

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°: *G13603-18*
SPECIFIC BATCH N°: *G13603-18*
ANALYSIS N°: *50411*
MANUFACTURING DATE: *10-03-2014*
EXPIRY DATE: *03-2018*
UNITS RELEASED: *1729*
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 (7.5319/EEC or 81/851/EEC).

Reviewed by:

In-process Control (QA)

Released by:

Qualified Person (QP)

Date: 30/04/14

30/04/14



ANALYSIS CERTIFICATE
Producto Acabado

Producto/Product: BUSCOPAN COMPOSITUM		Código/Code : 45522 E	
Lote/Batch: G13603	Caducidad/Expiry: (*)	Cantidad/Amount: 2000L	
Fecha Fabricación/Manufac.Date: 10.03.14		Formato: 100ml	Reporte/Report: 558927
Recibido/Received : 12.03.14	Nº Análisis/Analysis : 52411	Fecha Análisis/O Analysis Date/O: 27.03.14	Fecha Análisis/M Analysis Date/M: 26.03.14
Prescripción análisis : TS nº 1011243-5610-02 (00.10.2009)		Tipo Lote/Use of batch: Producción/Production	

ENSAYO/TEST	ESPECIFICACION/SPECIFICATION	RESULTADOS/RESULTS
1. DESCRIPTION 1.1 LIQUID . COLOUR	Clear, slightly yellow solution, filled into amber-coloured injection vials. Inert odour.	Complies Complies
1.7 ODOUR		Complies
2. PHYSICO-CHEMICAL DETERMINATIONS 2.2 PH	5.0 - 6.0	5.4 Complies
2.9.1 IDENTIFICATION BY TLC	AD1: Corresponding to standard	Complies
2.9.2 IDENTIFICATION BY HPLC	AD1: Corresponding to standard Phenol: Corresponding to standard Dipyron: Corresponding to standard	Complies Complies Complies
2.9.5 OTHER IDENTIFICATIONS	Bromide: Positive Sodium: Positive	Complies Complies
2.10 CLARITY OF SOLUTION	≤ 1	< 1
2.11 COLOUR OF SOLUTION	≤ Y6	< Y6
2.19 EXTRACTABLE VOLUME	Format 30 ml: 30.0 - 33.0 ml Format 50 ml: 50.0 - 55.0 ml Format 100 ml: 100.0 - 110.0 ml	102.0 - 104.0 ml Complies Complies
2.42 SUB-VISIBLE PARTICLES	Not more than 6000 particles × 10µm/injection vial Not more than 600 particles × 25µm/injection vial Practically free from particles	Complies Complies Complies
2.44 VISIBLE PARTICLES		
3. ASSAY 3.5 HPLC	AD1: 0.58 - 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-Methylaminopyrine (%): For information only 4-Aminopyrene (%): For information only	0.40 g/100 ml 45.1 g/100 ml 45.4 g/100 ml 5.0 % ND
4. MICROBIOLOGICAL DETERMINATIONS 4.1 STERILITY TEST	Complies with Eur. Ph. 9.5.2.	Complies
6. IMPURITIES 6.16 ACTIVE INGREDIENT DECOMPOSITION	AD12: ≤ 0.5% decomposed to AD1 BA 345 83: ≤ 1.5% decomposed to AD1 BA 790 83: ≤ 1.0% decomposed to AD1 Any other impurity: ≤ 0.5% decomposed to AD1 Total of all impurities: ≤ 2.5% decomposed to AD1	ND ND ND ND ND
7. PRESERVATIVES 7.2 PHENOL	0.47 - 0.53 g/100 ml (*): Specific for climatic zones. *End of report*	0.49 g/100 ml

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

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