richterpharma ag

Adresse / address:

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Richter Pharma AG
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Analysenzertifikat / Certificate of analysis

Produkt / Product: **Rifen 100mg/ml injekció ló szarvasmarha és sertés részére A.U.V. 100ml**
Chargennr. / batch no.: **0516318AA** Herstelldatum / manufacturing date: **17.05.2016**
Menge / Quantity: **907** Ablaufdatum / expiry date: **04.2019**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
General characteristics:		
Appearance:	clear, colourless to almost colourless or yellowish or brownish solution	complies
Colour:	n.m.t. B6 - Y6 - BY6	B7
Clarity:	clear	clear
pH:	6.0 - 7.5	6.7
Density [g/cm3] 20°C:	1.038 - 1.048	1.045
Visible particles:	none	complies
Filling volume:	n.l.t. 100ml	102 ml
Identity:		
Ketoprofen:	1)Principle peak in the sample and standard chromatogram must correspond in retention time 2) Rf-value of sample and standard spot must correspond	1)complies 2)complies
Benzyl alcohol:	1)Peak in the sample chromatogram must correspond in relative retention time to the peak in the standard chromatogram 2) Rf-value of sample and standard spot must correspond	1)complies 2)complies
Arginine:	Sample spot must correspond to standard	complies
Content:		
Ketoprofen:	100 mg/ml (95.0 - 105.0 mg/ml)	97.9 mg/ml
Benzyl alcohol:	10 mg/ml (9.0 - 11.0 mg/ml)	9.9 mg/ml
Impurities:*		
Ketoprofen imp. A:	≤ 0.50%	<0.3 %
Single unknown impurity:	≤ 0.50%	<0.3 %
Total impurities:	≤ 1.0%	<0.3 %
Sterility:	sterile	sterile
	*Reporting Limit 0.3% according to CVMP/VICH/838/99-Rev.1	

"I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP"

Freigabedatum / date of release: 01.07.2016

Sachkundige Person / Qualified Person: Dr. Bernd Follrich i.a.