LABIANA Life Sciences, S.A.

BE 0076/14

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:	G13403F-16
SPECIFIC BATCH Nº:	G13403F-16
ANALYSIS Nº:	50939
MANUFACTURING DATE:	02-06-2014
EXPIRY DATE:	06-2019
UNITS RELEASED:	563
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: 30/07/2014

Released by:

Qualified Person (QP)

30/07/14

Diszpó: BE8055019036 Vevő: Dr. Székely Kft. File név: BE00000391 Egyedi sorszám: BE0000001711 7 másolat
Szállító: Boehringer animal health Oldal/Lap 2 / 1 Anyaglap: BE0076/14
Az eredetiről készült hiteles másolat.
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek! Nyomtatás dátuma: 2015.01.13
CertEx v3.03a

LABIANA Life Sciences, S.A.U.

ANALYSIS CERTIFICATE
Producto Acabado

Producto/Product: BISOLVON		Código/Code : 45588 E	
Lote/Batch: G13480	Caducidad/Expiry: (*)	Cantidad/Amount: 2000 L	
Fecha Fabricación/Manufac.Date: 02.06.14		Formato: 500 ml	Reporte/Report: 590897
Recibido/Received : 04.06.14 Nº Análisis/Analysis : 50939		Fecha Análisis/Q Analysis Date/Q: 20.06.14 Fecha Análisis/R Analysis Date/R: 20.06.14	
Prescripción análisis : 101 8502 561C-04 (12.10.2010)		Tipo Lote/Use of batch: Producción/Production	

ANÁLISIS/TEST	ESPECIFICACIÓN/SPECIFICATION	RESULTADOS/RESULTS
1. DESCRIPCION 1.1 LIQUID . COLOUR	Clear and colourless solution,practically free from particles.filled into injection vials Almost imperceptible.	Complies Complies
1.7 ODOUR		Complies
2. PHYSICO-CHEMICAL DETERMINATIONS 2.2 PH	3.0 - 4.0	3.1
2.4 RELATIVE DENSITY	0.9845 - 1.0045 (20°C)	1.0008
2.9 IDENTIFICATION 2.9.1 IDENTIFICATION BY TLC	N-A 274 CL: Corresponding to standard Methylparahydroxybenzoate:Corresponding to standard Propylparahydroxybenzoate:Corresponding to standard	Complies Complies Complies
2.9.2 IDENTIFICATION BY HPLC	N-A 274 CL: Corresponding to standard Methylparahydroxybenzoate Corresponding to standard Propylparahydroxybenzoate:Corresponding to standard	Complies Complies Complies
2.10 CLARITY OF SOLUTION	≤ 1	≤ 1
2.11 COLOUR OF SOLUTION	≤ BG9	≤ BG9
2.19 EXTRACTABLE VOLUME	Format 50 ml : 50.0 - 55.0 ml Format 100 ml : 100.0 - 110.0 ml Format 250 ml : 250.0 - 260.0 ml Complies with Ph. Eur. 8Ed.	102.0 - 104.0 ml Complies
2.42 SUB-VISIBLE PARTICLES		
3. ASSAY 3.6 HPLC	N-A 274 CL : 285.0 - 315.0 mg/100.0 ml	304.1 mg/100 ml
4. MICROBIOLOGICAL DETERMINATIONS 4.3 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-A 273 CL ≤ 0.3% N-A 274 CL equivalent to ≤ 0.3% N-A 1740 CL Each individual unknown impurities ≤ 0.3% calculated as % decomposed N-A 274 CL Total impurities: ≤ 1.3%	0.2 % 0.1 % 0.07 % 0.3%
7. PRESERVATIVES 7.5 METHYLPARABEN /PROPYLPARABEN	Methylparahydroxybenzoate: 66.5 - 73.5 mg/100.0 ml Propylparahydroxybenzoate: 28.5-31.5 mg/100.0 ml *End of report*	70.7 mg/100.0 ml 30.2 mg/100.0 ml

Firma/Signature	Aprobado-Rechazado/Approved-Rejected
20/06/14 Control Calidad Quality Control	20/06/14 Dirección Técnica Technical Manager

Polig. Ind. Can Parellada
Vereda,26 08228 Terrassa
Barcelona/Spain

Tel. 34 93 736 97 00
e-mail: life-sciences@labiana.com
Fax 34 93 786 25 58

\CALIDAD\ANAL_ACA.DOT