



DEXDOMITOR 0.5MG/ML VET INJ X10ML BGHURO

CERTIFICATE OF ANALYSIS

Page: 1(3)

Product Number: 134010
Batch Number: 17R3098
Order Number: 80794426

Date of Manufacture: 11.05.2017
Date of Expiration: 04.2020
Storage: Room Temp. +15..25°C
Specification: Hungary (108609) 03.05.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
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Clarity of solution	100182-2	clear	clear	Espp0
Colour of solution	100182-2	colourless	colourless	Espp0
Partic. matter, presence of visible partic.	100178-2	practically no particles	practically no particles	Espp0
Volume in container	100179-2	10.0 ml - 11.0 ml	10.6 ml	Espp0
pH	100177-2	4.0 - 6.0	5.0	Espp0
Ident., dexametomidine, HPLC	100173-2	positive	positive	Espp0
Ident., dexmedetomidine, UV	100175-3	positive	positive	Espp0
Assay, dexmedetomidine HCl, %	100172-3	95.0 % - 105.0 %	100.7 %	Espp0
Ident., methyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Espp0
Ident., methyl parahydroxybenzoate, UV	100175-3	positive	positive	Espp0
Assay, methyl parahydroxybenzoate %	100175-3	95 % - 105 %	100 %	Espp0
Ident., propyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Espp0
Ident., propyl parahydroxybenzoate, UV	100175-3	positive	positive	Espp0
Assay, propyl parahydroxybenzoate %	100175-3	95 % - 105 %	100 %	Espp0
Optical purity, levomevetomidine	100173-2	nm 1.0 %	<0.5 %	Espp0
Partic. matter, 10 µm or larger in cont.	133289-2	nm 6000	3	Espp0
Partic. matter, 25 µm or larger in cont.	133205-1	sterile	sterile	Espp0
Test for sterility	100590-2	nm 10 EU/ml	nm 10 EU/ml	Espp0
Bacterial endotoxins				

ORION PHARMA
 1410 Budapest, Főtelephely
 1410 Budapest, Keleti Művelődési Központ utca 19
 1410 Budapest, Főtelephely
 1410 Budapest, Keleti Művelődési Központ utca 19
 1410 Budapest, Főtelephely
 1410 Budapest, Keleti Művelődési Központ utca 19

PHOENIX Pharma Zrt.
 Főti Telephely
 2151 Főti, Keleti Művelődési Központ utca 19
 sz. másolatú példány
 Csak a piros szín hiteles!
 20-03



CERTIFICATE OF ANALYSIS

Page: 2/3

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BQHJRO

Product Number: 134010
Batch Number: 1783098
Order Number: 80704426

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
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The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person

Electronically approved 15.06.2017 14:20:58 by a Qualified Person Karin Salonen

Orion Corporation
02407 PIIANKKA
020700001
P.O. Box 61, 02101 Espoo
Tel: +358 (0)9 42500
Fax: +358 (0)9 4251815
Standard telephone number: 00358102030901010
Lähetyspaikka: 020700001
P.O. Box 61, 02101 Espoo
Tel: +358 (0)9 42500
Fax: +358 (0)9 4250777
Järjestelmä: 1: 210155016
Id: 31304391
Orion Corporation, Reg. no. 141974, Oronumitie 1, P.O. 02101 Espoo, Finland

PHOENIX Pharma Zrt.
Főút Telephely
2151 Fót, Keleti Márton út 19.
..... sz. másolati példány
Csak a piros szín hiteles!
20-03



BATCH CERTIFICATE

Product Number: 134010
Batch Number: 1783098
Order Number: 80794426
Date of Manufacture: 11.05.2017
Date of Expiration: 04.2020
Quantity: 1890 PCE
Marketing authorization number: EU/202033001
Manufacturing site: Orion Corporation, Espoo plant
Oriontie 1 FI-02200 ESPOO
GMP Compliance of Manufact. site: 80384206-08-02-002015
Quality control site: Orion Corporation, Espoo plant
Oriontie 1 FI-02200 ESPOO
GMP Compliance of Quality Ctrl site: 80384206-08-02-002015
Packaging site: Orion Corporation, Espoo plant
Oriontie 1 FI-02200 ESPOO
GMP Compliance of Packaging site: 00364206-08-02-002015

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 15.06.2017 14:20:56 by a Qualified Person Kari Salonen

Orion Corporation

Manufacturing Release Number: 003706-01-00-000794

ORIONTIE 1
Espoo FI-02200 ESPOO
P.O. Box 429 00010 TERVOLA
Tel: +358 10 426 1201
Fax: +358 10 426 3815

Teollisuuskatu 8, 00100 TUUSULA
P.O. Box 429 00010 TERVOLA
Tel: +358 10 426 1201
Fax: +358 10 426 3777

Vuolteenkatu 2, 00100 TUUSULA
P.O. Box 429 00010 TERVOLA
Tel: +358 10 426 601
Fax: +358 10 426 8211

Manufacturing Release Number: 003706-01-00-000794

Orion Corporation Registration/Registrazione Oriontie 1, FI-02200 Espoo, Finland