

2151 Fót
Keleti Márton u. 19.
Tel: 27/537-100
Fax: 27/537-100



DOMOSEDAN 10MG/ML VET INJ 5ML HUEN

CERTIFICATE OF ANALYSIS

Page: 1(3)

Product Number: 133975
Batch Number: 1808692
Order Number: 80827996
Date of Manufacture: 06.09.2017
Date of Expiration: 09.2020
Storage: +15..25 °C
Specification: Hungary (108660) 16.01.2017

TESTS

VOLUME IN CONT.	METHOD	REQUIREMENTS	RESULTS	Q.L.T.Y CTRL SITE
Clarity of solution	100477-2	5,00 ml - 5,75 ml	5,20 ml	Espoo
Colour of solution	100493-2	clear	clear	Espoo
Partic.matter, pres. of foreign partic.	100494-2	colourless	colourless	Espoo
pH	100473-2	practically no particles	practically no particles	Espoo
Ident., delonidine HCl: HPLC	100432-2	4,0 - 5,5	4,3	Espoo
Assay, delonidine HCl, %	100642-4	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100642-4	95,0 % - 105,0 %	101,0 %	Espoo
Assay, methyl parahydroxybenzoate, HPLC	100642-4	positive	positive	Espoo
Related substances	100642-4	90,0 % - 110,0 %	99,7 %	Espoo
Test for sterility	100642-4	nmt 1 %	nmt 1 %	Espoo
Bacterial endotoxins	113205-1	sterile	sterile	Espoo
	100670-2	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 of the EU and (when within the EU) with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 24.11.2017 16:17:09 by a Qualified Person Katri Salonen

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 ORION FTYKRYMA
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 P.O.Box 63, 02101 ESPOO
 Tel. +358 10 4261
 Fax +358 10 426 3813
 Manufacturing license number 005354/06 08.00.04/2017
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 Tel. +358 10 4261

Domosedan injekció AUV
 Gysz:1806652 Lej:20/09/30
 Kisz:5ml Me.:darab
 DR. SZÉKELY KFT. részére

PHOENIX Pharma Zrt.
 Fóti telephely
 2151 Fót, Keleti M. u. 19.
 Csak a piros szín hiteles!
 20-03



DOMOSSEDAN 10MG/ML VET INJ 5ML HUEN

BATCH CERTIFICATE

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Product Number: 133975
Batch Number: 1808652
Order Number: 80827996
Date of Manufacture: 06.09.2017
Date of Expiration: 09.2020
Quantity: 1050 PCE

Marketing authorization number:
UPH-322-05/13-01/855
140013, NPV/0094/001, 1454
2079/1/06, LT/2/02/1418/001
VN/RP/02/1451
0022-1919-04.01.2013, 323-01-00026-14-001

Manufacturing site:
Orion Corporation, Espoo plant
Orioninte 1 FI-02200 ESPOO
005703/06.08.02.00/2015
Quality control site:
Orion Corporation, Espoo plant
Orioninte 1 FI-02200 ESPOO
005703/06.08.02.00/2015
GMP Compliance of Quality Ctrl site:
Orion Corporation, Espoo plant
Orioninte 1 FI-02200 ESPOO
005703/06.08.02.00/2015
Packaging site:
Orion Corporation, Espoo plant
Orioninte 1 FI-02200 ESPOO
005703/06.08.02.00/2015
GMP Compliance of Packaging site:
Orion Corporation, Espoo plant
Orioninte 1 FI-02200 ESPOO
005703/06.08.02.00/2015

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20-03



DOMOSSEDAN 10MG/ML VET INJ 5ML HUEN

BATCH CERTIFICATE

Page: 3(3)

Product Number: 133975
Batch Number: 1806652
Order Number: 80827996

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Electronically approved 24.11.2017 16:17:09 by a Qualified Person Katri Salonen

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PHOENIX Pharma Zrt.

Fóti telephely
2151 Fót, Keleti M. u. 19.
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20-03

Min.biz.:

2.pld. Kijadva: 18/04/25

Meoszám: 171200152/07/T