

CERTIFICATE OF ANALYSIS



DOMOSÉDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133975
 Batch Number: 1839546
 Order Number: 80872474
 Date of Manufacture: 06.08.2017
 Date of Expiration: 06.2020
 Storage: +15...25 °C
 Specification: Hungary (108660) 16.01.2017

| TESTS | METHOD | REQUIREMENTS | RESULTS | Q.LTY CTRL SITE |
|--|----------|--------------------------|--------------------------|-----------------|
| Volume in cont. | 100477-2 | 5,00 ml - 5,75 ml | 5,20 ml | Esppoo |
| Clarity of solution | 100483-2 | clear | clear | Esppoo |
| Colour of solution | 100494-2 | colourless | colourless | Esppoo |
| Partic. matter, pres. of foreign partic. | 100473-2 | practically no particles | practically no particles | Esppoo |
| pH | 100432-2 | 4,0 - 5,5 | 4,3 | Esppoo |
| Ident., detomidine HCl, HPLC | 100642-4 | positive | positive | Esppoo |
| Assay, detomidine HCl, % | 100642-4 | 95,0 % - 105,0 % | 101,0 % | Esppoo |
| Ident., methyl parahydroxybenzoate, HPLC | 100642-4 | positive | positive | Esppoo |
| Assay, methyl parahydroxybenzoate, % | 100642-4 | 90,0 % - 110,0 % | 99,7 % | Esppoo |
| Related substances | 100642-4 | nmt 1 % | nmt 1 % | Esppoo |
| Test for sterility | 113205-1 | sterile | sterile | Esppoo |
| Bacterial endotoxins | 100670-2 | nmt 25 EU/ml | nmt 25 EU/ml | Esppoo |

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 28.05.2018 16:19:54 by a Qualified Person Katri Salonen

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Manufacturing license number: 0161/MSC.06.04.02018

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DOMOSÉDAN INJEKCIÓ AUV
 Gysz:1839546
 Lej:20/09/30
 Me.:darab
 ZRT. részére

MEDIMPEX GYÓGYSZER ZRT.
 1158 Bp., Rákospalotai határút 2.
 Nagy Miklós utca 5-7.
 Minőségbiztosító szakasszisztens
 Csak a piros szín hiteles

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PROBÁRAK
2017
Cseppentő
2161 Főút
1158 Budapest

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BATCH CERTIFICATE



DOMOSDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133875
Batch Number: 1839546
Order Number: 80872474

Date of Manufacture: 06.06.2017
Date of Expiration: 09.2020

Quantity: 730 PCE

Marketing authorization number: UPI-322-05/13-01/855
140013, NPV/0084/001, 1454
2078/1/08, LT/2/02/1418/001
V/NRP/02/1451
0022-1918-04-01.2013, 323-01-00026-14-001

Manufacturing site: Orion Corporation, Espoo plant
Orionitie 1 FI-02200 ESPOO
GMP Compliance of Manufact. site: 005703/08.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant
Orionitie 1 FI-02200 ESPOO
GMP Compliance of Quality Ctrl site: 005703/08.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant
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GMP Compliance of Packaging site: 005703/08.08.02.00/2015

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Manufacturing license number: 001616/05.05.00/04/2018

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let

DOMOSÉDAN INJEKCIÓ 5ML
Gysz:1839546 Lej:20/09/30
Kisz:5ML Me.:Doboz
SZÉKELY KFT részére

Medimpex Gy. Zrt.
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20-02
MINDEN NAP
1981.03.19
17.03.21

Meoszáma:180700237/07/T 5.pld. Kiadva: 19/03/29

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BATCH CERTIFICATE



DOMOSÉDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133975
Batch Number: 16395-46
Order Number: 80872474

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 28.05.2018 16:19:54 by a Qualified Person Katri Salonen

Orion Corporation Manufacturing license number:016160006/01602916

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|---|---|---|--|
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|---|---|---|--|

Orion Corporation. Registered office and main office: Oskarikatie 1, FI-02301 Espoo, Finland.

Meoszáma:190400037MBT

1.pld. Kiadva: 19/04/11

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Nagy Minőség Biz.:
Minőségbiztosító szakasszisztens
Csak a piros szín hiteles

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