REIG JOFRE

LABORATORIO REIG JOFRÉ, S.A.

CERTIFICATE OF BATCH RELEASE

C/ Gran Capitán 10, Polígono industrial Fontsanta, Sant Joan Despí, 08970 Barcelona, Spain, Tel: +34 934 806 719 Fax: +34 934 806 721

Titular Laboratory	AMOMED				
Product	001721 LANDIOLOL 300mg V.LIO.AMO				
Prod. Order No.	L156924	**Quality Order No.**	OC125105		
Batch No.	1805	**Expiry date**	11/2021		
Manufacturing date:	16 Nov 2018	**Manufactured units**	5513 UN		
		Released units	5421 UN		
		Expected units	6160 UN	**Yield (*)**	88,00

Remarks:

Yield <95% due to filtration losses and vials rejected during visual inspection.
Batch and yield comply

Reig Jofré Group Quality Assurance System certifies that the Manufacturing and Control process for the above mentioned product has been carried out according to Procedures previously approved by the customer and complies with Good manufacturing Practices (GMP)

(*) Released units: finished product except samples.
Balance of Released units

QC Status: Complies

Final Batch Approval **Mercè Pujol** 20 Dec 2018

Qualified Person

The name, surname and position that are shown in the section for approval of this certificate have been included using an electronic signature with the company computer system. This electronic signature is equivalent to a handwritten signature, and the integrity and authorship of the same are guaranteed on this document.

LABORATORIO REIG JOFRÉ, S.A.

CERTIFICATE OF ANALYSIS

REIG JOFRE

Order No. OC125105

C/ Gran Capitán 10, Polígono industrial Fontsanta, Sant Joan Despí, 08970 Barcelona, Spain, Tel: +34 934 806 719 Fax: +34 934 806 721

Product No.	001721	LANDIOLOL 300mg V.LIO.AMO	
Quality Plan No.	001721 / 1	**Pharmaceutical form**	Powder for solution for injection
Batch No.	1805	**Expiry date**	11/2021
Prod. Order No.	L156924	**Manufacturing date**	16/11/2018

TESTS	SPECIFICATION LIMITS	RESULTS
Characteristics		
Appearance	White or almost white powder	Complies
Tests		
Appearance of solution		
Clarity and colour of reconstituted solution	Clear, free of visible particles and bubbles	Complies
Reconstitution time	Less than 120 sec	30 sec
Osmolality	42 - 63 mOsm/kg	57 mOsm/kg
pH	6.1 - 7.1	6.6
Water	NMT 2.0 %	0.7 %
Uniformity of dosage units		
Uniformity of dosage units (2,9,40) Mass variation A1	AV 10 ó 30<=L1 / 30; 0,75M < xi < 1,25M	Acceptable 0,37401
Identification		
HPLC: rt	Coincides with standard	Complies
HPLC: UV	Coincides with standard	Complies
Assay		
Assay (HPLC)	95.0 - 105.0 %	99.5 %

Continue on page 2

QC Status: Approved **Date:** 19/12/18 **Signature:** Josep Saperas

LABORATORIO REIG JOFRÉ, S.A.

CERTIFICATE OF ANALYSIS

REIG JOFRE

Order No. OC125105

C/ Gran Capitán 10, Polígono industrial Fontsanta, Sant Joan Despí, 08970 Barcelona, Spain, Tel: +34 934 806 719 Fax: +34 934 806 721

Product No.	001721	LANDIOLOL 300mg V.LIO.AMO	
Quality Plan No.	001721 / 1	**Pharmaceutical form**	Powder for solution for injection
Batch No.	1805	**Expiry date**	11/2021
Prod. Order No.	L156924	**Manufacturing date**	16/11/2018

TESTS	SPECIFICATION LIMITS	RESULTS
		Continued from page 1
Related compounds		
Impurity M-1	NMT 0.10 %	0.08 %
Impurity I-1	NMT 0.20 %	0.18 %
Impurity I-2	NMT 0.10 %	< 0.05 %
Impurity A	NMT 0.15 %	< 0.05 %
Impurity B	NMT 0.15 %	ND %
Impurity D	NMT 0.15 %	ND %
Impurity F	NMT 0.15 %	< 0.05 %
Greatest single unspecified	NMT 0.10 %	< 0.05 %
Total impurities	NMT 0.5 %	0.26 %
Tests		
Microbiological control		
Bacterial endotoxins	NMT 1.0 IU/mg	< 0.1 IU/mg
Sterility	Sterile	Complies
Particles		
Visible Particles	Practically free from particles	Complies

Continue on page 3

QC Status: Approved **Date:** 19/12/18 **Signature:** Josep Saperas

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Product No.	001721	LANDIOLOL 300mg V.LIO.AMO	
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Batch No.	1805	**Expiry date**	11/2021
Prod. Order No.	L156924	**Manufacturing date**	16/11/2018

TESTS	SPECIFICATION LIMITS	RESULTS
		Continued from page 2
Sub-visible Particles >=10 microns	NMT 6000 part/vial	200 part/vial
Sub-visible Particles >=25 microns	NMT 600 part/vial	7 part/vial
Primary Packaging		
Vial	Mould 50 ml vial	Complies
Stopper	Chlorobutyl stopper	Complies
Seal	Flip-off yellow capsule	Complies
Secondary Packaging		
Box	50 vials	Complies

QC Status: Approved **Date:** 19/12/18 **Signature:** Josep Saperas

CERTIFICADO DE PESADAS

ESPECIALIDAD: 001721 LANDIOLOL 300mg V.LIO.AMO

Nº OP: **L156924**

Nº picking: 111565

PRODUCTO PRECEDENTE: P00157-1801V (MICAFUNGIN 100mg V.LIO RJ)

LOTE: 1805 CADUCIDAD:11/2021

CANTIDAD: 6.160 CALCULO CADUCIDAD : 36M+PM

REGISTRO PESADA: 16/11/18

Nº Producto	Descripción	Cantidad	Ud. de medida	Lote RJ	Lote Proveedor	Riqueza Real	Cantidad pesada	Ud. de medida	Tara	Cantidad sobrante	Udad. de medida	Realizado por:
A10607	LANDIOLOL HIDROCLORURO SV	1.956,06354	G	097508	LT-DLDL/001/17-18	0,99690	1.956,00000	G	22,00000	0,00000	KG	1183
A01252	MANITOL D 60 Ph.Eur.	1.949,99974	G	099205	124	1,00000	1.950,00000	G	12,00000	0,00000	KG	1183
A01325	HIDROXIDO SODICO PRS LENTEJAS EP	4,00030	G	101049	18690901	1,00000	4,00000	G	2,53700	6,04400	KG	1183

RESPONSABLE PESADAS:

16/11/18