BE 0113/15

LABIANA Life Sciences, S.A.

CERTIFICATE OF RELEASE

A) BASIC DATA

PRODUCT:	*BUSCOPAN COMP. 100 ML*
COUNTRY:	*HUNGARY*
PRODUCT CODE LABIANA:	*54144*
MANUFACTURING SPECIFICATION Nº:	*C 0380-01-06*
TESTING SPECIFICATION Nº:	*1011243-A18R-01*
LABIANA BATCH Nº:	*H13607-21*
SPECIFIC BATCH Nº:	*H13607-21*
ANALYSIS Nº:	*53882*
MANUFACTURING DATE:	*11-05-2015*
EXPIRY DATE:	*05-2019*
UNITS RELEASED:	*3761*
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: 09-06-15

Released by:

Qualified Person (QP)

09/06/15

I.ABIANA Life Sciences, S.A.U.

ANALYSIS CERTIFICATE
Producto Acabado

Producto/Product: BUSCOPAN COMPOSITUM			Código/Code : 45582 E
Lote/Batch: 513607	Caducidad/Expiry: (*)		Cantidad/Amount: 2009 L
Fecha Fabricación/Manufac.Date: 11.05.15		Formato: 100 ml	Reporte/Report: 721358
Recibida/Received : 13.05.15 Nº Análisis/Analysis : 50682		Fecha Análisis/Q Analysis Date/Q: 05.06.15 Fecha Análisis/M Analysis Date/M: 28.05.15	
Prescripción análisis : TS nº 1011243-561C-02 (08.10.2009)		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.	Complies
. 1.7 ODOUR	Phenolic odour.	Complies
2. PHYSICO-CHEMICAL DETERMINATIONS		
. 2.2 PH	5.0 - 6.0	5.4
. 2.9.1 IDENTIFICATION BY TLC	ADI: Corresponding to standard	Complies
. 2.9.2 IDENTIFICATION BY HPLC	ADI: Corresponding to standard	Complies
	Phenol: Corresponding to standard	Complies
	Dipyrone: Corresponding to standard	Complies
2.9.5 OTHER IDENTIFICATIONS	Bromide: Positive	Complies
	Sodium: Positive	Complies
. 2.10 CLARITY OF SOLUTION	≤ 3	< 1
. 2.11 COLOUR OF SOLUTION	≤ Y6	< Y6
. 2.19 EXTRACTABLE VOLUME	Format 20 ml: 20.0 - 23.0 ml	NP
	Format 50 ml: 50.0 - 55.0 ml	NP
	Format 100 ml: 100.0 - 110.0 ml	100.0 - 104.0 ml
. 2.42 SUB-VISIBLE PARTICLES	Not more than 6000 particles ≥ 10µm/injection vial	Complies
	Not more than 600 particles ≥ 25µm/injection vial	Complies
2.44 VISIBLE PARTICLES	Practically free from particles	Complies
3. ASSAY		
. 3.5 HPLC	ADI: 0.38 - 0.42 g/100 ml	0.40 g/100ml
	Dipyrone and related substances with which it is in chemical equilibrium: 47.5 - 52.5 g/100 ml	47.9 g/100ml
	Dipyrone content (g/100ml): For information only	45.7 g/100ml
	4-Methylaminoantipyrine (%): For information only	5.0 %
	4-Aminophenazone (%): For information only	ND
4. MICROBIOLOGICAL DETERMINATIONS		
. 4.1 STERILITY TEST	Complies with Eur. Ph. 8Ed.	Complies
6. IMPURITIES		
. 6.16 ACTIVE INGREDIENT DECOMPOSITION	ADI2: ≤ 0.5% decomposed to ADI	ND
	BA 345 88: ≤ 1.5% decomposed to ADI	ND
	BA 790 83: ≤ 1.0% decomposed to ADI	ND
	Any other impurity: ≤ 0.5% decomposed to ADI	ND
	Total of all impurities: ≤ 2.5% decomposed to ADI	ND
7. PRESERVATIVES		
. 7.2 PHENOL	0.47 - 0.53 g/100 ml	0.51 g/100ml
	(*) Specific for climatic zones.	
	End of report	

Firma/Signature		(Aprobado-Rechazado)/Approved-Rejected
08/06/15 Control Calidad Quality Control	08/06/15 Dirección Técnica Technical Manager	

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