

Adresse / address:

TOLN AGRO ALLATGYOGYAS. KFT.
Rakoczi UT 146
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HUNGARY

Richter Pharma AG
 Feldgasse 19
 A-4600 Wels

Analysenzertifikat / Certificate of analysis

Produkt / Product: **Butomidol 10 mg/ml injection A.U.V 10ml**
 Chargennr. / batch no.: **0713360AG** Herstellungsdatum / manufacturing date: **04.07.2013**
 Menge / Quantity: **480** Ablaufdatum / expiry date: **06.2016**

Prüfungen / Tests	Spezifikation / Specifications	Ist-Werte / Results
General characteristics:		
Appearance:	clear, colourless to almost colourless solution	complies
Clarity:	clear	clear
Colour:	not more than B8	B9
pH:	3.0 - 5.5	3.4
Density [g/cm³]:	1.0055 - 1.0085	1.0076
Identity:		
Butorphanol:	Principle peak in the sample and standard chromatogram must correspond in retention time	complies
Benzethonium:	Peak in the sample chromatogram must correspond in relative retention time to the peak in the standard chromatogram	complies
Sodium:	Absorption at 589nm occurs	complies
Chloride:	2 drops 0.1N silver nitrate added, a white to off-white precipitate occurs	complies
Tatrate:	a purple colour is produced	complies
Content:		
Butorphanol as base:	10 mg/ml (9.5 - 10.5 mg/ml)	10.1 mg/ml
Benzethonium chloride:	100 mcg/ml (90.0 - 110.0 mcg/ml)	92.2 mcg/ml
Impurities:*		
Single unknown impurity:	≤ 0.50%	< LOD
Total impurities:	≤ 1.0%	< LOD
Sterility:	sterile	sterile

* Reporting Limit 0.3%
 according to
 CVMP/VICH/838/99-Final

"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: 18.11.2013

Sachkundige Person / Qualified Person: Mag. pharm. Judith Zacherl