

Domitor 1mg/ml oldatos injekció  
 Gysz:1709022 Lej:18/12/31  
 Kisz:10ml Me.:darab  
 PRIM-A-VET GYŰGYSZ.KFT., részére

2151 Fót  
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DOMITOR 1MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

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Product Number: 133978  
 Batch Number: 1709022  
 Order Number: 40709600  
 Date of Manufacture: 28.12.2015  
 Date of Expiration: 12.2018  
 Storage: Room temp. +15...25°C  
 Specification: Hungary (108659) 04.04.2013

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL SITE
Average volume in container	100677-2	ml 10,0 ml	10,7 ml	Espono
Volume in container	100677-2	10,0 ml ± 1,0 ml	10,7 ml	Espono
Clarity of solution	100493-2	clear	clear	Espono
Colour of solution	100494-2	colourless	colourless	Espono
Particulates, pres. of foreign partic.	100473-2	practically no particles	practically no particles	Espono
pH	100432-2	4,5 - 6,0	4,8	Espono
Ident. medetomidine HCl, HPLC	101539-3	positive	positive	Espono
Assay, medetomidine HCl, %	101539-3	99,0 % - 105,0 %	101,0 %	Espono
Related substances, total	101539-3	max 0,5 %	< 0,1 %	Espono
Ident., methyl parahydroxybenzoate, HPLC	101539-3	positive	positive	Espono
Ident., propyl parahydroxybenzoate, HPLC	101539-3	positive	positive	Espono
Assay, methyl parahydroxybenzoate, %	101539-3	90,0 % - 110,0 %	101,1 %	Espono
Assay, propyl parahydroxybenzoate, %	101539-3	90,0 % - 110,0 %	97,8 %	Espono
Test for sterility	113205-1	sterile	sterile	Espono
Bacterial endotox.	100589-2	nmf 10 IU/ml	nmf 10 IU/ml	Espono

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PHOENIX Pharma Zrt.  
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 2151 Fót, Keleti M. u. 19.  
 Csak a piros szín hiteles!  
 20-03



# CERTIFICATE OF ANALYSIS

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**DOMITOR 1MG/ML VET INU 10ML HUEN**

Product Number: 133978  
 Batch Number: 1709022  
 Order Number: 60703500

TESTS	METHOD	REQUIREMENTS	RESULTS	QALTY CTRL SITE
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The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 08.04.2016 15:11:29 by a Qualified Person Kari Sakonen

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**PHOENIX Pharma Zrt.**  
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BATCH CERTIFICATE

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DOMITOR 1MG/ML VET INJ FORML HUEN

Product Number: 133978  
Batch Number: 1708022  
Order Number: 80703800

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 08.04.2016 15:11:23 by a Qualified Person Kari Salonen

Orion Corporation

Manufacturing licence number 02287 (valid to 08/04/2017)

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BATCH CERTIFICATE

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**DONITOR 1MG/ML VET INJ 10ML HUEN**

Product Number: 133978  
Batch Number: 1709022  
Order Number: 80703600

Date of Manufacture: 28.12.2015  
Date of Expiration: 12.2018

Quantity: 900 PCE

Marketing authorization number:

UPH-322-0573-01887  
NIPV/09933001, VANNP/02/1453  
LT/20/2/1416001, 33487/13  
022-1918-04.01.2013, 140012  
323-01-00025-14.001, 1455

Manufacturing site:

GMP Compliance of Manufact. site:

Orion Corporation, Espoo plant  
Olkantie 1 FI-02200 ESPPO  
12212.01.01/2014

Quality control site:

GMP Compliance of Quality Ctrl site: 12212.01.01/2014

Packaging site:

GMP Compliance of Packaging site: 12212.01.01/2014

Orion Corporation, Espoo plant  
Olkantie 1 FI-02200 ESPPO

Orion Corporation

Manufacturing site number: 00121106 00 004201

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