

Adresse / address:

TolnAgro Allatgyogyaszati Kft.
Rakoczi ut 142-146
H-7100 SZEKSZARD

Richter Pharma AG
Feldgasse 19
A-4600 Wels

Analysenzertifikat / Certificate of analysis

Produkt / Product: **Rifen 100mg/ml injekció ló szarvasmarha és sertés részére A.U.V. 100ml**
Chargennr. / batch no.: **0915597AB** Herstellungsdatum / manufacturing date: **28.09.2015**
Menge / Quantity: **1.156** Ablaufdatum / expiry date: **08.2018**

| 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 | B8 |
| Clarity: | clear | clear |
| pH: | 6.0 - 7.5 | 6.9 |
| Density [g/cm³] 20°C: | 1.038 - 1.048 | 1.044 |
| 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: | 100mg/ml (95 - 105mg/ml) | 99.6 mg/ml |
| Benzyl alcohol: | 10mg/ml (9 - 11mg/ml) | 10.0 mg/ml |
| Impurities:* | | |
| Ketoprofen imp. A: | ≤ 0.50% | <LOD |
| Single unknown impurity: | ≤ 0.50% | <LOQ |
| Total impurities: | ≤ 1.0% | <LOQ |
| Sterility: | sterile | sterile |
| *LOD=0.007% LOQ=0.020% | | |

"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: 13.11.2015

Sachkundige Person / Qualified Person: Dr. Irene Pfaffenzeller