



CERTIFICATE OF ANALYSIS

Page 103

DOMOSSEDAN 10MG/ML VET INJ 5ML HUEN
 Product Number: 133975
 Batch Number: 1673283
 Order Number: 80690163

Date of Manufacture: 30.12.2014
 Date of Expiration: 12.2017
 Storage: Room temp +15-25°C
 Specification: Hungary/108560/22.10.2008

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Volume in cart:	100477-2	5.00 ml - 5.75 ml	5.30 ml	Esboo
Clarity of solution	100493-2	clear	clear	Esboo
Colour of solution	100494-2	colourless	colourless	Esboo
Particulates, pres. of foreign parts:	100479-2	practically no particles	practically no particles	Esboo
pH	100432-2	4.0 - 5.5	4.3	Esboo
Ident., deltamethrin HCl HPLC	100642-4	positive	positive	Esboo
Assay, deltamethrin HCl	100642-4	9.8 mg/ml - 10.5 mg/ml	10.3 mg/ml	Esboo
Ident., methyl parathion/azoxystrobin HPLC	100642-4	positive	positive	Esboo
Assay methyl parathion/azoxystrobin	100642-4	0.9 mg/ml - 1.1 mg/ml	1.0 mg/ml	Esboo
Retained substances	113205-1	nm 1 %	nm 1 %	Esboo
Test for sterility	113205-1	sterile	sterile	Esboo
Bacterial endotoxins	100670-2	nm 25 EU/ml	nm 25 EU/ml	Esboo

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 08.09.2015 15:34:52 by a Qualified Person Kálmán Sakonyi

Orion Corporation
 Orion Terveistalaja
 Osoykatie 1, 01500 Espoo
 P.O. Box 420, 01500 Espoo
 Tel: +358 10 4241
 Fax: +358 10 423115

Transmittalung Station TLRU
 P.O. Box 420, 2000 Turku
 Tel: +358 10 4240
 Fax: +358 10 423777

Valuovärd F. 46590 Uusimaa
 P.O. Box 100, 00010 Helsinki
 Tel: +358 10 42411
 Fax: +358 10 424044

Árnyváltó Árt. 24105 Sáró
 P.O. Box 100, 2000 Székesfehérvár
 Tel: +36 11 10 110
 Fax: +36 11 10 110

Orion Corporation, Department Office and Laboratory, Osoykatie 1, P.O. Box 420, Finland

DR. SZÉKELY KFT.
 Fót Telephely
 Keleti Márton u. 19.
 2151 Fót
 Tel: 27/537-100
 Fax: 27/537-100



BATCH CERTIFICATE

Page 2/3

DOMOSEDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133876
Batch Number: 1873283
Order Number: 80660183

Date of Manufacture: 30.12.2014
Date of Expiration: 12.2017

Quantity: 500 PCE

Marketing authorization number:

UPA 322-08/13-81885
140013, NPV/0094/001, 1454
20794/06, LT/202/1416/001
VAN/P/02/1451
0022-1818-04-01-2013, 003-01-10026-14-001

Manufacturing site:

Orion Corporation, Espoo plant
Orientalie 3 FI-02200 ESPOO

GMP Compliance of Manufact. site:

122/12.01.01/2014

Quality control site:

Orion Corporation, Espoo plant
PO Box 65 FI-02101 ESPOO

GMP Compliance of Quality Ctrl site:

122/12.01.01/2014

Packaging site:

Orion Corporation, Espoo plant
Oskariitie 1 FI-02200 ESPOO

GMP Compliance of Packaging site:

122/12.01.01/2014

Orion Corporation

Manufacturing licence number 0037190-04-001/2013

ORION OYJ
Department 4, 02200 ESPOO
P.O. Box 65, 02101 ESPOO
FI-02101 FIN
Tel: +358 9 428 6114
Fax: +358 9 428 6113

Orion Corporation, Espoo plant
P.O. Box 65, 02101 FIN
Tel: +358 9 428 6114
Fax: +358 9 428 6113

Orion Corporation, Espoo plant
P.O. Box 65, 02101 FIN
Tel: +358 9 428 6114
Fax: +358 9 428 6113

Orion Corporation, Espoo plant
P.O. Box 65, 02101 FIN
Tel: +358 9 428 6114
Fax: +358 9 428 6113

Orion Corporation, Espoo plant
P.O. Box 65, 02101 FIN
Tel: +358 9 428 6114
Fax: +358 9 428 6113

Orion Corporation Zrt.
Ipari telephely
2051 Fő, Keleti Művelő út 10.
sz. másolat példány
2014.01.01.



BATCH CERTIFICATE

Page 3/31

DOMOSEDAN 10MG/ML VET INJ S/M/L HUEN
Product Number: 133975
Batch Number: 1873283
Order Number: 80880183

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorization and in compliance with current Good Manufacturing Practices. The batch samples with the signed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 08 09 2015 15:04:52 by a Qualified Person Kálm Salonen

Owner/Company	Manufacturer/Manufacturer's Representative	Manufacturer/Manufacturer's Representative	Manufacturer/Manufacturer's Representative
UNION ITALIA S.p.A. Via Salaria, 2200/00199 P.O. Box 41, 00191 ESQO Tel: +39 06 4201 Fax: +39 06 4201	Tropicana S.p.A. P.O. Box 41, 00191 ESQO Tel: +39 06 4201 Fax: +39 06 4201	Vichitana, 11000 LERONG P.O. Box 178, 20001 KAOHSIANG Tel: +66 2 250 1111 Fax: +66 2 250 1111	Amvint S.p.A. P.O. Box 178, 20001 KAOHSIANG Tel: +66 2 250 1111

Other Contact: Regional Office and domestic: Quarantine 1 (801200) Esqo, P.O. Box 41

ORION Pharma Zrt.
Egyetem utca
1068 Pál, Keleti Merten út 16.
Min. birodalom
Egyetem utca 16. 1068 Pál

Meoszám: 150900370/07/T

3.pld. Kiadva: 16/03/03