

**CERTIFICATE OF RELEASE**

**A) BASIC DATA**

PRODUCT: **BISOLVON INJ. 100 ML**

COUNTRY: **AUSTRIA**

PRODUCT CODE LABIANA: **50884**

MANUFACTURING SPECIFICATION N°: **C 0390-01-06**

TESTING SPECIFICATION N°: **101 8502-F87R-01**

LABIANA BATCH N°: **H13405A-18**

SPECIFIC BATCH N°: **H13405A-18**

ANALYSIS N°: **54516**

MANUFACTURING DATE: **14-09-2015**

EXPIRY DATE: **09-2020**

UNITS RELEASED: **1142**

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:

*Glor*

In-process Control (QA)

*[Signature]*

Qualified Person (QP)

Date: **08-10-15**

**08/10/15**

# CERTIFICATE OF ANALYSIS

## Producto Acabado

Producto/Product: BISOVLON		Código/Code : 45580 E	
Lote/Batch: H13405	Caducidad/Expiry: (*)	Cantidad/Amount: 2000L	
Fecha Fabricación/Manufac.Date:14.09.15		Formato:100ml	Reporte/Report:721347
Recibido/Received : 18.09.15	Fecha Análisis/Q Analysis Date/Q: 28.09.15		
Nº Análisis/Analysis : 54516	Fecha Análisis/M Analysis Date/W: 07.10.15		
Prescripción análisis : 101 8502 561C-04 (12.10.2010)		Tipo Lote/Use of batch: Producción/Production	

**ENSAYO/TEST****ESPECIFICACION/SPECIFICATION****RESULTADOS/RESULTS**

1. DESCRIPTION	Clear and colourless solution, practically free from particles, filled into injection vials. Almost imperceptible.	Complies
1.1 LIQUID, COLOUR		Complies
1.7 ODOUR		3.1
2. PHYSICO-CHEMICAL DETERMINATIONS	3.0 - 4.0	1.0025
2.2 PH	0.9945 - 1.0045 ( 20°C )	
2.4 RELATIVE DENSITY		
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	≤ 89	< 89
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.	NP 102.0 - 106.0 ml NP Complies
2.42 SUB-VISIBLE PARTICLES		
3. ASSAY	N-A 274 CL : 285.0 - 315.0 mg/100.0 ml	304.1 mg/100.0 ml
3.5 HPLC		
4. MICROBIOLOGICAL DETERMINATIONS	Complies with Ph. Eur. 8Ed.	Complies
4.1 STERILITY TEST		
6. IMPURITIES	≤ 1.0% N-A 274 CL equivalent to ≤ 0.7% N-AB 773 XX ≤ 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%	0.03 % 0.1 %  0.02 % 0.1 %
6.16 ACTIVE INGREDIENT DECOMPOSITION		
7. PRESERVATIVES	Methylparahydroxybenzoate: 66.5 - 73.5 mg/100.0 ml Propylparahydroxybenzoate: 28.5-31.5 mg/100.0 ml (*) Specific for climatic zones. *End of report*	70.8 mg/100.0 ml 30.0 mg/100.0 ml
7.5 METHYLPARABEN /PROPYLPARABEN		

Firma/Signature	Aprobado-Rechazada/Approved-Rejected
 07.10.15 Control Calidad Quality Control	 08/10/15 LUISA REYES ALCALDE Dirección Técnica Technical Manager

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