



CERTIFICATE OF ANALYSIS

DEXDOMITOR 0,1MG/ML VÍNJU 1X15ML HUSIRO

Product Number: 138513
 Batch Number: 1702742
 Order Number: 88702109
 Date of Manufacture: 02.02.2015
 Date of Expiration: 01.2018
 Storage: Room temp. +15...25°C
 Specification: 180118598-01 (MAGY 35862) 24.02.2014

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL SITE
Clarity of solution	1001B2-2	clear	clear	ESPO0
Colour of solution	1001B2-2	colourless	colourless	ESPO0
Clarity of solution	1001B1-2	clear	clear	ESPO0
Colour of solution	1001B1-2	colourless	colourless	ESPO0
Particulate matter, presence of visib. partic.	100178-2	practically no particles	practically no particles	ESPO0
Extractable volume	113204-1	15,0 ml - 16,0 ml	16,0 ml	ESPO0
pH	100177-2	4,0 - 6,0	5,1	ESPO0
Ident.: dexmedetomidine, HPLC	116853-1	positive	positive	ESPO0
Ident.: dexmedetomidine, UV	116834-1	positive	positive	ESPO0
Assay: dexmedetomidine HCl, %	116834-1	95,0 % - 105,0 %	95,1 %	ESPO0
Ident.: methyl parahydroxybenzoate, HPLC	116834-1	positive	positive	ESPO0
Ident.: methyl parahydroxybenzoate, UV	116834-1	95 % - 105 %	100 %	ESPO0
Assay: methyl parahydroxybenzoate, %	116834-1	92,5 % - 105,0 %	100,2 %	ESPO0
Ident.: propyl parahydroxybenzoate, HPLC	116834-1	positive	positive	ESPO0
Ident.: propyl parahydroxybenzoate, UV	116834-1	positive	positive	ESPO0
Assay: propyl parahydroxybenzoate, %	116834-1	95 % - 105 %	99 %	ESPO0
Assay: propyl parahydroxybenzoate, %	116834-1	92,5 % - 105,0 %	96,7 %	ESPO0
Optical purity: dexmedetomidine	116834-1	min 1,0 %	< 0,5 %	ESPO0
Degrad. prod.: any unspecified	116834-1	max 0,2 %	< 0,1 %	ESPO0

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DEXDOMITOR 0.1MG/ML VINJ 1X15ML HUSIRO

Product Number: 139513
Batch Number: 1702742
Order Number: 80702109

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Dehydratprod., total unspecified	1166344-1	nmf 1.0 %	< 0.1 %	Espp00
Degradprod., 4-hydroxybenzoic acid	1166344-1	nmf 1.0 %	< 0.3 %	Espp00
Residual solvents	1165486-1	comply with USP 68	comply with USP 68	Espp00
Particulate, 10 µm or larger in cont.	113289-2	nmf 6000	31	Espp00
Particulate, 25 µm or larger in cont.	113289-2	not eou	0	Espp01
Bacterial endotoxins	116687-1	nmf 10 EU/ml	nmf 10 EU/ml	Espp00
Test for sterility	113705-1	sterile	sterile	Espp04

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 29.02.2016 15:25:43 by a Qualified Person Kari Salonen

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Other Countries: Requirements and/or specific QMS for EU, USA, Japan



BATCH CERTIFICATE

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DEXDOMITOR 0.1MG/ML VJN3 1X15ML HUSIRO

Product Number: 138813
Batch Number: 1702749
Order Number: B0792709
Date of Manufacture: 02.02.2015
Date of Expiration: 01.2018
Quantity: 210 PCE
Marketing authorization number: EU/2/02/033/004
Manufacturing site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPCO
GMP Compliance of Manufact site: 122/12.01.01/2014
Quality control site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPCO
GMP Compliance of Quality Ctrl site: 122/12.01.01/2014
Packaging site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPCO
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.

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