

DOMOSEDAN INJEKCIÓ 5ML

Gysz: 2010469

Kisz: 5ML

SZÉKELY KFT részére

Lej: 2022-03-08

Me: Doboz

Szállító:

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

Tel: +36-1-414-6476

e-mail: qa@mpx.hu



CERTIFICATE OF ANALYSIS

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DOMOSEDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133975  
Batch Number: 2010469  
Order Number: 81030245  
Date of Manufacture: 08.03.2019  
Date of Expiration: 03.2022  
Storage: +15...25 °C  
Specification: Hungary (106880) 01.01.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Volume in cont.	100477-2	5,00 ml - 5,75 ml	5,20 ml	Esboo
Clarity of solution	100493-2	clear	clear	Esboo
Colour of solution	100494-2	colourless	colourless	Esboo
Partic.matter. pres. of foreign partic.	100473-2	practically no particles	practically no particles	Esboo
pH	100432-2	4,0 - 5,5	4,3	Esboo
Ident., detomidine HCl, HPLC	100642-4	positive	positive	Esboo
Assay, detomidine HCl, %	100642-4	95,0 % - 105,0 %	100,7 %	Esboo
Ident., methyl parahydroxybenzoate, HPLC	100642-4	positive	positive	Esboo
Assay, methyl parahydroxybenzoate, %	100642-4	90,0 % - 110,0 %	98,3 %	Esboo
Related substances	100642-4	nmt 1 %	nmt 1 %	Esboo
Test for sterility	113705-1	sterile	sterile	Esboo
Bacterial endotoxins	120386-1	nmt 25 EU/ml	nmt 25 EU/ml	Esboo

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 29.06.2020 10:45:16 by a Qualified Person Hanna Strand

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Trade Commission: Registered office: and business: Úrkút u. 11-12/105 Úrkút, Hungary

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BATCH CERTIFICATE

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DOMOSDAN 10MG/ML VET INJ 5ML HUEN

**Product Number:** 133975  
**Batch Number:** 2010469  
**Order Number:** 81030245

**Date of Manufacture:** 08.03.2019  
**Date of Expiration:** 03.2022

**Quantity:** 850 PCE  
**Strength/Potency:** 10 mg/ml  
**Dosage form:** Solution for injection  
**Package size:** 5 ml  
**Package type:** Vial

**Marketing authorization number:** UPN-322-05/13-01/855  
180156, NPV/0094/001  
2079/106  
0022-1919-04.01.2013  
323-01-00024-14-001

**Manufacturing site:** Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO  
**GMP Compliance of Manufact. site:** 00395306.08.02.00/2017

**Quality control site:** Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO  
**GMP Compliance of Quality Ctrl site:** 00395306.08.02.00/2017

**Packaging site:** Orion Corporation, Espoo plant  
Oriontie 1 FI-02200 ESPOO  
**GMP Compliance of Packaging site:** 00395306.08.02.00/2017

Orion Corporation

Orion Corporation, Espoo plant, Oriontie 1, FI-02200 ESPOO

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Tel: +36-1-414 6476

Orion Corporation, Rákospalotaihatárút 2, 1158 Budapest, Hungary

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