

CERTIFICATE OF ANALYSIS



DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010  
 Batch Number: 1927691  
 Order Number: 80980755  
 Date of Manufacture: 10.05.2019  
 Date of Expiration: 04.2022  
 Storage: +15...25 °C  
 Specification: Hungary (108598) 01.01.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QlTY CTRL SITE
Clarity of solution	100182-2	clear	clear	Espoo
Colour of solution	100182-2	colourless	colourless	Espoo
Partic.matter, presence of visib.panic.	100178-2	practically no particles	practically no particles	Espoo
Volume in container	100179-2	10.0 ml - 11.0 ml	10.5 ml	Espoo
pH	100177-2	4.0 - 6.0	5.0	Espoo
Ident., dexmedetomidine, HPLC	100173-2	positive	positive	Espoo
Ident., dexmedetomidine, UV	100175-3	positive	positive	Espoo
Assay, dexmedetomidine HCl, %	100175-3	95.0 % - 105.0 %	101.3 %	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, UV	100175-3	positive	positive	Espoo
Assay, methyl parahydroxybenzoate %	100175-3	95 % - 105 %	100 %	Espoo
Ident., propyl parahydroxybenzoate, UV	100175-3	positive	positive	Espoo
Ident., propyl parahydroxybenzoate, HPLC	100173-2	positive	positive	Espoo
Assay, propyl parahydroxybenzoate %	100175-3	95 % - 105 %	100 %	Espoo
Optical purity, levomedetomidine	100173-2	nmt 1.0 %	17	Espoo
Partic.matter, 10 µm or larger in cont.	113289-2	nmt 6000	0	Espoo
Partic.matter, 25 µm or larger in cont.	113289-2	nmt 600	sterile	Espoo
Test for sterility	113205-1	sterile	nmt 10 EU/ml	Espoo
Bacterial endotoxins.	116697-1	nmt 10 EU/ml		Espoo

Orion Corporation  
 Manufacturing license number 004833-06, 08, 06, 04, 02, 01, 19

ORION-FARMA  
 Olemusentie 1, 02200 ESPOO  
 P.O.Box 65, 02101 ESPOO  
 Tel. +358 10 4261  
 Fax +358 10 426 3813

Terveystiete 8, 20160 TURKU  
 P.O.Box 42, 20101 TURKU  
 Tel. +358 10 426 61  
 Fax +358 10 426 7777

Väljelmä 8, 20700 KUOPIO  
 P.O.Box 178, 20701 KUOPIO  
 Tel. +358 10 428 611  
 Fax +358 10 428 6444

Joukkotie 7, 24100 SALO  
 Tel. +358 10 426 1

Orion Corporation. Registered office and domicile: Chemiutus 1, FI-02200 Espoo, Finland

CERTIFICATE OF ANALYSIS



DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010  
Batch Number: 1927691  
Order Number: 809680755

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
-------	--------	--------------	---------	----------------

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 18.11.2019 14:28:29 by a Qualified Person Marko Kuosmanen

Manufacturing license number: 00483106.08.00.04/2019

Orion Corporation  
ORION PHARMA  
Oriontie 1, 02200 ESPOO  
P.O.Box 65, 02101 ESPOO  
Tel: +358 10 426 111  
Fax: +358 10 426 3815

Jenőpálinka 8, 20360 TURKTI  
P.O.Box 42, 20101 TURKTI  
Tel: +358 10 426 692  
Fax: +358 10 426 777

Vollkorn 8, 70700 KUMRIG  
P.O.Box 1780, 70201 KUMRIG  
Tel: +358 10 428 611  
Fax: +358 10 428 644

Joennumlahi 7, 24100 SALO  
Tel: +358 10 426 1

Orion Corporation, Registered office and domicile: Oriontie 1, FI-02200 Espoo, Finland



BATCH CERTIFICATE



DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010  
Batch Number: 1927691  
Order Number: 80980755

Date of Manufacture: 10.05.2019  
Date of Expiration: 04.2022

Quantity: 800 PCE

Marketing authorization number: EU/2/02/033/001

Manufacturing site: Orion Corporation, Espoo plant  
Orionintie 1 FI-02200 ESPOO

GMP Compliance of Manufact. site: 003953/06.08.02.00/2017

Quality control site: Orion Corporation, Espoo plant  
Orionintie 1 FI-02200 ESPOO

GMP Compliance of Quality Ctrl site: 003953/06.08.02.00/2017

Packaging site: Orion Corporation, Espoo plant  
Orionintie 1 FI-02200 ESPOO

GMP Compliance of Packaging site: 003953/06.08.02.00/2017

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 18.11.2019 14:28:29 by a Qualified Person Marko Kuosmanen

Orion Corporation Manufacturing license number 004815/06.08.00.04/2019

ORION FARMACEUTICALS  
P.O. Box 61 02101 ESPOO  
Tel: +358 10 426 611  
Fax: +358 10 426 3815

Tasavälikatu 8, 20160 TURKU  
P.O. Box 425 20101 TURKU  
Tel: +358 10 426 611  
Fax: +358 10 426 7777

Näätäntie 8, 02700 KUOPIO  
P.O. Box 790 02701 KUOPIO  
Tel: +358 10 428 611  
Fax: +358 10 428 6444

Jessunilantie 7, 21100 SALO  
Tel: +358 10 426 611

Orion Corporation. Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland