

LABIANA Life Sciences, S.A.

3E 0076/14

CERTIFICATE OF RELEASE

A) BASIC DATA

PRODUCT: *BISOLVON INJ. 100 ML*
COUNTRY: *HUNGARY*
PRODUCT CODE LABIANA: *54119*
MANUFACTURING SPECIFICATION N°: *C 0390-01-06*
TESTING SPECIFICATION N°: *101850-A18R-03*
LABIANA BATCH N°: *G13403F-16*
SPECIFIC BATCH N°: *G13403F-16*
ANALYSIS N°: *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 (75319/EEC or 81/851/EEC).

Reviewed by:

In-process Control (QA)

Date:

30.10.2014

Released by:

Qualified Person (QP)

30.10.14

ANALYSIS CERTIFICATE

Producto Acabado

Producto/Product: BISDEVON		Código/Code: 45588 E	
Lote/Batch: G13480	Cantidad/Expiry: (*)	Cantidad/Amount: 2000 L	
Fecha Fabricación/Manufac. Date: 02.06.14		Formato: 500 ml	
Reporte/Report: 590997		Fecha Análisis/Analysis Date/Q: 20.06.14	
Recibido/Received N° Análisis/Analysis: 50939		Fecha Análisis/Analysis Date/M: 20.06.14	
Prescripción analysis: 101 BSB2 5610-04 (12.10.2010)		Tipo Lote/Use of Batch: Producción/Production	

ENSYDULSE

1. DESCRIPCIÓN
1.3 LÍQUIDO. COLORES
2. FÍSICO-QUÍMICO
2.1 pH
2.4 DENSIDAD RELATIVA
2.9 IDENTIFICACIÓN
2.9.1 IDENTIFICACIÓN BY I.C
2.9.2 IDENTIFICACIÓN BY HPLC
- 2.10 CLARIDAD DE SOLUCIÓN
2.11 COLORES DE SOLUCIÓN
2.19 VOLUMEN EXTRAÍBLE
- 2.42 SMI-VISIBILIDAD DE PARTÍCULAS
3. ASAYO
3.5 HPLC
4. MICROBIOLOGÍA
4.3 ESTERILIDAD TEST
6. IMPURETATS
6.16 ACTIU INGREDIENT DECOMPOSICIÓN
7. PRESERVATIVES
7.5 METHYLPARABEN /PROPYL PARABEN

ESPECIFICACION/SPECIFICATION

Clear and colourless solution, practically free from particles, filled into injection vials. Almost imperceptible.

3.0 - 4.0
0.9945 - 1.0045 @ 20°C

N-A 274 CL: Corresponding to standard
Methylparahydroxybenzoate: Corresponding to standard
Propylparahydroxybenzoate: Corresponding to standard
N-A 274 CL: Corresponding to standard
Methylparahydroxybenzoate: Corresponding to standard
Propylparahydroxybenzoate: Corresponding to standard

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. BEd.

N-A 274 CL : 285.0 - 315.0 mg/100.0 ml
Complies with Ph. Eur. 8Ed.

≤ 1.0% N-A 274 CL equivalent to ≤ 0.7% N-A 173 2X
≤ 0.3% N-A 274 CL equivalent to ≤ 0.3% N-A 1740 CL
Each individual unknown impurities
≤ 0.1% calculated as % decomposed N-A 274 CL
Total impurities: = 1.3%

Methylparahydroxybenzoate: 65.5 - 73.5 mg/100.0 ml
Propylparahydroxybenzoate: 28.5-31.5 mg/100.0 ml
end of report

RESUL TADOS/RESULTS

Complies
Complies

3.1
1.0028

Complies
Complies
Complies
Complies
Complies

< 1
< 60

102.0 - 104.0 ml

Complies

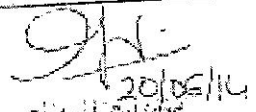

104.1 mg/100 ml

Complies

0.2 %
0.1 %

0.07 %
0.37%

70.7 mg/100.0 ml
30.2 mg/100.0 ml

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