2151 Fót
Keleti Márton u. 19.
Tel:27/537-100
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Dexdomitor 0,5mg/ml injekciós oldat
Gysz:1672207 Lej:18/05/31
Kisz:10ml Me.:darab
DR. SZÉKELY KFT. részére

ORION

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010
Batch Number: 1672207
Order Number: 80859363

Date of Manufacture: 22.06.2015
Date of Expiration: 05.2018
Storage: Room temp. +15..25°C
Specification: Hungary(108598) 19.11.2014

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Clarity of solution	100182-2	clear	clear	Espoo
Colour of solution	100182-2	colourless	colourless	Espoo
Partic.meter, presence of visib.partic.	100178-2	practically no particles	practically no particles	Espoo
Volume in container	100179-2	10,0 ml - 11,0 ml	10,6 ml	Espoo
pH	100177-2	4,0 - 6,0	4,9	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 %	100,2 %	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 %	101 %	Espoo
Ident., propyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Espoo
Ident., propyl parahydroxybenzoate, UV	100175-3	positive	positive	Espoo
Assay, propyl parahydroxybenzoate %	100176-3	95 % - 105 %	96 %	Espoo
Optical purity, levomedetomidine	100173-2	nmt 1,0 %	< 0,5 %	Espoo
Partic.matter, 10 µm or larger in cont.	113289-2	nmt 6000	18	Espoo
Partic.matter, 25 µm or larger in cont.	113289-2	nmt 600	0	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins	100590-2	nmt 10 EU/ml	nmt 10 EU/ml	Espoo

Orion Corporation — Manufacturing license number 00287/06-02-03/04/2015

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

ORION

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010
Batch Number: 1672207
Order Number: 80659663

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE

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 03.09.2015 14:45:56 by a Qualified Person Katri Salonen

ORION

BATCH CERTIFICATE

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number:	134910
Batch Number:	1672207
Order Number:	80659863
Date of Manufacture:	22.06.2015
Date of Expiration:	05.2018
Quantity:	600 PCE
Marketing authorization number:	EU/2/02/033/001
Manufacturing site:	Orion Corporation, Espoo plant Orionintie 3 FI-02200 ESPOO
GMP Compliance of Manufact. site:	122/12.01.01/2014
Quality control site:	Orion Corporation, Espoo plant PO Box 65 FI-02101 ESPOO
GMP Compliance of Quality Ctrl site:	122/12.01.01/2014
Packaging site:	Orion Corporation, Espoo plant Orionintie 3 FI-02200 ESPOO
GMP Compliance of Packaging site:	122/12.01.01/2014

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 03.09.2015 14:45:58 by a Qualified Person Katri Salonen

Orion Corporation
Manufacturing licence number 00757/06.01.00.04/2015

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