

DEXDOMITOR 0,1 MG/ML INJEKCIÓS OLD. 15ML  
 Gysz:1896409 Lej:21/08/31  
 Kisz:15ML Me.:Doboz  
 SZÉKELY KFT részére

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Page: 1(3)

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 136513  
 Batch Number: 1896409  
 Order Number: 80938044

Date of Manufacture: 24.09.2018  
 Date of Expiration: 06.2021  
 Storage: +15...25 °C  
 Specification: Hungary (136862) 23.10.2017

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., dexmedetomidine, HPLC	116653-1	positive	positive	Espoo
Ident., dexmedetomidine, UV	116634-1	positive	positive	Espoo
Assay, dexmedetomidine HCl, %	116634-1	95,0 % - 105,0 %	100,0 %	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 %	99 %	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	52	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

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Manufacturing license number 006356/06.08.04.2018

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

Meoszám:190500017MBT

2.pld. Kiadva: 19/05/16

MEDIMPEX GYÓGYSZER ZRT.  
 1158 Bp., Rákospalotai határút 2.  
 Nagyné Kári Éva  
 Minőségirányítási szakasszisztens  
 Csak a piros szín hiteles

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**DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO**

Product Number: 138513  
Batch Number: 1896409  
Order Number: 80938044

**CERTIFICATE OF ANALYSIS**

Page: 2(3)

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY 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 17.04.2019 12:55:49 by a Qualified Person Márko Kuosmanen

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DEXDOMITOR 0,1 MG/ML INJEKCIÓS OLD. 15ML  
Gysz:1896409  
Kisz:15ML  
SZEKELY KFT részére  
Lej:21/08/31  
Me.:Doboz

MEDIMPEX GYÓGYSZER ZRT.  
1158 Bp., Rákospalotai határút 2.  
Nagyne Káti Éva  
Működési területi szakasszisztens  
Csak a piros színű hiteles

2.pld. Kiadva: 19/05/16

Meoszá: 190500017MBT



DEXDOMITOR 0.1MG/ML V.I.NU 1X15ML HUSIRO

BATCH CERTIFICATE

Page: 3(3)

Meoszárn: 190500017MBT

2. pld.

Kiadva: 19/05/16

Product Number: 138513  
Batch Number: 1896409  
Order Number: 80938044

Date of Manufacture: 24.09.2018  
Date of Expiration: 08.2021

Quantity: 353 PCE

Marketing authorization number: EU/2/02/03/004

Manufacturing site:

GMP Compliance of Manufact. site: Orion Corporation, Espoo plant  
Orionite 1 FI-02200 ESPOO  
003953/06.08.02.00/2017

Quality control site:

GMP Compliance of Quality Ctrl site: Orion Corporation, Espoo plant  
Orionite 1 FI-02200 ESPOO  
003953/06.08.02.00/2017

Packaging site:

GMP Compliance of Packaging site: Orion Corporation, Espoo plant  
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003953/06.08.02.00/2017

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Electronically approved 17.04.2019 12:55:49 by a Qualified Person Marko Kuosmanen

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