

Comforion Vet 100mg/ml injekció A
 Gysz:1484008
 Kisz:10x100ml
 Me.:doboz
 DR. SZÉKELY KFT. részére

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COMFORION VET 100 MG/ML INJ 10X100MLPLHU
 Product Number 128020
 Batch Number 1484008
 Order Number 80433221

Date of Manufacture: 28.05.2012
 Date of Expiration: 05.2015
 Storage: Room temp: +15..25°C
 Specification: Hungary(108631) 01.02.2011

CERTIFICATE OF ANALYSIS

TESTS	METHOD	REQUIREMENTS	RESULTS
Clarity of solution	113164-1	clear	clear
Colour of solution	108918-2	nmt ref. suspension I colourness to yellowish nmt ref. solution QV5	nmt ref. solution QV5
Appearance of container	108913-2	amber glass injectable 100 ml - 105 ml nmt ref. solution V5	amber glass injectable 104 ml
pH	108904-2	6,2 - 6,8	6,4
Identification, ketoprofen, HPLC	108919-3	positive	positive
Identification, ketoprofen, UV spectrum	108919-3	positive	positive
Assay, ketoprofen, per stated amount	108919-3	95,0 % - 105,0 %	102,3 %
Identification, benzyl alcohol, HPLC	108919-3	positive	positive
Identification, benzyl alcohol, UV spect	108919-3	positive	positive
Assay, benzyl alcohol per stated amount	108919-3	90,0 % - 110,0 %	102,0 %
Identification, arginine	108981-2	positive	positive
Assay, arginine per stated amount	108987-2	90,0 % - 110,0 %	101,8 %
Partic. cont., 10 µm or larger in cont.	118130-1	nmt 3000	7
Partic. cont., 25 µm or larger in cont.	118130-1	nmt 300	4
Test for sterility	113205-1	sterile	sterile
Bacterial endotoxins	140744-1	nmt 150 EU/ml	nmt 150 EU/ml

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 Csak a piros szín hiteles!
 20-09



CERTIFICATE OF ANALYSIS

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COMPRON VET 100 MG/ML INJ 10X100MLPLHU
Product Number: 128020
Batch Number: 144008
Order Number: 80439221

TESTS	METHOD	REQUIREMENTS	RESULTS
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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 02.10.2012 08:25:46 by a Qualified Person Orko Lehtinen

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Csak a piros színű hitelesítéssel!
20-03