

## CERTIFICATE OF CONFORMANCE (CoC)

1.	NAME OF THE PRODUCT	Buscopan Compositum Solution for Injection, 100 ml
2.	NAME OF THE RELEASING COMPANY	Labiana Life Sciences, S.A.
3.	LABIANA ARTICLE NUMBER	20054145
4.	BIX@ SKU NUMBER	10-138135
5.	LABIANA BATCH NUMBER	N13603-02
6.	ACTIVE INGREDIENTS	0.4 g/100 ml butylscopolamine and 50g/100ml metamizole
7.	DOSAGE FORM	Solution for injection
8.	TYPE OF PRIMARY PACKAGE	Amber glass vial with rubber stopper and cap with tab
9.	PACKAGE SIZE	100 ml
10.	IMPORTING COUNTRY	Poland
11.	MARKETING AUTHORIZATION NUMBER	1135/01
12.	MANUFACTURING AUTHORIZATION NUMBER	4268 E
13.	MANUFACTURING SPECIFICATION	C 0380-01-06
14.	TESTING SPECIFICATION	78625-p510ts5037v01
15.	DATE OF MANUFACTURE (DD-MM-YYYY)	30-03-2020
16.	DATE OF EXPIRY (MM-YYYY)	03-2024
17.	BATCH / LOT QUANTITY RELEASED	7007

## 18. CERTIFICATION STATEMENT

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records have been reviewed and found to be in compliance with GMP. Any deviations have been assessed prior to batch release. The batch has been released by a Qualified Person.

## 19. LOCAL REQUIREMENTS

20. SIGNATURE OF QUALITY UNIT // DATE

 02 JUN 2020

21. SIGNATURE OF QUALIFIED PERSON / DATE

 02 JUN 2020

22. CERTIFICATE OF ANALYSIS

attached

# CERTIFICATE OF ANALYSIS

**Product:** BUSCOPAN COMPOSITUM

**Analysis type:** Finished Product

**Batch:** N13603

**Code:** 11045582

**Registry:** 1016186

**Production Date:** 30/03/2020

**Batch size:** 2000 L

**Analysis Number:** 52.205 (60780,60781)

**Page Number:** 46837

**Expiry Date:** (\*)

**Analysis date:** 11/05/2020

**Result:** Within specifications

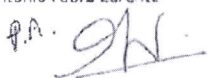

**Format:** 100 ml

**Bibliography:** T.S. No. 1011243-561C-02 (08.10.2009)

Test	Specification	Result
- Description: Liquid	Clear, slightly yellow solution, filled into amber-coloured injection vials	Complies
- Odour	Phenolic odour	Complies
- Identification by T.L.C	AD1: Corresponding to standard	Complies
- Identification by H.P.L.C.	AD1: Corresponding to standard	Complies
- Identification by H.P.L.C.	Phenol: Corresponding to standard	Complies
- Identification by H.P.L.C.	Dipyron: Corresponding to standard	Complies
- Other identification	Bromide: Positive	Complies
- Other identification	Sodium: Positive	Complies
- Clarity of the solution	<= I	Complies
- Colour of the solution	<= Y6	Complies
- Related Substances by TLC	AD12: <= 0.5 % decomposed to AD1	ND
- Related Substances by TLC	BA 345 BR: <= 1.5 % decomposed to AD1	ND
- Related Substances by TLC	BA 790 BR: <= 1.0 % decomposed to AD1	ND
- Related Substances by TLC	Any other impurity: <= 0.5 % decomposed to AD1	ND
- Related Substances by TLC	Total of all impurities: <= 2.5 % decomposed to AD1	ND
- pH	5.0 - 6.0	5.5
- Extractable Volume	100.0 - 110.0 ml	Complies
- Visible particles	Practically free from particles	Complies
- Subvisible particles	Not more than 6000 particles >= 10 µm/injection vial	Complies
- Subvisible particles	Not more than 600 particles >= 25 µm/injection vial	Complies
- Assay by H.P.L.C.	AD1: 0.38 - 0.42 g/100 ml	0.41 g/100.0 ml
- Assay by H.P.L.C.	Dipyron and related subst. with which it is in chemical equilibrium: 47.5 - 52.5 g/100 ml	50.1 g/100.0 ml
- Assay by H.P.L.C.	Dipyron content (g/100ml): For information only	47.4 g/100.0 ml
- Assay by H.P.L.C.	4-Methylaminoantipyrine (%): For information only	5.5 %
- Assay by H.P.L.C.	4-Aminophenazone (%): For information only	ND
- Preservative by H.P.L.C.	Phenol: 0.47 - 0.53 g/100 ml	0.48 g/100.0 ml
- Sterility Test	Complies with current Ph. Eur.	Complies

**Comments:** (\*) Specific for climatic zones.

GMP tested

<p><b>Reviewed by Quality Control</b></p> <p>Antonio Fabra Lorente</p>  <p>Date: 21/05/2020</p>	<p><b>Approved by Qualified Person</b></p> <p>Luisa Reyes Alcalde</p>  <p>Date: 21/05/2020</p>
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