



DOMOSÉDAN 10 MG/ML VET INJ 20 ML HU EN

CERTIFICATE OF ANALYSIS

Product Number: 140700
Batch Number: 2010284
Order Number: 81023074

Date of Manufacture: 23.04.2020
Date of Expiration: 04.2023
Storage: +15..25 °C
Specification: Hungary (108661) 15.10.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QALTY CTRL SITE
Volume in container	100477-2	20,0 ml - 22,0 ml	21,0 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	4,0 - 5,5	4,2	Espoo
Ident., detomidine HCl, HPLC	100642-4	positive	positive	Espoo
Assay, detomidine HCl, %	100642-4	95,0 % - 105,0 %	101,4 %	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100642-4	positive	positive	Espoo
Assay, methyl parahydroxybenzoate, %	100642-4	90,0 % - 110,0 %	102,1 %	Espoo
Related subst.	100642-4	nmt 1,0 %	<0,1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins	120386-1	nmt 25 EU/ml	nmt 25 EU/ml	Espoo

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 02.07.2020 09:42:19 by a Qualified Person Hanna Strand

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 ORION FÁRMA
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Manufacturing license number: TMLFA2019/000712

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DOMOSÉDAN INJEKCIÓ 20ML
Gysz: 2010284
Kisz: 20ML
SZÉKELY KFT részére
Lej: 23/04/23
Me.: Doboz

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp. Rákospalotai határút 2.
Nagyvárosi út 12.
Művelődési központ
Mindösszebiztosító szakasszisztens
Csak a piros színű hiteles



BATCH CERTIFICATE

DOMOSÉDAN 10 MG/ML VET INJ 20 ML HU EN

Meoszá: 20080001MBT

Product Number: 140700
Batch Number: 2010284
Order Number: 81023074

Date of Manufacture: 23.04.2020
Date of Expiration: 04.2023

Quantity: 480 PCE
Strength/Potency: 10 mg/ml
Dosage form: Solution for Injection
Package size: 20 ml
Package type: Vial

Marketing authorization number: UP/1-322-05/13-01/855
NPN/00984/001, 2079/1/06
L17/2/02/1418/002
V/NRP/02/1451
0022-1919-04.01.2013

Manufacturing site: Orion Corporation, Espoo plant

GMP Compliance of Manufact. site: Orioninte 1 FI-02200 ESPPO
003953/06.08.02.00/2017

Quality control site: Orion Corporation, Espoo plant

GMP Compliance of Quality Ctrl site: Orioninte 1 FI-02200 ESPPO
003953/06.08.02.00/2017

Packaging site: Orion Corporation, Espoo plant

GMP Compliance of Packaging site: Orioninte 1 FI-02200 ESPPO
003953/06.08.02.00/2017

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Nagyvív Kan Eya
Minőségirítési szakasszisztens
Csak a piros szín hiteles

5. pld., Kiadva: 20/10/14

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Kisz: 20ML
Lej: 23/04/23
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