



CERTIFICATE OF ANALYSIS

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ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
 Batch Number: 1649408
 Order Number: B0032943

Date of Manufacture: 19.01.2015
 Date of Expiration: 01.2018
 Storage: Room Temp +18, 28°C
 Spec. Ref: Hungary(108652) 04 04 2013

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL. SITE
Colour of solution	10004-04-2	colourless	colourless	Espono
Average volume in container	1000229-2	ml 10.0 ml	10.5 ml	Espono
Volume in cont.	1000229-2	10.0 ml - 11.0 ml	10.5 ml	Espono
Particulates, presence of visb. partic.	1000473-2	practically no particles	practically no particles	Espono
Clarity of solution	1000493-2	clear	clear	Espono
pH	1000432-2	4.0 - 6.0	4.4	Espono
Isrenal, sibpamozole HCl, HPLC	1000643-3	positive	positive	Espono
Isrenal, methylparatydroxybenzoate, HPLC	1000643-3	positive	positive	Espono
Asalay, atipamezole HCl	1000643-3	4.75 mg/ml - 5.25 mg/ml	5.15 mg/ml	Espono
Asalay, methylparatydroxybenzoate	1000643-3	0.50 mg/ml - 1.10 mg/ml	1.01 mg/ml	Espono
Related substances	1000643-3	ppm 1.0 %	< 0.1 %	Espono
Test for sterility	1133205-1	sterile	sterile	Espono
Bacteriostatic/antibiotics	1000650-2	ppm 10 EU/ml	ppm 10 EU/ml	Espono

Orion Corporation
 Quality Management
 Orion Corporation, Espoo, Finland
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Manufacturing Number: B0032943 of 04.04.2013

Manufacturing Plant: 20300 TIRANU
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Quality Control Site: 20300 TIRANU
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ANTISEDAN 61MG/ML VET INJ 10ML HUEN
Product Number: 133861
Batch Number: 1848406
Order Number: 20032941

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL. 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 20 04 2016 15:41:54 by a Qualified Person Johannes Heilmann

<p>Orion Corporation LAINEN PLAZA Konttori 1, 02200 ESPOO P.O. Box 60, 00101 FIN-000 Tel +358 10 220 Fax +358 10 28 3115</p>	<p>Antiseedan pakkauksen numero 020760012016 Toukokuun 8. päivä 2016 EUROOPAN UNIONIN TUOMAKSI Tel +358 10 220 Fax +358 10 28 3115</p>	<p>Orion Corporation LAINEN PLAZA Konttori 1, 02200 ESPOO P.O. Box 60, 00101 FIN-000 Tel +358 10 220 Fax +358 10 28 3115</p>	<p>Orion Corporation LAINEN PLAZA Konttori 1, 02200 ESPOO P.O. Box 60, 00101 FIN-000 Tel +358 10 220 Fax +358 10 28 3115</p>
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Orion Corporation Zrt.
Min. 1512/2016
2150 Pót, Köztársaság út 19.
..... sz. művelési példány
Gazdasági és Innovációs
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