



CERTIFICATE OF ANALYSIS

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COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128020  
 Batch Number: 1667857  
 Order Number: 80659863

Date of Manufacture: 27.05.2015  
 Date of Expiration: 04.2018  
 Storage: Store below +30°C  
 Specifications: Hungary(100637) D1.02.2011

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL. SITE
Clarity of solution	513104-1	clear nml ref. suspension 1 colourless to yellowish nml ref. solution GY5 nml ref. solution Y5	clear	Esppó
Colour of solution	106916-2	amber glass inject. bottle	colourless to yellowish	Esppó
Appearance of container	106913-2	amber glass inject. bottle	amber glass inject. bottle	Esppó
Volume in container	106909-2	100 ml - 105 ml	104 ml	Esppó
pH	106904-2	6.2 - 6.8	6.4	Esppó
Identification, ketoprofen HPLC	106919-3	positive	positive	Esppó
Identification, ketoprofen UV spectrum	106919-3	positive	positive	Esppó
Assay, ketoprofen per stated amount	106918-3	85.0 % - 105.0 %	100.6 %	Esppó
Identification, benzyl alcohol HPLC	106919-3	positive	positive	Esppó
Identification, benzyl alcohol UV spect.	106919-3	positive	positive	Esppó
Assay, benzyl alcohol per stated amount	106919-3	90.0 % - 110.0 %	102.5 %	Esppó
Identification, arginine	106981-2	positive	positive	Esppó
Assay, arginine per stated amount	106981-2	80.0 % - 110.0 %	109.4 %	Esppó
Particle count, 10 µm or larger in cont.	116130-1	nml 3000	18	Esppó
Particle count, 25 µm or larger in cont.	116130-1	nml 300	16	Esppó
Test for sterility	113205-1	sterile	sterile	Esppó
Bacterial endotoxins	100744-1	nml 150 EU/ml	nml 150 EU/ml	Esppó

Orion Corporation      Manufacturing licence number: 0037116/01.00.00.0114

DRONINÁKA      Törzsvállalkozás, 2100 TÁTKU  
 Dombóvár, 8200 ÉSKEZŐ      Főút 42/a, 8200 TÁTKU  
 P.O.Box 62, 8200 ÉSKEZŐ      Tel: +36 80 423411  
 Tel: +36 80 42341      Fax: +36 80 42341  
 Fax: +36 80 42341      E-mail: orion@orion.hu

Újpesti Gyár      Vállalkozás, 2000 AKÁCSRÉNY  
 P.O.Box 42/a, 2000 AKÁCSRÉNY      Főút 42/a, 2000 AKÁCSRÉNY  
 Tel: +36 1 451 10 42341      Tel: +36 1 451 10 42341  
 Fax: +36 1 451 10 42341      E-mail: orion@orion.hu

Újpesti Gyár      Készletkezelés és Logisztika      Dombóvár, Főút 42/a, 8200 ÉSKEZŐ, HUNGÁRIA

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CERTIFICATE OF ANALYSIS

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COMFORION VET 108MG/ML INJ 10X100ML FLHD

Product Number: 129820

Batch Number: 1667657

Order Number: 8065983

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY 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. This batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 05.08.2015 15:22:00 by a Qualified Person Keith Salonen

ORION ZILIANA

Orionway 1, 02100 FSJ000  
P.O. Box 47, 02001 ERMUJ  
Tel: +31 (0)4581  
Fax: +31 (0)45818111

Orionway 1, 02100 FSJ000  
P.O. Box 47, 02001 ERMUJ  
Tel: +31 (0)4581  
Fax: +31 (0)45818111

Orionway 1, 02100 FSJ000  
P.O. Box 47, 02001 ERMUJ  
Tel: +31 (0)4581  
Fax: +31 (0)45818111

Orionway 1, 02100 FSJ000  
P.O. Box 47, 02001 ERMUJ  
Tel: +31 (0)4581  
Fax: +31 (0)45818111

Orionway 1, 02100 FSJ000  
P.O. Box 47, 02001 ERMUJ  
Tel: +31 (0)4581  
Fax: +31 (0)45818111

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BATCH CERTIFICATE

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CONFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128020  
Batch Number: 1987957  
Order Number: 80869863

Date of Manufacture: 27.05.2015  
Date of Expiration: 04.2018

Quantity: 100 PCE

Marketing authorization number: 23471/08 MGSZH AT  
189208

Manufacturing site: Orion Corporation, Espoo plant  
Ohtaantie 3 FI-02200 ESPOO

GMP Compliance of Manufact site: 122/12.01.01/2014

Quality control site: Orion Corporation, Espoo plant  
P.O. Box 69 FI-02101 ESPOO

GMP Compliance of Quality Ctrl site: 122/12.01.01/2014

Quality control site: Medburn Scientific Ltd.  
Saxon Way WELDON/UK GR 80N

GMP Compliance of Quality Ctrl site: 1. UK MIA 14988 INSP  
2. GMP 14988/36740-0007

Packaging site: Orion Corporation, Espoo plant  
Ohtaantie 3 FI-02200 ESPOO

GMP Compliance of Packaging site: 122/12.01.01/2014

How to Contact: Manufacturing license number: 06317190 (01/01/2015)

ORION-FINLAND  
Suomen Terveystuote  
Toukokatu 10, 02060 Espoo  
Tel: +358 (0)20  
Fax: +358 (0)20 3811

Impromedica & Solutio TURKU  
P.O. Box 417, 20101 Turku  
Tel: +358 (0)10 3582  
Fax: +358 (0)10 3231

Veritas B. MONTAICHO  
P.O. Box 1, 20081 KUMMI  
Tel: +358 (0)43 661  
Fax: +358 (0)43 644

Orion Corporation, Espoo plant  
Ohtaantie 3, FI-02200 Espoo, Finland

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BATCH CERTIFICATE

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COMFORION VET 100MG/ML INJ 10X100ML PLHU  
Product Number: 126020  
Batch Number: 1667857  
Order Number: 8058963

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 06.08.2015 15:22:00 by a Qualified Person Kim Salonen

Orion Corporation	Manufacturing Centre number: 003715a 00000011
Orion Biologics	
Orionmuur 1, 02100 Espoo	
P.O. Box 61, 02101 Espoo	
Tel: +358 10 2361	
Fax: +358 10 256 815	
	Insinööritie 1, 01101 Tuusula
	P.O. Box 121, 01101 Tuusula
	Tel: +358 10 23602
	Fax: +358 10 43 7117
	Vesilankä 2, 01100 Kumpi
	P.O. Box 176, 01101 Kumpi
	Tel: +358 10 43 811
	Fax: +358 10 43 813
	Joukankatu 1, 21100 Säkylä
	P.O. Box 176, 21101 Kumpi
	Tel: +358 10 43 811
	Fax: +358 10 43 813

Over Supervision: Kytövedenoffi/valvonta/ Orionvet / FI/02000 Pyyri, Finland

15.08.2015 15:22:00  
Kim Salonen  
Min.biz...