



CERTIFICATE OF ANALYSIS

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DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 138513
Batch Number: 1655633
Order Number: 80642942

Date of Manufacture: 15.12.2014
Date of Expiration: 11.2017
Storage: Room temp. +15..25°C
Specification: 1001696-01(Mat:138882) 24.02.2014

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Clarity of solution	100182-2	clear	clear	Espoo
Colour of solution	100182-2	colourless	colourless	Espoo
Clarity of solution	100181-2	clear	clear	Espoo
Colour of solution	100181-2	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 %	99,8 %	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
Assay, methyl parahydroxybenzoate, %	116634-1	92,5 % - 105,0 %	99,3 %	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 %	99 %	Espoo
Assay, propyl parahydroxybenzoate, %	116634-1	92,5 % - 105,0 %	98,7 %	Espoo
Optical purity, levomedetomidine	116653-1	nml 1,0 %	0,5 %	Espoo
Degrad prod., any unspecified	116634-1	nml 0,2 %	0,2 %	Espoo
Degrad prod., total unspecified	116634-1	nml 1,0 %	0,3 %	Espoo

Orion Corporation

Manufacturing license number 000136-16 01 00 047311

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CERTIFICATE OF ANALYSIS

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

Product Number: 138513
Batch Number: 1655633
Order Number: 80842942

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Degrad.prod., 4-hydroxybenzoic acid	116634-1	nml 1,0 %	< 0,3 %	Espoo
Residual solvents	118546-1	comply with USP US	comply with USP US	Espoo
Partic.matter, 10 µm or larger in cont.	113289-2	nml 6000	64	Espoo
Partic.matter, 25 µm or larger in cont.	113289-2	nml 600	1	Espoo
Bacterial endotoxins	116697-1	nml 10 EU/ml	nml 10 EU/ml	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 05.06.2016 15:54:39 by a Qualified Person Kairi Salonen

Orion Corporation

Manufacturing licence number 000716/06 of 00-01/2014

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BATCH CERTIFICATE

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DEXDOMITOR 0.1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 138513
Batch Number: 1655633
Order Number: 80642942

Date of Manufacture: 15.12.2014
Date of Expiration: 11.2017

Quantity: 200 PCE

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

Manufacturing site: Orion Corporation, Espoo plant
Oriontie 3 FI-02200 ESPOO

GMP Compliance of Manufact. site: 122/12.01.01/2014

Quality control site: Orion Corporation, Espoo plant
PO Box 65 FI-02101 ESPOO

GMP Compliance of Quality Ctrl site: 122/12.01.01/2014

Packaging site: Orion Corporation, Espoo plant
Oriontie 3 FI-02200 ESPOO

GMP Compliance of Packaging site: 122/12.01.01/2014

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 05.06.2015 15:54:39 by a Qualified Person Katri Salonen

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