

Dexdomitor 0,1mg/ml infjekció  
 Gysz:1501597 Lej:15/01/31  
 Kisz:15ml Me.:doboz  
 DR. SZÉKELY KFT. részére

2151 Főt,  
 Keleti Márton u. 19.  
 Tel:27/537-100  
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CERTIFICATE OF ANALYSIS

**DEXDOMITOR 0,1MG/ML V.I.N.J 1X15ML HUSIRO**  
 Product Number: 138513  
 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:138882) 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	clear
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., dexametomidine, HPLC	116653-1	positive	positive
Ident., dexametomidine, UV	116634-1	positive	positive
Assay, dexametomidine 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, UV	116634-1	positive	positive
Assay, propyl parahydroxybenzoate %	116634-1	95 % - 105 %	99 %
Optical purity, levomedetomidine	116653-1	nml 1,0 %	< 0,5 %
Degrad.prod, any unspecified	116634-1	nml 0,2 %	< 0,1 %
Degrad.prod, total unspecified	116634-1	nml 1,0 %	< 0,1 %
Degrad.prod, 4-hydroxybenzoic acid	116634-1	nml 1,0 %	< 0,1 %
Residual solvents	116546-1	comply with USP 05	comply with USP 05

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**PHOENIX Pharma Zrt.**  
 Főút Telephely  
 2151 Főút, Keleti Márton ut 19.  
 ..... sz. másolat példány  
 Csak a piros szín hitelesítési  
 20-03



CERTIFICATE OF ANALYSIS

DEXDOMITOR 0,1MG/ML V.INJ 1X15ML HUSIRO  
Product Number: 136513  
Batch Number: 1501697  
Order Number: 80453093

TESTS	METHOD	REQUIREMENTS	RESULTS
Particulate matter, 10 µm or larger in cont.	113289-2	nmt 6000	62
Particulate matter, 25 µm or larger in cont.	113289-2	nmt 600	0
Bacterial endotoxins	116897-1	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 Otko Lehtinen

Orion Corporation

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sz. maszkok példányai  
Csak a piros színű művelet!  
20-03

Kiadva: 14/08/11 5.pld.

Meoszám: 130100506/07/T