

Adresse / address:

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

Richter Pharma AG
Feldgasse 19
A-4600 Wels

Analysenzertifikat / Certificate of analysis

Produkt / Product: **Primalen injekció A.U.V 100ml**
Chargennr. / batch no.: **0414219AB** Herstellungsdatum / manufacturing date: **09.04.2014**
Menge / Quantity: **5666** Ablaufdatum / expiry date: **06.04.2016**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
General characteristics:		
Appearance:	clear, colourless to slightly yellowish solution	complies
Clarity:	clear	clear
pH-value:	3.7 - 5.0	4.4
Density [g/cm³] 20°C:	1.160 - 1.177	1.170
Filling volume:	100ml (97 - 103ml)	102ml
Identity:		
Calcium:	characteristic absorption at 422.7nm	complies
Magnesium:	characteristic absorption at 285.2nm	complies
Calciumglycerophosphate:	a greenish-yellowish precipitate occurs	complies
Caffeine:	retention times of the analyte in standard and sample solution must correspond	complies
Assay:		
Calcium:	2.56g/100ml (2.432 - 2.688g/100ml)	2.538 g/100ml
Magnesium chloride hexahydrate:	6.4g/100ml (6.08 - 6.72g/100ml)	6.37 g/100ml
Caffeine:	2.5g/100ml (2.375 - 2.625g/100ml)	2.537 g/100ml
Calciumglycerophosphate:	6.6g/100ml (5.94 - 7.26g/100ml)	6.66 g/100ml
Endotoxins:	< 12.6 E.U./ml	< 0.5 E.U./ml
Sterility:	sterile	sterile

Freigabedatum / date of release:

22.05.2014

Sachkundige Person / Qualified Person:

Dr. Bernd Follrich