DEXDOMITOR 0,5MG/ML INJEKCIÓS OLD. 10ML
Gysz: 2019199 Lej: 2023-05-31
Kisz: 10ML Me: Doboz
SZÉKELY KFT részére

Szállító:
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ORION

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010
Batch Number: 2019199
Order Number: 81032661

Date of Manufacture: 22.06.2020
Date of Expiration: 05.2023
Storage: +15..25 °C
Specification: Hungary (108598) 19.05.2020

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.partic.	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	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 %	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, HPLC	100175-3	positive	positive	Espoo
Ident., propyl parahydroxybenzoate, UV	100175-3	positive	positive	Espoo
Assay, propyl parahydroxybenzoate %	100175-3	95 % - 105 %	100 %	Espoo
Optical purity, levomedetomidine	100173-2	nmt 1,0 %	0,5 %	Espoo
Partic.matter, 10 µm or larger in cont.	113289-2	nmt 6000	15	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.	116697-1	nmt 10 EU/ml	nmt 10 EU/ml	Espoo

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Manufacturing license number FIMEA/2019/0010712

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

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number:	134010
Batch Number:	2019199
Order Number:	81032661

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 14.09.2020 14:31:19 by a Qualified Person Johanna Heiman

Orion Corporation

Manufacturing license number FIMEA/2019/000732

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ORION

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

BATCH CERTIFICATE

Product Number:	134010
Batch Number:	2019199
Order Number:	81032661
Date of Manufacture:	22.06.2020
Date of Expiration:	05.2023
Quantity:	800 PCE
Strength/Potency:	0.5 mg/ml
Dosage form:	Solution for injection
Package size:	10 ml
Package type:	Vial
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

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BATCH CERTIFICATE

DEXDOMITOR 0.5MG/ML VET INJ1X10ML BGHURO

Product Number: 134010
Batch Number: 2019199
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Electronically approved 14.09.2020 14:31:19 by a Qualified Person Johanna Heiman

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