



## CERTIFICATE OF RELEASE

### A) BASIC DATA

PRODUCT: BUSCOPAN COM. 100 ML  
COUNTRY: AUSTRIA  
PRODUCT CODE LABIANA: 50878  
MANUFACTURING SPECIFICATION N°: C 0380-01-06  
TESTING SPECIFICATION N°: 1011243-A18R-01  
LABIANA BATCH N°: G13610-28  
SPECIFIC BATCH N°: G13610-28  
ANALYSIS N°: 51584  
MANUFACTURING DATE: 30-07-2014  
EXPIRY DATE: 07-2018  
UNITS RELEASED: 1745

### 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)

Released by:

  
Qualified Person (QP)  
1809/14

Date: 19/09/14



## ANALYSIS CERTIFICATE

### Producto Acabado

Producto/Product: BUSCOPAN COMPOSITUM		Código/Code : 45582 E	
Lote/Batch: G13610	Caducidad/Expiry: (*)		Cantidad/Amount: 2000 L
Fecha Fabricación/Manufac.Date: 30.07.14		Formato: 100 ml	Reporte/Report: 697447
Recibido/Received : 06.08.14	Fecha Análisis/Q Analysis Date/Q: 16.09.14		Fecha Análisis/M Analysis Date/M: 01.09.14
Nº Análisis/Analysis : 51584			
Prescripción análisis : TS nº 1011243-561C-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	5.3
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
	Dipyrrone: 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	
	Format 50 ml: 50.0 - 55.0 ml	
	Format 100 ml: 100.0 - 110.0 ml	102.0 - 104.0ml
2.42 SUB-VISIBLE PARTICLES	Not more than 6000 particles ≥ 10µm/injection vial	Complies
	Not more than 600 particles ≥ 25µm/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/100 ml
	Dipyrrone and related substances with which it is in chemical equilibrium: 47.5 - 52.5 g/100 ml	48.3 g/100 ml
	Dipyrrone content (g/100ml): For information only	45.9 g/100 ml
	4-Methylaminoantipyrine (%): For information only	5.2 %
	4-Aminophenazone (%): 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: ≤ 0.5% decomposed to AD1	ND
	BA 345 BR: ≤ 1.5% decomposed to AD1	ND
	BA 790 BR: ≤ 1.0% decomposed to AD1	ND
	Any other impurity: ≤ 0.5% decomposed to AD1	ND
	Total of all impurities: ≤ 2.5% decomposed to AD1	ND
7. PRESERVATIVES		
7.2 PHENOL	0.47 - 0.53 g/100 ml	0.48 g/100 ml
	(*) Specific for climatic zones	
	*End of report*	

Finna/Signature			Aprobado/Rechazado/Approved/Rejected
Control Calidad Quality Control	Dirección Técnica Technical Manager		

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