

DEXDOMITOR 0,1 MG/ML INJEKCIÓS OLD. 15ML
 Gysz: 2011280 Lej: 2022-09-30
 Kisz: 15ML Me: Doboz
 SZÉKELY KFT részére

Szállító:
 Medimpex Gy. Zrt.
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CERTIFICATE OF ANALYSIS



DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 138513
 Batch Number: 2011280
 Order Number: 81025973

Date of Manufacture: 29.10.2019
 Date of Expiration: 09.2022
 Storage: +15...25 °C
 Specification: Hungary (136862) 27.09.2019

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.partic.	100178-2	practically no particles	practically no particles	Espoo
Extractable volume	113204-1	15,0 ml - 16,0 ml	15,5 ml	Espoo
pH	100177-2	4,0 - 6,0	5,0	Espoo
Ident., dexametomidine, HPLC	116653-1	positive	positive	Espoo
Ident., dexmedetomidine, UV	116634-1	positive	positive	Espoo
Assay, dexmedetomidine HCl, %	116634-1	95,0 % - 105,0 %	101,1 %	Espoo
Ident., methyl parahydroxybenzoate, HPLC	116634-1	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, UV	116634-1	positive	positive	Espoo
Assay, methyl parahydroxybenzoate %	116634-1	95 % - 105 %	98 %	Espoo
Ident., propyl parahydroxybenzoate, HPLC	116634-1	positive	positive	Espoo
Ident., propyl parahydroxybenzoate, UV	116634-1	positive	positive	Espoo
Assay, propyl parahydroxybenzoate %	116634-1	95 % - 105 %	98 %	Espoo
Optical purity, levomedetomidine	116653-1	nmt 1,0 %	<0,5 %	Espoo
Partic.matter, 10 µm or larger in cont.	113289-2	nmt 6000	46	Espoo
Partic.matter, 25 µm or larger in cont.	113289-2	nmt 600	0	Espoo
Bacterial endotoxins	116697-1	nmt 10 EU/ml	nmt 10 EU/ml	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo

Orion Corporation Manufacturing license number: FIN/A-2019/006732

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

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DEXDOMITOR 0,1MG/ML V.I.N.U 1X15ML HUSIRO

Product Number: 138513
Batch Number: 2011280
Order Number: 81025873

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY 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 06.07.2020 15:40:20 by a Qualified Person Hanna Strand

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DEXDOMITOR 0,1 MG/ML INJEKCIÓS OLD. 15ML
Gysz: 2011280 Lej: 2022-09-30
Kisz: 15ML Me: Doboz
SZÉKELY KFT részére

Szállító:
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DEXDOMITOR 0.1MG/ML V.I.NJ 1X15ML HUSIRO

BATCH CERTIFICATE

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Product Number: 138513
Batch Number: 2011280
Order Number: 81025973

Date of Manufacture: 29.10.2019
Date of Expiration: 09.2022

Quantity: 320 PCE
Strength/Potency: 0.1 mg/ml
Dosage form: Solution for injection
Package size: 15 ml
Package type: Vial

Marketing authorization number: EU/2/02/033/004

Manufacturing site: Orion Corporation, Espoo plant

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

Quality control site: Orion Corporation, Espoo plant

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

Packaging site: Orion Corporation, Espoo plant

GMP Compliance of Packaging site: 003953/06.08.02.00/2017

Orion Corporation Manufacturing license number FINELA/2019/000732

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BATCH CERTIFICATE

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DEXDOMITOR 0.1MG/ML V.JNU 1X15ML HUSIRO

Product Number: 138513
Batch Number: 2011280
Order Number: 81025973

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 06.07.2020 15:40:20 by a Qualified Person Hanna Strand

Orion Corporation
Manufacturing license number FINFA/2019/000712

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