

Feldgasse 19, A-4600 Wels

Tel. +43 7242 490-0

Fax +43 7242 490-17

e-mail: office@richter-pharma.at

www.richter-pharma.at

Firmenbuchnummer FN 128054 s

Landesgericht Wels

UID-Nr. ATU36881102, DVR 0056928



Certificate of Compliance

Name of the product:	Doxapram-V
Importing Country:	Germany
Marketing Authorization Number:	5737.00.00
Strength/Potency:	20mg/ml
Dosage form:	Solution for injection
Package size:	10 ml
Quantity:	2090 pc.
Batch Number:	1216836AA
Date of manufacture:	07.12.2016
Expiry Date:	05.12.2018
Manufacturing site:	Richter Pharma AG, Durisolstrasse 14, 4600 Wels
Manufacturing authorisation no.:	481035

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(s) 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 were reviewed and found to be in compliance with GMP.

Date: 16. MRZ. 2017

Name and position of the person authorizing the batch release:



Dr. Dietmar Payrhuber
Qualified person
Richter Pharma AG
Wels (Austria)

Adresse / address:
Albrecht GmbH
Hauptstraße 6-9
D-88326 AULENDORF

Richter Pharma AG
Feldgasse 19
A-4600 Wels

Analysenzertifikat / Certificate of analysis

Produkt / Product: **Doxapram-V 10ml**
Chargennr. / batch no.: **1216836AA** Herstellungsdatum / manufacturing date: **07.12.2016**
Menge / Quantity: **2090** Ablaufdatum / expiry date: **05.12.2018**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
Aussehen der Lösung:	klar, farblos	complies
Füllvolumen:	min. 10ml	10.5ml
ph-Wert der Lösung:	3,5 - 5,0	4.7
Gehalt Doxapram-HCl:	19,0 - 21,0mg/ml	20.7 mg/ml
Gehalt Chlorobutanol:	4,50 - 5,75mg/ml	4.85 mg/ml
Sterilität:	steril	steril

Freigabedatum / date of release: 16.03.2017

Sachkundige Person / Qualified Person: Dr. Dietmar Payrhuber

