

DOMITOR 1MG/ML INJEKCIÓ 10 ML

Gysz: 2006578

Kisz: 10ML

SZÉKELY KFT részére

Lej: 2023-01-30

Me: Doboz

Szállító:

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

Tel: +36-1-414-6476

e-mail: qa@mpx.hu

Page: 1(4)

CERTIFICATE OF ANALYSIS



DOMITOR 1MG/ML VET INJ 10ML HUEN

Product Number: 133978  
 Batch Number: 2006578  
 Order Number: 81020610

Date of Manufacture: 30.01.2020  
 Date of Expiration: 01.2023  
 Storage: +15..25 °C  
 Specification: Hungary (108653) 01.01.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Average volume in container	100677-2	nlt 10,0 ml	10,5 ml	Espoo
Volume in container	100677-2	10,0 ml - 11,0 ml	10,5 ml	Espoo
Clarity of solution	100493-2	clear	clear	Espoo
Colour of solution	100494-2	colourless	colourless	Espoo
Partic.matter, pres. of foreign partic.	100473-2	practically no particles	practically no particles	Espoo
pH	100432-2	4,5 - 6,0	4,9	Espoo
Ident., medetomidine HCl, HPLC	101539-3	positive	positive	Espoo
Assay, medetomidine HCl, %	101539-3	95,0 % - 105,0 %	101,0 %	Espoo
Related substances, total	101539-3	nmt 0,5 %	<0,1 %	Espoo
Ident., methyl parahydroxybenzoate, HPLC	101539-3	positive	positive	Espoo
Ident., propyl parahydroxybenzoate, HPLC	101539-3	positive	positive	Espoo
Assay, methyl parahydroxybenzoate, %	101539-3	90,0 % - 110,0 %	99,5 %	Espoo
Assay, propyl parahydroxybenzoate, %	101539-3	90,0 % - 110,0 %	99,0 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins.	120384-1	nmt 10 IU/ml	nmt 10 IU/ml	Espoo

Orion Corporation Manufacturing license number ETMEA/2019/00732

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Page: 2(4)

DOMITOR 1MG/ML VET INJ 10ML HUEN

Product Number: 133978  
Batch Number: 2006578  
Order Number: 81020610

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
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I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 05.06.2023 15:45:07 by a Qualified Person Hanna Strand

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Gysz: 2006578 Lej: 2023-01-30  
Kisz: 10ML Me: Doboz  
SZÉKELY KFT részére

Szállító:  
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Page: 3(4)

BATCH CERTIFICATE



DOMITOR 1MG/ML VET INJ 10ML HUEN

Product Number: 133978  
Batch Number: 2006578  
Order Number: 81020610  
Date of Manufacture: 30.01.2020  
Date of Expiration: 01.2023  
Quantity: 800 PCE  
Strength/Potency: 1 mg/ml  
Dosage form: Solution for injection  
Package size: 10 ml  
Package type: Vial  
Marketing authorization number: UP/1-322-05/13-01/857  
NP/V/0093/001, V/NRP/02/1453  
LT/2/02/1416/001, 3348/1/13  
022-1918-04.01.2013, 140012  
323-01-00025-14-001, 1453  
Manufacturing site: Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO  
GMP Compliance of Manufact. site: 003953/06.08.02.00/2017  
Quality control site: Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO  
GMP Compliance of Quality Ctrl site: 003953/06.08.02.00/2017  
Packaging site: Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO  
GMP Compliance of Packaging site: 003953/06.08.02.00/2017

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