAJO/TEST**

- DESCRIPTION
  - 1.1 LIQUID , COLOUR
  - 1.7 ODOUR
- PHYSICO-CHEMICAL DETERMINATIONS
  - 2.2 PH
  - 2.9.1 IDENTIFICATION BY TLC
  - 2.9.2 IDENTIFICATION BY HPLC
  - 2.9.5 OTHER IDENTIFICATIONS
  - 2.10 CLARITY OF SOLUTION
  - 2.11 COLOUR OF SOLUTION
  - 2.19 EXTRACTABLE VOLUME
  - 2.42 SUB-VISIBLE PARTICLES
  - 2.44 VISIBLE PARTICLES
- ASSAY
  - 3.5 HPLC
- MICROBIOLOGICAL DETERMINATIONS
  - 4.1 STERILITY TEST
- IMPURITIES:
  - 6.16 ACTIVE INGREDIENT DECOMPOSITION
- PRESERVATIVES
  - 7.2 PHENOL

**ESPECIFICACION/SPECIFICATION**

Clear, slightly yellow solution, filled into amber-coloured injection vials.  
 Phenolic odour.

5.0 - 6.0  
 AD1: Corresponding to standard  
 AD1: Corresponding to standard  
 Phenol: Corresponding to standard  
 Dipyrone: Corresponding to standard  
 Bromide: Positive  
 Sodium: Positive  
 ≤ I  
 ≤ Y6  
 Format 30 ml: 30.0 - 33.0 ml  
 Format 50 ml: 50.0 - 55.0 ml  
 Format 100 ml: 100.0 - 110.0 ml  
 Not more than 6000 particles ≥ 10µm/injection vial  
 Not more than 600 particles ≥ 25µm/injection vial  
 Practically free from particles

AD1: 0.38 - 0.42 g/100 ml  
 Dipyrone and related substances with which it is in chemical equilibrium: 47.5 - 52.5 g/100 ml  
 Dipyrone content (g/100ml): For information only  
 4-Methylaminoantipyrine (%): For information only  
 4-Aminophenazone (%): For information only

Complies with Eur. Ph. 8Ed.

AD12: ≤ 0.5% decomposed to AD1  
 EA 345 BR: ≤ 1.5% decomposed to AD1  
 EA 790 BR: ≤ 1.0% decomposed to AD1  
 Any other impurity: ≤ 0.5% decomposed to AD1  
 Total of all impurities: ≤ 2.5% decomposed to AD1

0.47 - 0.53 g/100 ml  
 (\*) Specific for climatic zones.  
 \*End of report\*

**RESULTADOS/RESULT**

Complies  
 Complies

5.4  
 Complies  
 Complies  
 Complies  
 Complies  
 Complies  
 Complies  
 < I  
 < Y6  
 NP  
 NP  
 102.0 - 104.0 ml  
 Complies  
 Complies  
 Complies

0.40 g/100 ml

49.3 g/100 ml  
 47.2 g/100 ml  
 4.7 %  
 ND

Complies

ND  
 ND  
 ND  
 ND  
 ND

0.47 g/100 ml

Firme/Signature			Aprobado/Rechazado/Approved/Rejected
	Control Calidad Quality Control	Dirección Técnica Technical Manager	

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C.I.F. A-06069775