

Adresse / address:

Toln Agro Allatgyogyas. Kft.
Rakoczi UT 146
7100 Szekszard
Hungary

Richter Pharma AG
Feldgasse 19
A-4600 Wels

Analysezertifikat / Certificate of analysis

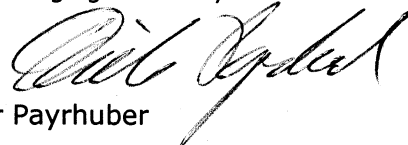
Produkt / Product:	Spasium comp. 500 mg/ml + 4 mg/ml solution for injection	
Chargennr. / batch no.:	0816549AG	Herstelldatum / manufacturing date: 18.08.2016
Menge / Quantity:	2080	Ablaufdatum / expiry date: 07.2019

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
General characteristics:		
Appearance:	clear, yellowish solution	complies
Clarity:	clear	clear
Colour:	n.m.t. GY3 -Y3	GY3
pH-value:	5.0 – 6.0	5.5
Density [g/cm³]:	1.130 – 1.190	1.161 g/cm ³
Visible particles:	none	complies
Filling volume:	n.l.t. 100ml	103 ml
Identity:		
Metamizole (1):	peak pattern in the sample chromatogram corresponds in retention time to the peak pattern in the standard chromatogram	complies
Metamizole (2):	deep red solution is generated	complies
Hyoscine butylbromide (1):	peak in the sample chromatogram corresponds in retention time to the peak in the standard chromatogram	complies
Hyoscine butylbromide (2):	Rf-value of sample and standard spot must correspond	complies
Phenol (1):	peak in the sample chromatogram corresponds in retention time to the peak in the standard chromatogram	complies
Phenol (2):	characteristic odour	complies
Sodium:	yellow to orange coloured flame	complies
Bromide:	white precipitate occurs	complies
Content:		
Metamizole sodium x 1 H₂O	500.0 mg/ml (475.0 – 525.0 mg/ml)	502.8 mg/ml
Hyoscine butylbromide:	4.0 mg/ml (3.80 – 4.20 mg/ml)	4.13 mg/ml
Phenol:	5.0 mg/ml (4.625 – 5.50 mg/ml)	4.971 mg/ml
Impurities:		
Related to metamizole sodium:		
4-aminoantipyrine:	≤ 0.50%	< 0.3 %
Single unknown impurity:	≤ 0.50%	< 0.3 %
Total impurities:	≤ 1.0%	< 0.3 %
Related to hyoscine butylbromide:		
Single unknown impurity:	≤ 0.50%	< 0.3 %
Total impurities:	≤ 1.0%	< 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:

22.03.2017



Sachkundige Person / Qualified Person:

Dr. Dietmar Payrhuber