

## CERTIFICATE OF ANALYSIS



DOMOSÉDAN 10 MG/ML VET INJ 20 ML HU EN

Meoszám: 190700045MBT

Product Number: 140700  
 Batch Number: 1903168  
 Order Number: 80948800

Date of Manufacture: 2012.2018  
 Date of Expiration: 12.2021  
 Storage: +15..25 °C  
 Specification: Hungary (108661) 01.01.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
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Volume in container	100477-2	20.0 ml - 22.0 ml	21.0 ml	Espp0
Clarity of solution	100493-2	clear	clear	Espp0
Colour of solution	100494-2	colourless	colourless	Espp0
Particulate matter, pres. of foreign partic.	100473-2	practically no particles	practically no particles	Espp0
pH	100432-2	4.0 - 5.5	4.3	Espp0
Ident., detomidine HCl, HPCL	100642-4	positive	positive	Espp0
Assay, detomidine HCl, %	100642-4	95.0 % - 105.0 %	100.6 %	Espp0
Ident., methyl parahydroxybenzoate, HPCL	100642-4	positive	positive	Espp0
Assay, methyl parahydroxybenzoate, %	100642-4	90.0 % - 110.0 %	101.6 %	Espp0
Related substances	100642-4	nmt 1 %	<0 %	Espp0
Test for sterility	113205-1	sterile	sterile	Espp0
Bacterial endotoxins	120395-1	nmt 25 EU/ml	nmt 25 EU/ml	Espp0

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 11.06.2019 12:41:54 by a Qualified Person Mirna Jaakkola

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 Minőségbiztonsági és Részegszerszármazékok oszt. vezetője: Dr. Kovács Zoltán  
 Csak a piros színi hiteles

8. pld., Kiadva: 20/03/25

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DOMOSDAN INJEKCIÓ 20ML  
Gysz: 1903168  
Kisz: 20ML  
Lej: 21/12/20  
Me.: DoboZ  
SZÉKELY KFT részére



### BATCH CERTIFICATE

DOMOSDAN 10 MG/ML VET INJ 20 ML HU EN

Product Number: 140700  
Batch Number: 1903168  
Order Number: 80848800

Date of Manufacture: 20.12.2018  
Date of Expiration: 12.2021

Quantity: 800 PCE

Marketing authorization number: UPI-322-05/13-01/855  
NPV/0094/001, 2079/106  
LT/2021/418/002  
V/NRP/02/1451  
0022-1919-04.01.2013

Manufacturing site: Orion Corporation, Espoo plant  
Oriintitie 1 FI-02200 ESPOO  
GMP Compliance of Manufact. site: 003953/06.08.02.00/2017

Quality control site: Orion Corporation, Espoo plant  
Oriintitie 1 FI-02200 ESPOO  
GMP Compliance of Quality Ctrl site: 003953/06.08.02.00/2017

Packaging site: Orion Corporation, Espoo plant  
Oriintitie 1 FI-02200 ESPOO  
GMP Compliance of Packaging site: 003953/06.08.02.00/2017

Manufacturing license number: 000356/06.08.00.04/2018

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BATCH CERTIFICATE

DOMOSEBAN 10 MG/ML VET INJ 20 ML HU EN

Product Number: 140700  
Batch Number: 1903168  
Order Number: 80948900

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 11.06.2019 12:41:54 by a Qualified Person Mirna Jaakkola

MEDIMPEX GYÓGYSZER ZRT.  
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Orion Corporation Manufacturing license number 06335806.08.00.04.2018

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