

**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: **Primalen injekció A.U.V 100ml**  
 Chargennr. / batch no.: **0316192AA** Herstellungsdatum / manufacturing date: **17.03.2016**  
 Menge / Quantity: **6725** Ablaufdatum / expiry date: **15.03.2018**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
<b>General characteristics:</b>		
<b>Appearance:</b>	clear, colourless to slightly yellowish solution	complies
<b>Clarity:</b>	clear	clear
<b>pH-value:</b>	3.7 - 5.0	4.5
<b>Density [g/cm<sup>3</sup>] 20°C:</b>	1.160 - 1.177	1.170
<b>Filling volume:</b>	100ml (97 - 103ml)	103 ml
<b>Identity:</b>		
<b>Calcium:</b>	characteristic absorption at 422.7nm	complies
<b>Magnesium:</b>	characteristic absorption at 285.2nm	complies
<b>Calciumglycerophosphate:</b>	a greenish-yellowish precipitate occurs	complies
<b>Caffeine:</b>	retention times of the analyte in standard and sample solution must correspond	complies
<b>Assay:</b>		
<b>Calcium:</b>	2.56g/100ml (2.432 - 2.688g/100ml)	2.607 g/100ml
<b>Magnesium chloride hexahydrate:</b>	6.4g/100ml (6.08 - 6.72g/100ml)	6.29 g/100ml
<b>Caffeine:</b>	2.5g/100ml (2.375 - 2.625g/100ml)	2.525 g/100ml
<b>Calciumglycerophosphate:</b>	6.6g/100ml (5.94 - 7.26g/100ml)	6.64 g/100ml
<b>Endotoxins:</b>	< 12.6 E.U./ml	< 0.5 E.U./ml
<b>Sterility:</b>	sterile	sterile

Freigabedatum / date of release: 13.04.2016

Sachkundige Person / Qualified Person: Dr. Irene Pfaffenzeller