



DOMOSSEDAN 10 MG/ML VET INJ 20 ML HU EN

CERTIFICATE OF ANALYSIS

Product Number: 140700
 Batch Number: 1804287
 Order Number: 80827996
 Date of Manufacture: 22.08.2017
 Date of Expiration: 08.2020
 Storage: +15..25 °C
 Specification: Hungary (108661) 19.12.2016

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY 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	4.3	Espoo
Ident., detomidine HCl, HPLC	100642-4	positive	positive	Espoo
Assay, detomidine HCl, %	100642-4	95.0 % - 105.0 %	100.5 %	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100642-4	positive	positive	Espoo
Assay, methyl parahydroxybenzoate, %	100642-4	90.0 % - 110.0 %	103.7 %	Espoo
Related substances	100642-4	nmt 1 %	<1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins	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 17.11.2017 15:20:32 by a Qualified Person Kaija Salonen

Orion Corporation
 Manufacturing license number 00554406.08.00.04/2017

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 Csak a piros szín hiteles!
 20-03



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BATCH CERTIFICATE

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Product Number: 140700
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Date of Manufacture: 22.08.2017
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Quantity: 105 PCE

Marketing authorization number: UP/I-322-05/13-01/855
NP/V/0094/001, 2079/1/06
LT/2/02/1418/002
V/NRP/02/1451
0022-1919-04.01.2013

Manufacturing site: Orion Corporation, Espoo plant
Orioninte 1 FI-02200 ESPOO
GMP Compliance of Manufact. site: 005703/06.08.02.00/2015

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

Packaging site: Orion Corporation, Espoo plant
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GMP Compliance of Packaging site: 005703/06.08.02.00/2015

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