ORION

CERTIFICATE OF ANALYSIS

DEXDOMITOR 0,1MG/ML V.INJ 1X15ML HUSIRO

Product Number: 136513
Batch Number: 1501597
Order Number: 80453093

Date of Manufacture: 27.02.2012
Date of Expiration: 01.2015
Storage: Room temp. +15..25°C
Specification: 10011696-01(Mat:136862) 15.07.2011

TESTS	METHOD	REQUIREMENTS	RESULTS
Clarity of solution	100182-2	clear	clear
Colour of solution	100182-2	colourless	colourless
Clarity of solution	100181-2	clear	clear
Colour of solution	100181-2	colourless	colourless
Partic.matter, presence of visib.partic.	100178-2	practically no particles	practically no particles
Extractable volume	113204-1	15,0 ml - 16,0 ml	15,5 ml
pH	100177-2	4,0 - 6,0	4,9
Ident., dexmedetomidine, HPLC	116653-1	positive	positive
Ident., dexmedetomidine, UV	116634-1	positive	positive
Assay, dexmedetomidine HCl, %	116634-1	95,0 % - 105,0 %	100,6 %
Ident., methyl parahydroxybenzoate, HPLC	116634-1	positive	positive
Ident., methyl parahydroxybenzoate, UV	116634-1	positive	positive
Assay, methyl parahydroxybenzoate %	116634-1	95 % - 105 %	100 %
Ident., propyl parahydroxybenzoate, HPLC	116634-1	positive	positive
Ident., propyl parahydroxybenzoate, UV	116634-1	positive	positive
Assay, propyl parahydroxybenzoate %	116634-1	95 % - 105 %	99 %
Optical purity, levomedetomidine	116653-1	nmt 1,0 %	< 0,5 %
Degrad.prod., any unspecified	116634-1	nmt 0,2 %	< 0,1 %
Degrad.prod., total unspecified	116634-1	nmt 1,0 %	< 0,1 %
Degrad.prod., 4-hydroxybenzoic acid	116634-1	nmt 1,0 %	< 0,1 %
Residual solvents	116546-1	comply with USP 0$	comply with USP 0$

Orion Corporation

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TESTS	METHOD	REQUIREMENTS	RESULTS
Partic.matter, 10 µm or larger in cont.	113289-2	nmt 6000	62
Partic.matter, 25 µm or larger in cont.	113289-2	nmt 600	0
Bacterial endotoxins	116697-1	nmt 10 EU/ml	nmt 10 EU/ml
Test for sterility	113205-1	sterile	sterile

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 21.12.2012 13:24:05 by a Qualified Person Okko Lehtinen

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