

COMFORION VET 100MG/ML INJEKCIÓ 10X100ML
 Gysz:1824179 Lej:21/01/31
 Kisz:10X100ML Me.:Doboz
 SZÉKELY KFT részére

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Comforion Vet 100mg/ml injekció A
 Gysz:1824179 Lej:21/01/31
 Kisz:10x100ml Me.:doboz
 MEDIMPEX GYÓGYSZER ZRT. részére

2151 F6t
 Keleti Márton u. 19.
 Tel:27/537-100
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COMFORION VET 100MG/ML INJ 10X100ML PLHU

CERTIFICATE OF ANALYSIS

Product Number: 128020
 Batch Number: 1824179
 Order Number: 80896033

Date of Manufacture: 07.02.2018
 Date of Expiration: 01.2021
 Storage: Below +30 °C
 Specification: Hungary (108831) 24.08.2018

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY CTRL SITE
Clarity of solution	113194-1	clear nmt ref. suspension I	clear	Esppoo
Colour of solution	108916-2	colourless to yellowish nmt ref. solution GY5	nmt ref. solution Y5	Esppoo
Appearance of container	108913-2	nmt ref. solution Y5 amber glass inject:bottle	amber glass inject:bottle	Esppoo
Volume in container	108906-2	100 ml - 105 ml	102 ml	Esppoo
pH	108804-2	6.2 - 6.8	6.4	Esppoo
Partic-matter, presence of visib.partic.	121755-1	practically no particles	practically no particles	Esppoo
Identification, ketoprofen, HPLC	108919-3	positive	positive	Esppoo
Identification, UV spectrum	108919-3	positive	positive	Esppoo
Assay, ketoprofen per stated amount	108919-3	95.0 % - 105.0 %	100.2 %	Esppoo
Identification, benzyl alcohol, HPLC	108919-3	positive	positive	Esppoo
Identification, benzyl alcohol, UV spect	108919-3	positive	positive	Esppoo
Assay, benzyl alcohol per stated amount	108919-3	90.0 % - 110.0 %	99.6 %	Esppoo
Identification, arginine	106881-2	positive	positive	Esppoo
Assay, arginine per stated amount	106881-2	90.0 % - 110.0 %	100.5 %	Esppoo
Test for sterility	113205-1	sterile	sterile	Esppoo
Bacterial endotoxins	121853-1	nmt 150 EU/ml	nmt 150 EU/ml	Esppoo

Orion Corporation, Registered office and domicile: Osmontie 1, P.O. Box 100, Tampere, Finland.
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Handwritten signature



CERTIFICATE OF ANALYSIS

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COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128020
Batch Number: 1824179
Order Number: 80858033

TESTS	METHOD	REQUIREMENTS	RESULTS	QTTY 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 15.03.2018 08:27:19 by a Qualified Person Kati Salonen

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BATCH CERTIFICATE

COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128020
Batch Number: 182479
Order Number: 80856033

Date of Manufacture: 07.02.2018
Date of Expiration: 01.2021

Quantity: 94 PCE

Marketing authorization number: 23471/08 MGSZH ATI
1852/08

Manufacturing site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO

GMP Compliance of Manufact. site: 005703/08.08.02.00/2015

Quality control site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO

GMP Compliance of Quality Ctrl site: 005703/08.08.02.00/2015

Packaging site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPOO

GMP Compliance of Packaging site: 005703/08.08.02.00/2015

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 15.03.2018 09:27:19 by a Qualified Person Katri Salonen

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