AOP Orphan Pharmaceuticals AG

A-1160 Vienna . Wilhelminenstraße 91/II f . Austria
T +43-1-503 72 44 . F +43-1-503 72 44-5 . office@aoporphan.com . www.aoporphan.com

AOP ORPHAN
FOCUS ON RARE DISEASES

BATCH CERTIFICATE for INVESTIGATIONAL MEDICINAL PRODUCTS

Name of product:	LDLL300 (AOP Landiolol Hydrochloride Lyophilisate)
Strength/potency:	300 mg
Dosage form:	Lyophilisate
Intended country	UK
Package size / type:	1 kit á 20 glass vials
Batch number:	0037 (Bulk batch 1805)
Packaging number	BPR No. 0079 (BPR 002)
Study number:	EudraCT 2017-001785-14 (EU DCP NL/H/3368/001/DC)
Retest date:	11/2021

Date of manufacture:	16 Nov 2018
Released quantity:	130 kits
API manufacturer:	Metha API PVT. LTD., Gut No. 546, Behind Plot No. N-211, Village- Kumbhavli, Taluka Palghar, Dist.: Thane, Maharashtra, India
API batch number:	LT-DLDL/001/17-18
Bulk manufacturer/ QC testing	Laboratorio Reig Jofré, S.A., C/Gran Capitán 10, Polígono Industrial Fontsanta, Sant Joan Depsí, 08970 Barcelona, Spain
(Manufacturing authorization No / Certificate(s) of cGMP Compliance):	039101 (1155E) / NCF/1801/001/CAT
Packaging	CSM Clinical Supplies Management Europe GmbH Am Kronberger Hang 3 65824 Schwalbach a. Ts., Germany
(Manufacturing authorization No / Certificate(s) of cGMP Compliance):	DE_HE_01_MIA_2016_0088 / DE_HE_01_GMP_2017_0034
Batch Release	AOP Orphan Pharmaceuticals AG
(Manufacturing authorization No / Certificate(s) of cGMP Compliance):	480933 / 480933-0014
Results of analytical analysis:	Specifications achieved according to Reig Jofre CoA 1804 from 19 Dec 2018 (release)
Packaging material:	Label: MLP 001 200649
	Carton: MLP 002 200650
Correct:	☑ yes ☐ no
Deviations:	☐ no ☑ yes, Report No.: AOP IN-19-037

All deviations that may influence the release of the batch have been reviewed and approved in accordance with an established deviation procedure.

AOP Orphan Pharmaceuticals AG

A-1160 Vienna . Wilhelminenstraße 91/II f . Austria
T +43-1-503 72 44 . F +43-1-503 72 44-5 . office@aoporphan.com . www.aoporphan.com

AOP ORPHAN
FOCUS ON RARE DISEASES

BATCH CERTIFICATE for INVESTIGATIONAL MEDICINAL PRODUCTS

Name of product:	LDLL300 (AOP Landiolol Hydrochloride Lyophilisate)
Strength/potency:	300 mg
Dosage form:	Lyophilisate
Intended country	UK
Package size / type:	1 kit á 20 glass vials
Batch number:	0037 (Bulk batch 1805)
Packaging number	BPR No. 0079 (BPR 002)
Study number:	EudraCT 2017-001785-14 (EU DCP NL/H/3368/001/DC)
Retest date:	11/2021

Comments:

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. I hereby certify that this batch complies with the requirements of Article 13.3 of Directive 2001/20/EC.

The batch is certified for the Clinical Trial

Batch certification: Dr. Klaus Hofstädter 02. MAI 2019

Qualified Person / Name / Date / Signature