

richterpharma ag

Adresse / address:

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RUMÄNIEN

Richter Pharma AG
Feldgasse 19
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Analysenzertifikat / Certificate of analysis

Produkt / Product: **Novasul Solution for injection of Metamizol sodium 500mg/ml for horse cattle | dog 100ml**
Chargenr. / batch no.: **0915604AC** Herstellungsdatum / manufacturing date: **30.09.2015**
Menge / Quantity: **3.104** Ablaufdatum / expiry date: **08.2018**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
Appearance:	clear, yellowish solution, pract. free from particulate matters	complies
Clarity:	clear	clear
Colour:	n.m.t. BY2, GY2, Y2	GY3
pH-value:	6.5 - 7.8	7.0
Density (g/cm3):	1.1546 - 1.1642	1.1594
Identity/Assay:		
Metamizole-Sodium:	500.0 mg/ml (475.0 - 525.0 mg/ml)	500.2 mg/ml
Benzyl alcohol:	10.0 mg/ml (9.0 - 11.0 mg/ml)	10.0 mg/ml
Impurities:		
4-Aminoantipyrine:	≤ 1.0 %	< LOD
Phenazone:	≤ 1.0 %	< LOD
Single unknown	≤ 1.0 %	< 0.3 %
Impurities:		
Total impurities:	≤ 2.0 %	< 0.3 %
Sterility	sterile	sterile

"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:

03.12.2015

Sachkundige Person / Qualified Person:

Dr. Irene Pfaffensteller