



COMFORION VET 100MG/ML INJ 10X100ML PLHU

CERTIFICATE OF ANALYSIS

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Product Number: 120020  
 Batch Number: 1780556  
 Order Number: 80795265  
 Date of Manufacture: 13.04.2017  
 Date of Expiration: 03.2020  
 Storage: Store below +50°C  
 Specification: Hungary (10863-1) 24.06.2016

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL SITE
Clarity of solution	113164-1	clear ppt ref. suspension I colorless to yellowish ppt ref. solution GYS	clear ppt ref. solution Y5	Espp0
Colour of solution	108916-2	amber glass injec.bottle 100 ml - 105 ml 6.2 - 6.8	amber glass injec.bottle 100 ml 6.4	Espp0
Appearance of container Volume in container	108913-2 108809-2	amber glass injec.bottle 100 ml - 105 ml		Espp0
pH	127755-1	practically no particles	practically no particles	Espp0
Particulate matter, presence of visib. partic.	108919-3	positive	positive	Espp0
Identification, ketoprofen, HPLC	108919-3	positive	positive	Espp0
Identification, ketoprofen, UV spectrum	108919-3	96.0 % - 105.0 %	100.7 %	Espp0
Assay, ketoprofen per stated amount	108919-3	positive	positive	Espp0
Identification, benzyl alcohol, HPLC	108919-3	positive	positive	Espp0
Assay, benzyl alcohol per stated amount	108919-3	90.0 % - 110.0 %	101.0 %	Espp0
Identification, aq.ingre	108919-3	positive	positive	Espp0
Assay, aq.ingre per stated amount	108919-3	90.0 % - 110.0 %	100.4 %	Espp0
Test for sterility	113205-1	sterile	sterile	Espp0
Bacterial endotoxins	121853-1	ppm 150 EU/ml	ppm 150 EU/ml	Espp0

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CERTIFICATE OF ANALYSIS

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COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128020  
Batch Number: 1790556  
Order Number: 80795266

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.LTY 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 20-09-2017 15:53:33 by a Qualified Person Károl Salamon

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az másolat példány  
hitelesítésre szánt hitelesítéssel  
2017.09.20



COMFORION VET 100MG/ML INJ 10X100ML PL.HU

BATCH CERTIFICATE

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Product Number: 12R020  
Batch Number: 17R0556  
Order Number: R0795296

Date of Manufacture: 13.04.2017  
Date of Expiration: 03.2020

Quantity: 84 PCX

Marketing authorization number: 23477/08 MSZFH ATN  
195208

Manufacturing site: Orion Corporation, Espoo plant  
Choninki 1 FI-02200 ESPOO  
GMP Compliance of Manufact. site: 00364208 08 02 002015

Quality control site: Orion Corporation, Espoo plant  
Choninki 1 FI-02200 ESPOO  
GMP Compliance of Quality Ctrl site: 00364208 08 02 002015

Packaging site: Orion Corporation, Espoo plant  
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GMP Compliance of Packaging site: 00364208 08 02 002015

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..... sz. másolatú példány  
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..... sz. másolatú példány



BATCH CERTIFICATE

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COMFORION VET 100MG/ML INJ 10X100ML PLHU

Product Number: 128020  
Batch Number: 1780556  
Order Number: 80785296

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.

Effectively approved 28.08.2017 13:53:33 by a Qualified Person Kari Salonen

<p>Orion Corporation          US REGISTRATION          Orion Inc, 12201 Shiloh          P.O. Box 51, Canton, OH          44705-0051, USA          Tel: +1 330 427 1000          Fax: +1 330 427 1000</p>	<p>Manufacturing location number: 80072340 (HU0102001)</p> <p>Regulatory contact: Kari Salonen          P.O. Box 51, 00001          Tel: +358 10 220 7775          Fax: +358 10 220 7775</p>	<p>Sales and service contact:          P.O. Box 1000, 00001          Tel: +358 10 220 7775          Fax: +358 10 220 7775</p>	<p>Amendment 2 3110 S.A. 2          P.O. Box 1000          Tel: +358 10 220 7775          Fax: +358 10 220 7775</p>
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