



CERTIFICATE OF ANALYSIS

DOMITOR 1MG/ML VET INJ 10ML HUEN

Product Number: 133978
 Batch Number: 1812436
 Order Number: 80839728
 Date of Manufacture: 20.09.2017
 Date of Expiration: 09.2020
 Storage: +15..25 °C
 Specification: Hungary (108653) 04.07.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CONTROL SITE
Average volume in container	100677-2	nlt 10,0 ml	10,5 ml	Espoo
Volume in container	100677-2	10,0 ml - 11,0 ml	10,5 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	4,5 - 6,0	4,9	Espoo
Ident., medetomidine HCl HPLC	101539-3	positive	positive	Espoo
Assay, medetomidine HCl, %	101539-3	95,0 % - 105,0 %	100,8 %	Espoo
Related substances, total	101539-3	nmt 0,5 %	<0,1 %	Espoo
Ident., methyl parahydroxybenzoate, HPLC	101539-3	positive	positive	Espoo
Ident., propyl parahydroxybenzoate, HPLC	101539-3	positive	positive	Espoo
Assay, methyl parahydroxybenzoate, %	101539-3	90,0 % - 110,0 %	99,7 %	Espoo
Assay, propyl parahydroxybenzoate, %	101539-3	90,0 % - 110,0 %	98,4 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotox	100589-2	nmt 10 IU/ml	nmt 10 IU/ml	Espoo

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 sz. másolati példány
 Csak a piros szín hiteles!
 20-03



CERTIFICATE OF ANALYSIS

Page: 2/4

DOMITOR 1MG/ML VET INJ 10ML HUEN

Product Number: 133978
Batch Number: 1812436
Order Number: 80839728

TESTS	METHOD	REQUIREMENTS	RESULTS	QATY CTRL SITE
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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 20.12.2017 16:06:38 by a Qualified Person Kalin Salonen

Manufacturing licence number: 2843/001/2017

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BATCH CERTIFICATE

Page: 3/41

DOMITOR 1MG/ML VET INJ 10ML HUEN

Product Number: 133978
Batch Number: 1812436
Order Number: 80839728

Date of Manufacture: 20 09 2017
Date of Expiration: 09 2020

Quantity: 1580 PCE

Marketing authorization number: UPI/322-05/13-01/857
NP/V/0093/001, V/NRP/02/1453
LT/2/02/1416/001, 3348/1/3
022-1918-04 01 2013, 140012
323-01-00025-14-001, 1453

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

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

Packaging site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO
GMP Compliance of Packaging site: 005703/06.08.02.00/2015

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Page: 4(4)

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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.

Electrically approved 20.12.2017 16:06:38 by a Qualified Person Kati Salonen

Orion Corporation Manufacturing license number: 093551 (06/09/04-2017)

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M20-05 Biz.: 20-05