



DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

CERTIFICATE OF ANALYSIS

Product Number: 138513
Batch Number: 1824174
Order Number: 80853006

Date of Manufacture: 15.01.2018 ✓
Date of Expiration: 12.2020 ✓
Storage: +15, 25 °C ✓
Specification: Hungary (136862) 23.10.2017

PHOENIX Pharma Zrt.
Főtt Telephely
2151 Főtt, Keleti Maron út 19.
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20-03

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 %	100.5 %	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 %	100 %	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	34	Espoo
Partic matter, 25 µm or larger in cont	113289-2	nmt 600	2	Espoo
Bacterial endotoxins	116697-1	nmt 10 EU/ml	nmt 10 EU/ml	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo

Product description: DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO
Manufacturing licence number: 00148/06/08/0004/2016

ORION PHARMA
Oriontinté 1132001 (Slovakia)
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Államjogi: 9100 Kft (Czipp)
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Államjogi: 212100 S (Czipp)
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Product description: Registered medicinal product name: DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO



CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 138513
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Főtt Telephely
2151 Főtt, Keleth Maron út 19.
.....sz. masolat példány
Csak a város szin hiteles!
20-03

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 01.03.2018 16:06:10 by a Qualified Person Kain Salonen

Orion Corporation
 Orion Pharma
 Vuontehentie 1, 02200 Espoo
 P.O. Box 65, 02101 Espoo
 Tel: +358 10 426 281
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Manufacturing facilities: Orion Corporation, 00044, 2018
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 Vuontehentie 1, 00100 Helsinki
 Tel: +358 10 426 281



BATCH CERTIFICATE

DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 138513
 Batch Number: 1824174
 Order Number: 80853006
 Date of Manufacture: 15.01.2018
 Date of Expiration: 12.2020
 Quantity: 210 PCE

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

Manufacturing site: Orion Corporation, Espoo plant
 Orionintie 1 FI-02200 ESPOO
 GMP Compliance of Manufact. site: 005703/06.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant
 Orionintie 1 FI-02200 ESPOO
 GMP Compliance of Quality Ctrl site: 005703/06.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant
 Orionintie 1 FI-02200 ESPOO
 GMP Compliance of Packaging site: 005703/06.08.02.00/2015

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 01.03.2018 16:06:10 by a Qualified Person Kari Salonen

Orion Corporation

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Manufacturing license number: 002018/06/08/04/2015

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Vollständiger Text der UCP/CPD
 Produkt 200 30 40 81 08 014
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Orion Corporation, Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland

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 sz. masolati példány
 M. P. I. Z. :
 20-09

Kiadva: 18/07/13

6. pld.

szám: 180400343/07/T