LABIANA Life Sciences, S.A.

BE 0006/16

CERTIFICATE OF RELEASE

A) BASIC DATA

PRODUCT:	*BISOLVON INJ. 100 ML*
COUNTRY:	*HUNGARY*
PRODUCT CODE LABIANA:	*54119*
MANUFACTURING SPECIFICATION Nº:	*C 0390-01-06*
TESTING SPECIFICATION Nº:	*101850-A18R-03*
LABIANA BATCH Nº:	*H13401H-18*
SPECIFIC BATCH Nº:	*H13401H-18*
ANALYSIS Nº:	*53006*
MANUFACTURING DATE:	*02-02-2015*
EXPIRY DATE:	*02-2020*
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)

Date: 29-04-15

Released by:

Qualified Person (QP)

29/04/15

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ANALYSIS CERTIFICATE
Producto Acabado

Producto/Product: BISOLVON			Código/Code : 45580 I
Lote/Batch: M13401	Caducidad/Expiry: (*)		Cantidad/Amount: 2000L
Fecha Fabricación/Manufac.Date:02.02.15		Formato:100ml	Reporte/Report:709510
Recibido/Received : 09.02.15 Nº Análisis/Analysis : 53006		Fecha Análisis/O Analysis Date/O: 19.02.15 Fecha Análisis/M Analysis Date/M: 25.02.15	
Prescripción análisis : 101 8502 561C-04 (12.10.2010)			Tipo Lote/Use of batch: Producción/Production

ENSAYO/TEST	ESPECIFICACION/SPECIFICATION	RESULTADOS/RESULTS
1. DESCRIPTION		
. 1.1 LIQUID . COLOUR	Clear and colourless solution,practically free from particles,filled into injection vials	Complies
. 1.7 ODOUR	Almost imperceptible.	Complies
2. PHYSICO-CHEMICAL DETERMINATIONS		
. 2.2 PH	3.0 - 4.0	3.2
. 2.4 RELATIVE DENSITY	0.9945 - 1.0045 (20°C)	1.0019
. 2.9 IDENTIFICATION		
. 2.9.1 IDENTIFICATION BY TLC	N-A 274 CL: Corresponding to standard	Complies
	Methylparahydroxybenzoate:Corresponding to standard	Complies
	Propylparahydroxybenzoate:Corresponding to standard	Complies
. 2.9.2 IDENTIFICATION BY HPLC	N-A 274 CL: Corresponding to standard	Complies
	Methylparahydroxybenzoate:Corresponding to standard	Complies
	Propylparahydroxybenzoate:Corresponding to standard	Complies
. 2.10 CLARITY OF SOLUTION	≤ I	< I
. 2.11 COLOUR OF SOLUTION	≤ B9	< B9
. 2.19 EXTRACTABLE VOLUME	Format 50 ml : 50.0 - 55.0 ml	
	Format 100 ml : 100.0 - 110.0 ml	100.0 - 104.0 ml
	Format 250 ml : 250.0 - 260.0 ml	
. 2.42 SUB-VISIBLE PARTICLES	Complies with Ph. Eur. 8Ed.	Complies
3. ASSAY		
. 3.5 HPLC	N-A 274 CL : 285.0 - 315.0 mg/100.0 ml	302.8 mg/100.0 ml
4. MICROBIOLOGICAL DETERMINATIONS		
. 4.1 STERILITY TEST	Complies with Ph. Eur. 8Ed.	Complies
6. IMPURITIES		
. 6.16 ACTIVE INGREDIENT DECOMPOSITION	≤ 1.0% N-A 274 CL equivalent to ≤ 0.7% N-AB 773 XX	0.02 %
	≤ 0.3% N-A 274 CL equivalent to ≤ 0.3% N-A 1740 CL	0.02 %
	Each individual unknown impurities:	
	≤ 0.3% calculated as % decomposed N-A 274 CL	ND
	Total impurities: ≤ 1.3%	0.04 %
7. PRESERVATIVES		
. 7.5 METHYLPARABEN /PROPYLPARABEN	Methylparahydroxybenzoate: 66.5 - 73.5 mg/100.0 ml	70.2 mg/100.0 ml
	Propylparahydroxybenzoate: 28.5-31.5 mg/100.0 ml	29.9 mg/100.0 ml

(*)Specific for climatic zones.
End of report

Firma/Signature	Aprobado-Rechazado/Approved-Rejected
11/03/15 Control Calidad Quality Control	11/03/15 Dirección Técnica Technical Manager

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