

Dexdomitor 0,1mg/ml injekció
 Gysz:1655633 Lej:17/11/30
 Kisz:15ml Me.:doboz
 DR. SZÉKELY KFT. részére

2151 Föt
 Keleti Márton u. 19.
 Tel:27/537-100
 Fax:27/537-100



CERTIFICATE OF ANALYSIS

Page: 1/3

DEXDOMITOR 0,1MG/ML VÍNY 1X15ML HUSIRO

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

Date of Manufacture: 15.12.2014
 Date of Expiration: 11.2017
 Storage: Room temp. +15...25°C
 Specification: 10011896-01/Mat:138562/24-02-2014

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Clarity of solution	100182-2	clear	clear	Espp00
Colour of solution	100182-2	colourless	colourless	Espp00
Clarity of solution	100181-2	clear	clear	Espp00
Colour of solution	100181-2	colourless	colourless	Espp00
Particle matter, presence of visible particles	100176-2	practically no particles	practically no particles	Espp00
Extradisable volume	113204-1	19,0 ml - 19,0 ml	15,5 ml	Espp00
pH	100177-2	4,0 - 6,0	5,0	Espp00
Ident., dexmedetomidine, HPLC	116633-1	positive	positive	Espp00
Ident., dexmedetomidine, UV	116634-1	positive	positive	Espp00
Assay, dexmedetomidine HCl, %	116634-1	95,0 % - 105,0 %	99,8 %	Espp00
Ident., methyl parathydroxybenzoate, HPLC	116634-1	positive	positive	Espp00
Ident., methyl parathydroxybenzoate, UV	116634-1	positive	positive	Espp00
Assay, methyl parathydroxybenzoate, %	116634-1	95 % - 105 %	89 %	Espp00
Ident., propyl parathydroxybenzoate, HPLC	116634-1	positive	positive	Espp00
Ident., propyl parathydroxybenzoate, UV	116634-1	positive	positive	Espp00
Assay, propyl parathydroxybenzoate, %	116634-1	95 % - 105 %	99,3 %	Espp00
Assay, propyl parathydroxybenzoate, %	116634-1	95 % - 105 %	99,7 %	Espp00
Optical purity, levonmedetomidine	116634-1	nmI 1,0 %	0,5 %	Espp00
Degrad prod., any unspecified	116634-1	nmI 0,2 %	0,2 %	Espp00
Degrad prod., total unspecified	116634-1	nmI 1,0 %	0,3 %	Espp00

ORION PHARMA
 Ormaveit, 2200185000
 P.O. Box 63, 02101 TURKU
 Tel: +358 10 231
 Fax: +358 10 232 3113

Manufacturing licence number: 240/2011

ORION PHARMA
 Ormaveit, 2200185000
 P.O. Box 63, 02101 TURKU
 Tel: +358 10 231
 Fax: +358 10 232 3113

Manufacturing licence number: 240/2011

ORION PHARMA
 Ormaveit, 2200185000
 P.O. Box 63, 02101 TURKU
 Tel: +358 10 231
 Fax: +358 10 232 3113

Manufacturing licence number: 240/2011



CERTIFICATE OF ANALYSIS

DEXDOMITOR 0.1MG/ML VINYL 1X16ML HUSIRO

Product Number: 138513

Batch Number: 1659833

Order Number: 80842942

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Digital prod. 4-hydroxybenzoic acid	116534-1	nm 1.0 %	< 0.1 %	Esppo
Residual solvents	116546-1	comply with USP US	comply with USP US	Esppo
Particulate matter: 10 µm or larger in cont.	113289-2	nm 5000	64	Esppo
Particulate matter: 25 µm or larger in cont.	113299-2	nm 600	1	Esppo
Bacterial endotoxins	116567-1	nm 1.0 EU/ml	nm 10 EU/ml	Esppo
Test for sterility	113205-1	sterile	sterile	Esppo

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 05.08.2016 15:54:39 by a Qualified Person Kari Sjöman

Orion Corporation Manufacturing license number: 0010164 of 04/03/04

ORION FINECHEM
Imponenkatu 1, 02160 ESPOO
P.O. Box 1, 02001 ESPOO
Tel. +358 (0) 4521
Fax. +358 (0) 4581119

Temppelaukionkatu 1, 00100 HELSINKI
P.O. Box 315, 00101 HELSINKI
Tel. +358 (0) 2061
Fax. +358 (0) 217777

Valkoisa 4, 00100 ALTO
P.O. Box 176, 00101 ALTO
Tel. +358 (0) 47811
Fax. +358 (0) 478114

Imponenkatu 1, 21100 SÄCKÖ
Tel. +358 (0) 4288



BATCH CERTIFICATE

Page: 1/3

DEXDOMITOR 0.1MG/ML V.I.NU 1X16ML HUSIRO

Product Name: 138513
Batch Number: 1655613
Order Number: 80842942
Date of Manufacture: 15.12.2014
Date of Expiration: 11.2017
Quantity: 200 PCE
Marketing authorization number: EUZ0202030004
Manufacturing site: Orion Corporation, Espoo plant
Orionite 3 FI-02200 ESPOO
GMP Compliance of Manufact. site: 122712.01.01/2014
Quality control site: Orion Corporation, Espoo plant
PO Box 85, FI-02101 ESPOO
GMP Compliance of Quality Ctrl site: 122712.01.01/2014
Packaging site: Orion Corporation, Espoo plant
Orionite 3 FI-02200 ESPOO
GMP Compliance of Packaging site: 122712.01.01/2014

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 05.05.2015 15:54:39 by a Qualified Person Kari Salonen

Orion Corporation
Manufacturing licence number: 00074/06.01.00.01/2013
Espoo, Finland
Orion Corporation, Orionite 3
P.O. Box 43, 00071 Orion
FI-00043 Espoo
Tel: +358 9 422 1000
Fax: +358 9 422 1001
E-mail: orion@orion.fi
www.orion.fi
Espoo, Finland
Orion Corporation, Orionite 3
P.O. Box 129, 00071 Orion
FI-00012 Espoo
Tel: +358 9 422 1000
Fax: +358 9 422 1001
E-mail: orion@orion.fi
www.orion.fi
Espoo, Finland
Orion Corporation, Orionite 3
P.O. Box 129, 00071 Orion
FI-00012 Espoo
Tel: +358 9 422 1000
Fax: +358 9 422 1001
E-mail: orion@orion.fi
www.orion.fi