

DEXDOMITOR 0,5MG/ML INJEKCIÓS OLD. 10ML
 Gysz:1783098 Lej:20/04/30
 Kisz:10ML Me.:Doboz
 SZÉKELY KFT részére

Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel:+36-1-414-6477
 Fax:+36-1-414-6479

Dexdomitor 0,5mg/ml injekciós oldat
 Gysz:1783098 Lej:20/04/30
 Kisz:10ml Me.:darab
 MEDIMPEX GYÓGYSZER ZRT. részére

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



DEXDOMITOR 0,5MG/ML VET INJ 1X10ML BGHUR0

CERTIFICATE OF ANALYSIS

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Product Number: 134010
 Batch Number: 1783098
 Order Number: 80794428
 Date of Manufacture: 11.05.2017
 Date of Expiration: 04.2020
 Storage: Room Temp, +15, 25°C
 Specification: Hungary (1006198) 01.05.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
Clarity of solution	100182-2	clear	clear	Esppo
Colour of solution	100182-2	colourless	colourless	Esppo
Particulate matter, presence of visible particles	100178-2	practically no particles	practically no particles	Esppo
Volume in container	100178-2	10.0 ml - 11.0 ml	10.6 ml	Esppo
pH	100177-2	4.0 - 6.0	5.0	Esppo
Ident., dexamethasone, HPLC	100175-2	positive	positive	Esppo
Ident., dexamethasone, UV	100175-3	positive	positive	Esppo
Assay, dexamethasone HCl, %	100175-3	95.0 % - 105.0 %	100.7 %	Esppo
Ident., methyl parahydroxybenzoate HPLC	100175-3	positive	positive	Esppo
Ident., methyl parahydroxybenzoate, UV	100175-3	positive	positive	Esppo
Assay, methyl parahydroxybenzoate, %	100175-3	95 % - 105 %	100 %	Esppo
Ident., propyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Esppo
Ident., propyl parahydroxybenzoate, UV	100175-3	positive	positive	Esppo
Assay, propyl parahydroxybenzoate, %	100175-3	95 % - 105 %	100 %	Esppo
Optical purity, levonorgestrel	100173-2	nml 1.0 %	<0.5 %	Esppo
Particle matter, 10 µm or larger in cont.	11328B-2	nml 6000	13	Esppo
Particle matter, 25 µm or larger in cont.	11328B-2	nml 600	3	Esppo
Test for sterility	113205-1	sterile	sterile	Esppo
Bacterial endotoxins	10559C-2	nml 10 EU/mg	level 10 EU/mg	Esppo

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MEDIMPEX GYÓGYSZER ZRT.
 1158 Bp., Rákospalotai határút 2.
 Nagyménfőcsanak
 Minőségbiztosító szakasszisztens
 Csak a piros szín hiteles

Handwritten signature

DEXDOMITOR 0,5MG/ML INJEKCIÓS OLD. 10ML
Gysz:1783098 Lej:20/04/30
Kisz:10ML Me.:Doboz
SZÉKELY KFT részére

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CERTIFICATE OF ANALYSIS

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DEXDOMITOR 0,5MG/ML VET INJ1X10ML BQHJRO

Product Number: 134010
Batch Number: 1783098
Order Number: 80704426

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CONTROL SITE
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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 15.06.2017 14:20:56 by a Qualified Person Kari Salonen

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Gysz:1783098 Lej:20/04/30
Kisz:10ML Me.:Doboz
SZÉKELY KFT részére

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BATCH CERTIFICATE

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DEXDOMITOR 0,5MG/ML VET INJEKCIÓS OLD. 10ML, BSHURO

Product Number: 134010
Batch Number: 1783098
Order Number: 80194426

Date of Manufacture: 11.05.2017
Date of Expiration: 04.2020

Quantity: 1000 PCIE

Marketing authorization number: EU/2020/033001

Manufacturing site: Orion Corporation, Espoo plant
Originale 1 FI:02200 ESPCO
GMP Compliance of Manufact. site: 00392006.08.02.002015

Quality control site: Orion Corporation, Espoo plant
Originale 1 FI:02200 ESPCO
GMP Compliance of Quality Ctrl site: 00392006.08.02.002015

Packaging site: Orion Corporation, Espoo plant
Originale 1 FI:02200 ESPCO
GMP Compliance of Packaging site: 00392006.08.02.002015

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 16.05.2017 14:20:56 by a Qualified Person Károl Szepes

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Meoszám:170600576/07/T 8.pld. Kiadva: 19/03/29

Meoszám:190400043MBT 2.pld. Kiadva: 19/04/11

Medimpex Gy. Zrt.
1158 Bp., Rákospalotai határút 2.
Nagybánya: Min. biz. sz. 19/04/11
Minőségbiztosító szakasszisztens
Csak a piros szín hiteles!

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