



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

Product Number: 133991
 Batch Number: 1701486
 Order Number: 80895102

Date of Manufacture: 05.11.2015
 Date of Expiration: 11.2018
 Storage: Room Temp. +15..25°C
 Specification: Hungary (100862) 04.04.2013

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Colour of solution	100484-2	colourless	colourless	Esppo
Average volume in container	100229-2	nil 10.0 ml	10.5 ml	Esppo
Volume in cont.	100229-2	10.0 ml - 11.0 ml	10.5 ml	Esppo
Particulate matter, presence of visible partic	100473-2	practically no particles	practically no particles	Esppo
Clarity of solution	100493-2	clear	clear	Esppo
pH	100432-2	4.0 - 6.0	4.4	Esppo
Identl. atiparnazole HCl, HPLC	100843-3	positive	positive	Esppo
Identl. methyl parahydroxybenzoate, HPLC	100843-3	positive	positive	Esppo
Assay, aliparnazole HCl	100843-3	4.75 mg/ml - 5.25 mg/ml	5.05 mg/ml	Esppo
Assay, methyl parahydroxybenzoate	100843-3	0.50 mg/ml - 1.10 mg/ml	1.00 mg/ml	Esppo
Related substances	100843-3	nml 1.0 %	<0.1 %	Esppo
Test for sterility	113205-1	sterile	sterile	Esppo
Bacterial endotoxins	100850-2	nml 10 EU/ml	nml 10 EU/ml	Esppo

Orion Corporation
 Orion Plankkila
 P.O. Box 12200 Espoo
 FI-01510 Espoo
 Tel: +358 10 428 428
 Fax: +358 10 428 1815

Representative: Orion Pharma
 P.O. Box 41, 2000 Turku
 FI-20021 Turku
 Tel: +358 10 258 521
 Fax: +358 10 258 777

Orion Corporation, Registered office and domicile: Oronenkatu 1, FI-20020 Espoo, Finland

Ukrajna: Orion Pharma
 P.O. Box 12200 Espoo
 FI-01510 Espoo
 Tel: +358 10 428 428
 Fax: +358 10 428 544

Jermania: Orion Pharma
 P.O. Box 7, 21000 Slatk
 FI-01510 Slatk
 Tel: +358 10 428 428

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



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

CERTIFICATE OF ANALYSIS

Page: 2/4

Product Number: 133981
Batch Number: 1701488
Order Number: 80995102

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
-------	--------	--------------	---------	-----------------

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 25.02.2016 13:40:48 by a Qualified Person Khalid Salomon

Doha Corporation
ORION MALAYA
Orionmalaya Sdn Bhd
P.O. Box 41, 62100 BSEFOU
Tel: +318 10 4261
Fax: +318 10 426 3113

Manufacturing licence number 02117/06/06/04/2013

Regency Malaya Sdn Bhd
P.O. Box 10, 20101 TUKANU
Tel: +318 10 426 2777
Fax: +318 10 426 2777

Yohansen Sdn Bhd
P.O. Box 1786, 20201 KUNING
Tel: +318 10 426 6422
Fax: +318 10 426 6422

Jayemmalaya Sdn Bhd
Tel: +318 10 4261

PROFORMA FORM 100
No. 100/100/100/100
No. 100/100/100/100
No. 100/100/100/100
No. 100/100/100/100



ANTISEDAN SMGMIL VET INU 10ML HUEN

BATCH CERTIFICATE

Page: 3/4

Product Number: 133981
 Batch Number: 1701488
 Order Number: 80695102
 Date of Manufacture: 08.11.2015
 Date of Expiration: 11.2018
 Quantity: 450 PCE

Marketing authorization number: NPV/8015R/01
 UPJ: 322-05/13-01/856
 VNRP/02/1452, 3286/113, 1452
 L17/202/14/17/001, 140014
 0022-1920-04.01.2013, 323-01-00026-14-001

Manufacturing site: Orion Corporation, Espoo plant
 GMP Compliance of Manufact. site: 122/12.01.01/2014
 Orionville 1 FI-02200 ESPCO
 Quality control site: Orion Corporation, Espoo plant
 Orionville 1 FI-02200 ESPCO
 GMP Compliance of Quality Ctrl site: 122/12.01.01/2014
 Packaging site: Orion Corporation, Espoo plant
 Orionville 1 FI-02200 ESPCO
 GMP Compliance of Packaging site: 122/12.01.01/2014

These Certificates Manufacturing license number: 00117106.06.00.04/2014

ORION PHARMA
 Orionin tie, O200 ESPCO
 P.O. Box 45, 02000 ESPCO
 FI-020800000
 Tel: +358 10 253 8115
 Fax: +358 10 253 8114

Teimplanainn & Bheoctorais
 P.O. Box 43, 20101 TURKU
 FI-20510 10 2492
 Fax: +358 10 242 7777

Valheleua 1, 70000 NAANTALI
 P.O. Box 1726, 70001 NAANTALI
 FI-07000 10 253 8114
 Fax: +358 10 253 8114

Jamessuola 1, 24100 SALO
 FI-24100 10 253 8114
 Fax: +358 10 253 8114

Orion Corporation Regional Office and domestic operations, Orionin tie, Espoo, Finland

Document: Internal Use
 Not for Release
 This document is for internal use only
 and is not to be distributed
 outside the organization
 without the express written
 permission of Orion
 Copyright © 2015 Orion
 All rights reserved



ANTISEDAN 5MG/ML VET INJ 10ML HUEN

BATCH CERTIFICATE

Page: 4/4

Product Number: 133981
Batch Number: 1701486
Order Number: 80995102

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 25.02.2016 13:40:48 by a Qualified Person Kari Salonen

Orion Corporation	Manufacturing (order number 80995102) on 03/2016	
ORION FINLAND Oksanenkatu 1, 02200 ESPOO P.O. Box 10, 02101 ESPOO Tel: +358 (0)45 21 111 Fax: +358 (0)45 21 115	Tampereenkatu 4, 03010 TAMPERE P.O. Box 415, 03010 TAMPERE Tel: +358 (0)45 29 951 Fax: +358 (0)45 28 777	Yhdyskylä 7, 03010 TAMPERE P.O. Box 123, 03010 TAMPERE Tel: +358 (0)45 21 641 Fax: +358 (0)45 28 544
Orion Corporation, Registered office and domicile: Oksanenkatu 1, 02200 ESPOO, Finland		Jamenselkäentie 7, 21100 SALO Tel: +358 10 3261

ANTISEDAN 5MG/ML VET INJ 10ML HUEN
Tampereenkatu 4, 03010 Tampere
P.O. Box 415, 03010 Tampere
Tel: +358 (0)45 29 951
Fax: +358 (0)45 28 777