

Comforion Vet 100mg/ml injekció A
 Gysz:1812843 Lej:20/10/31
 Kisz:10x100ml Me.:doboz
 TOLNAGRO KFT. részére

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



CERTIFICATE OF ANALYSIS

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COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128625
 Batch Number: 1812843 ✓
 Order Number: 809N6025
 Date of Manufacture: 08.11.2017
 Date of Expiration: 10.2020
 Storage: Below +30 °C
 Specification: Hungary (108/31) 24.06.2016

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Clarity of solution	10316-1	clear nmt ref. suspension I	clear	Espeo
Colour of solution	106916-2	colourless to yellowish nmt ref. solution GY5 nmt ref. solution Y5	nmt ref. solution GY5	Espeo
Appearance of container	106913-2	amber glass inject.bottle	amber glass inject.bottle	Espeo
Volume in container	106909-2	100 ml - 105 ml	102 ml	Espeo
PH	106904-2	6.2 - 6.8	6.4	Espeo
Partic matter, presence of web partic.	121755-1	practically no particles	practically no particles	Espeo
Identification, ketoprofen, HPLC	106919-3	positive	positive	Espeo
Identification, ketoprofen, UV spectrum	106919-3	positive	positive	Espeo
Assay, ketoprofen per stated amount	106919-3	95.0 % - 105.0 %	102.8 %	Espeo
Identification, benzyl alcohol, HPLC	106919-3	positive	positive	Espeo
Identification, benzyl alcohol, UV spect	106919-3	positive	positive	Espeo
Assay, benzyl alcohol per stated amount	106919-3	90.0 % - 110.0 %	103.0 %	Espeo
Identification, arginine	106981-2	positive	positive	Espeo
Assay, arginine per stated amount	106987-2	90.0 % - 110.0 %	100.5 %	Espeo
Test for sterility	113225-1	sterile	sterile	Espeo
Bacteria, endotoxins	121661-1	nmt 150 EU/ml	nmt 150 EU/ml	Espeo

Manufactured under GMP conditions in Hungary
 Tolnagro Kft. 2151 Fót, Keleti Márton u. 19.
 Tel: +36 27 537 100 Fax: +36 27 537 100
 E-mail: info@tolnagro.hu
 www.tolnagro.hu

PHOENIX Pharma Zrt.
 Fóti telephely
 2151 Fót, Keleti M. u. 19.
 Csak a piros szín hiteles!
 20-03



CERTIFICATE OF ANALYSIS

COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 129320
Batch Number: 1812843
Order Number: 80836605

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
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I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved: 29.12.2017 12:59:16 by a Qualified Person: Kati Sauer

Product	Manufacturer	Control	Release
COMFORION VET 100MG/ML INJ 10X100ML PLHU	Orion Animal Health Ltd. Főti telephely 2151 Fót, Keleti M. u. 19. Tel: +36 (0)23 450 100 Fax: +36 (0)23 450 101	Orion Animal Health Ltd. Főti telephely 2151 Fót, Keleti M. u. 19. Tel: +36 (0)23 450 100 Fax: +36 (0)23 450 101	Orion Animal Health Ltd. Főti telephely 2151 Fót, Keleti M. u. 19. Tel: +36 (0)23 450 100 Fax: +36 (0)23 450 101

PHOENIX Pharma Zrt.
Fóti telephely
2151 Fót, Keleti M. u. 19.
Csak a piros szín hiteles!
20-03



BATCH CERTIFICATE

COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128520
Batch Number: 1812843
Order Number: 80836605

Date of Manufacture: 06.11.2017
Date of Expiration: 10.2020

Quantity: 72 PCE

Marketing authorization number: 23471/08 MGSZH ATI
1652 CS

Manufacturing site: Orion Corporation, Espoo plant
Ononitie 1 FI-02200 ESPOO
GMP Compliance of Manufact. site: 005703706 08 02 00/2015

Quality control site: Orion Corporation, Espoo plant
Ononitie 1 FI-02200 ESPOO
GMP Compliance of Quality Ctrl site: 005703706 08 02 00/2015

Packaging site: Orion Corporation, Espoo plant
Ononitie 1 FI-02200 ESPOO
GMP Compliance of Packaging site: 005703706 08 02 00/2015

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 29.12.2017 12:59:16 by a Qualified Person Katri Salonen

Manufacturing and packaging sites			
Orion Corporation, Espoo plant Ononitie 1 FI-02200 ESPOO GMP Compliance of Manufact. site: 005703706 08 02 00/2015	Orion Corporation, Espoo plant Ononitie 1 FI-02200 ESPOO GMP Compliance of Quality Ctrl site: 005703706 08 02 00/2015	Orion Corporation, Espoo plant Ononitie 1 FI-02200 ESPOO GMP Compliance of Packaging site: 005703706 08 02 00/2015	Orion Corporation, Espoo plant Ononitie 1 FI-02200 ESPOO GMP Compliance of Packaging site: 005703706 08 02 00/2015

PHOENIX Pharma Zrt.
Fóti telephely
2151 Fóti, Keleti M. u. 19.
Csak a piros szín hiteles!
Minőség: **2017**