

3E 0068/13

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°: F13612-15  
SPECIFIC BATCH N°: F13612-15  
ANALYSIS N°: 47899  
MANUFACTURING DATE: 27-05-2013  
EXPIRY DATE: 05-2017  
UNITS RELEASED: 1739  
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)

Date: 02.07.13.

Released by:

Qualified Person (QP)

02.07/13



Boehringer  
Ingelheim



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

Producto/Product: BUSCOPAN COMPOSITUM		Código/Code : 45582 E	
Lote/Batch: F13612	Caducidad/Expiry: (*)	Cantidad/Amount: 20001	
Fecha Fabricación/Manufac.Date: 27.05.13		Formato: 100ml	Reporte/Report: 608286
Recibido/Received : 29.05.13	Nº Análisis/Analysis : 47899	Fecha Análisis/Q Analysis Date/Q: 10.06.13	Fecha Análisis/M Analysis Date/M: 12.06.13
Prescripción análisis : TS nº 1011243-561C-02 (08.10.2009)		Tipo Lote/Use of batch: Producción/Production	

**ENSAYO/TEST**

1. DESCRIPTION
  - 1.1 LIQUID , COLOUR
  - 1.7 ODOUR
2. 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
3. ASSAY
  - 3.5 HPLC
4. MICROBIOLOGICAL DETERMINATIONS
  - 4.1 STERILITY TEST
6. IMPURITIES
  - 6.16 ACTIVE INGREDIENT DECOMPOSITION
7. 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  
 Dipyron: Corresponding to standard  
 Bromide: Positive  
 Sodium: Positive  
 $\leq I$   
 $\leq Y6$   
 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  $\geq 10\mu\text{m}$ /injection vial  
 Not more than 600 particles  $\geq 25\mu\text{m}$ /injection vial  
 Practically free from particles

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

Complies with Eur. Ph. 7Ed.

AD12:  $\leq 0.5\%$  decomposed to AD1  
 BA 345 BR:  $\leq 1.5\%$  decomposed to AD1  
 BA 790 BR:  $\leq 1.0\%$  decomposed to AD1  
 Any other impurity:  $\leq 0.5\%$  decomposed to AD1  
 Total of all impurities:  $\leq 2.5\%$  decomposed to AD1

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

**RESULTADOS/RESULTS**

Complies  
 Complies

5.4  
 Complies  
 Complies  
 Complies  
 Complies  
 Complies  
 $< I$   
 $< Y6$

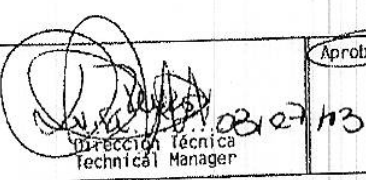
102.0 - 106.0 ml  
 Complies  
 Complies  
 Complies

0.39 g/100 ml  
 49.6 g/100 ml  
 47.0 g/100 ml  
 5.5 %  
 ND

Complies

ND  
 ND  
 ND  
 ND  
 ND

0.48 g/100 ml

Firma/Signature  Control Calidad Quality Control	Aprobado-Rechazado/Approved-Rejected  Dirección Técnica Technical Manager
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C.I.F. A-08069775

