

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

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

Date of Manufacture: 24.09.2018  
 Date of Expiration: 08.2021  
 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.particles	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, dexametomidine 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, UV	116634-1	95 % - 105 %	99 %	Espoo
Ident., propyl parahydroxybenzoate, HPLC	116634-1	positive	positive	Espoo
Assay, propyl parahydroxybenzoate, UV	116634-1	positive	positive	Espoo
Optical purity, levomedetomidine	116653-1	95 % - 105 %	98 %	Espoo
Partic.matter, 10 µm or larger in cont.	113289-2	nmt 1.0 %	<0,5 %	Espoo
Partic.matter, 25 µm or larger in cont.	113289-2	nmt 6000	52	Espoo
Bacterial endotoxins	116697-1	nmt 600	0	Espoo
Test for sterility	113205-1	nmt 10 EU/ml sterile	nmt 10 EU/ml sterile	Espoo

Manufacturing license number 066356/06.08.00.04/2018

Orion Corporation

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DEXDOMITOR 0,1 MG/ML INJEKCIÓS OLD. 15ML  
Gysz: 1896409 Lej: 2021-08-24  
Kisz: 15ML Me: Doboz  
SZÉKELY KFT részére

Szállító:  
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e-mail: qa@mpx.hu

Page: 2(3)

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DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

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

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 Marko Kuosmanen

Manufacturing license number:06635600638.00.04/2018

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Page: 3(3)

## BATCH CERTIFICATE



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

**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:** Orion Corporation, Espoo plant  
Orionitie 1 FI-02200 ESPOO  
**GMP Compliance of Manufact. site:** 003953/06.08.02.00/2017  
**Quality control site:** Orion Corporation, Espoo plant  
Orionitie 1 FI-02200 ESPOO  
**GMP Compliance of Quality Ctrl site:** 003953/06.08.02.00/2017  
**Packaging site:** Orion Corporation, Espoo plant  
Orionitie 1 FI-02200 ESPOO  
**GMP Compliance of Packaging site:** 003953/06.08.02.00/2017

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Manufacturing license number: 066356/06.08.00.04/2018

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