

Richter Pharma AG  
Feldgasse 19  
A-4600 Wels

## Analysenzertifikat / Certificate of analysis

Produkt / Product: **Butomidor 10 mg/ml injection A.U.V 10ml**  
Chargennr. / batch no.: **1217951AD** Herstellungsdatum / manufacturing date: **06.12.2017**  
Menge / Quantity: **518** Ablaufdatum / expiry date: **11.2020**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
<b>General characteristics:</b>		
<b>Appearance:</b>	clear, colourless to almost colourless solution	complies
<b>Clarity:</b>	clear	clear
<b>Colour:</b>	not more than B8	B9
<b>pH:</b>	3.0 - 5.5	3.4
<b>Density [g/cm<sup>3</sup>]:</b>	1.0055 - 1.0085	1.0077
<b>Identity:</b>		
<b>Butorphanol:</b>	Principle peak in the sample and standard chromatogram must correspond in retention time	complies
<b>Benzethonium:</b>	Peak in the sample chromatogram must correspond in relative retention time to the peak in the standard chromatogram	complies
<b>Sodium:</b>	Absorption at 589nm occurs	complies
<b>Chloride:</b>	2 drops 0.1N silver nitrate added, a white to off-white precipitate occurs	complies
<b>Tatrate:</b>	a purple colour is produced	complies
<b>Content:</b>		
<b>Butorphanol as base:</b>	10 mg/ml (9.5 - 10.5 mg/ml)	10.1 mg/ml
<b>Benzethonium chloride:</b>	100 mcg/ml (90.0 - 110.0 mcg/ml)	98.0 mcg/ml
<b>Impurities:*</b>		
<b>Single unknown impurity:</b>	≤ 0.50%	< 0.30 %
<b>Total impurities:</b>	≤ 1.0%	< 0.3 %
<b>Sterility:</b>	sterile	sterile
<b>* Reporting Limit 0.3% according to CVMP/VICH/838/99-Final</b>		

"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:

19.03.2018

Sachkundige Person / Qualified Person:

Dr. Dietmar Payrhuber