



CERTIFICATE OF RELEASE

A) BASIC DATA

PRODUCT: BUSCOPAN COMP. 100 ML
COUNTRY: SLOVENIA
PRODUCT CODE LABIANA: 54577
MANUFACTURING SPECIFICATION N°: C 0380-01-06
TESTING SPECIFICATION N°: 1011243-A18R-01
LABIANA BATCH N°: H13608-05
SPECIFIC BATCH N°: H13608-05
ANALYSIS N°: 54003
MANUFACTURING DATE: 08-06-2015
EXPIRY DATE: 06-2019
UNITS RELEASED: 2617
NAME OF THE RELEASING COMPANY: LABIANA Life Sciences, S.A., Spain

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:

Released by:


In-process Control (QA)


Qualified Person (QP)

Date:

01-07-15

01/07/15

ANALYSIS CERTIFICATE

Producto Acabado

Producto/Product: BUSCOPAN COMPOSITUM		Código/Code: 45587 F
Lote/Batch: H13608	Caducidad/Expiry: (*)	Cantidad/Amount: 2000L
Fecha Fabricación/Manufac. Date: 08.06.15	Formato: 100ml	Reporte/Report: 721260
Recibido/Received: 10.06.15 Nº Análisis/Analysis: 54003	Fecha Análisis/O Analysis Date/D: 23.06.15 Fecha Análisis/M Analysis Date/M: 29.06.15	
Prescripción análisis: TS nº 1011243-661C-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	AD1: Corresponding to standard	Complies
2.9.2 IDENTIFICATION BY HPLC	AD1: 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	< 1	< 1
2.11 COLOUR OF SOLUTION	< Y6	< Y6
2.19 EXTRACTABLE VOLUME	Format 30 ml: 30.0 - 33.0 ml	NP
	Format 50 ml: 50.0 - 55.0 ml	NP
	Format 100 ml: 100.0 - 110.0 ml	102.0 - 104.0 ml
2.42 SUB-VISIBLE PARTICLES	Not more than 6000 particles $\geq 10\mu\text{m}$ /injection vial	Complies
	Not more than 600 particles $\geq 25\mu\text{m}$ /injection vial	Complies
2.44 VISIBLE PARTICLES	Practically free from particles	Complies
3. ASSAY		
3.5 HPLC	AD1: 0.38 - 0.42 g/100 ml	0.39 g/100ml
	Dipyrone and related substances with which it is in chemical equilibrium: 47.5 - 52.5 g/100 ml	49.1 g/100ml
	Dipyrone content (g/100ml): For information only	47.1 g/100ml
	4-Methylaminocantipyrine (X): For information only	4.6 X
	4-Aminophenazone (X): For information only	ND
4. MICROBIOLOGICAL DETERMINATIONS		
4.1 STERILITY TEST	Complies with Eur. Ph. 8Ed.	Complies
6. IMPURITIES		
6.16 ACTIVE INGREDIENT DECOMPOSITION	AD12: $\leq 0.5\%$ decomposed to AD1	ND
	BA 345 BR: $\leq 1.5\%$ decomposed to AD1	ND
	BA 790 BR: $\leq 1.0\%$ decomposed to AD1	ND
	Any other impurity: $\leq 0.5\%$ decomposed to AD1	ND
	Total of all impurities: $\leq 2.5\%$ decomposed to AD1	ND
7. PRESERVATIVES		
7.2 PHENOL	0.47 - 0.53 g/100 ml	0.49 g/100ml
	(*) Specific for climatic zones.	
	End of report	

Firma/Signature			Aprobado/ Rechazado/ Aprobado/ Rechazado/
Control Calidad Quality Control	30.06.15	30/06/15	
	Control Calidad Quality Control	Director Técnico Technical Manager	

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