

**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°: *H13610-23*  
 SPECIFIC BATCH N°: *H13610-23*  
 ANALYSIS N°: *54174*  
 MANUFACTURING DATE: *02-07-2015*  
 EXPIRY DATE: *07-2019*  
 UNITS RELEASED: *1743*

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:

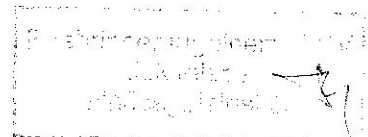
\_\_\_\_\_  
 In-process Control (QA)

Released by:

\_\_\_\_\_  
 Qualified Person (QP)

090915

Date: 09/09/15





## ANALYSIS CERTIFICATE

Producto Acabado

Producto/Product: BUSCOPAN COMPOSITION		Código/Code : 45522 E
Lote/Batch: H13610	Caducidad/Expiry: (x)	Cantidad/Amount: 2000L
Fecha Fabricación/Manufac. Date: 02.07.15	Formato: 100ml	Reporte/Report: 726352
Recibido/Received : 07.07.15 Nº Análisis/Analysis : 54174	Fecha Análisis/D Analysis Date/D: 27.07.15 Fecha Análisis/N Analysis Date/N: 22.07.15	
Prescripción análisis : TS nº 1011243-561c-02 (03.10.2009)		Tipo Lote/Use of batch: Producción/Production

ENSAJO/TEST	ESPECIFICACION/REQUIREMENT	RESULTADO/RESULTS
1. DESCRIPTION 1.1 LIQUID , COLOUR 1.7 OLOUR	Clear, slightly yellow solution, filled into amber-coloured injection vials. Phenolic odour.	Complies Complies
2. PHYSICO-CHEMICAL DETERMINATIONS 2.2 PH 2.9.1 IDENTIFICATION BY TLC 2.9.2 IDENTIFICATION BY HPLC 2.9.5 OTHER IDENTIFICATIONS	5.0 - 6.0 AD1: Corresponding to standard AD1: Corresponding to standard Phenol: Corresponding to standard Dipyrene: Corresponding to standard Bromide: Positive Sodium: Positive	5.4 Complies Complies Complies Complies Complies
2.10 CLARITY OF SOLUTION 2.11 COLOUR OF SOLUTION 2.19 EXTRACTABLE VOLUME	≤ I ≤ Y6 Format 30 ml: 33.0 - 33.0 zL 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	< I < Y6 NP NP 102.0 - 104.0 ml Complies Complies Complies
2.42 SUB-VISIBLE PARTICLES 2.44 VISIBLE PARTICLES 3. ASEAY 3.5 HPLC	AD1: 0.38 - 0.42 g/100 ml Dipyrene and related substances with which it is in chemical equilibrium: 47.5 - 52.5 g/100 ml Dipyrene content (g/100ml): For information only 4-Methylaminoantipyrine (%): for information only 4-Aminophenazone (%): For information only	0.40 g/100 ml 49.3 g/100 ml 47.2 g/100 ml 4.7 % ND
4. MICROBIOLOGICAL DETERMINATIONS 4.1 STERILITY TEST 6. IMPURITIES 6.16 ACTIVE INGREDIENT DECOMPOSITION	Complies with Eur. Ph. 8Ed. AD12: ≤ 0.5% decomposed to AD1 BA 345 ER: ≤ 1.5% decomposed to AD1 BA 790 ER: ≤ 1.0% decomposed to AD1 Any other impurity: ≤ 0.5% decomposed to AD1 Total of all impurities: ≤ 2.5% decomposed to AD1	Complies ND ND ND ND ND
7. PRESERVATIVES 7.2 PHENOL	0.47 - 0.53 g/100 ml (*) Specific for climatic zones. *End of report*	0.47 g/100 ml

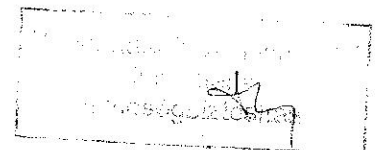
Firma/Signature   ..... 03.08.15 Control Calidad Quality Control	 ..... 08/08/15 Dirección Técnica Technical Manager	Aprobado/Rechazado/Approved/Rejected  <div style="text-align: center; font-size: 2em; font-weight: bold;">A</div>
---	--	---

Pollg. Ind. Can Ferellada  
Venús, 26 08228 Terrassa  
Barcelona/Spain

Tel. 34 93 736 97 90  
e-mail: life-sciences@labiana.com  
Fax 34 93 766 25 58

\\QA\LABOR\ANAL\_ACA.DTF

DIF A-08001775



Diszpó: BE8055025085 Vevő: Dr. Székely Kft. File név: BE00000626 Egyedi sorszám: BE0000003449 18 másolat  
 Szállító: Boehringer animal health Oldal/Lap 2 / 2 Anyaglap: BE0068/16  
 Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2016.10.26  
 Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

**CertEx v3.03a**