

# SANOCHEMIA PHARMAZEUTIKA AG

A-2491 Neufeld/Leitha, Landeggerstr. 7, Tel.: +43-2624-52342-0. Fax: +43-2624-52342-143

## BATCH CERTIFICATE

NAME OF PRODUCT

**ALVEGESIC VET. 10 mg/ml**  
**Injection solution ad.us.vet**

Packaging Size:	10 ml
No. of packages:	600
Country:	Hungary/Lithuania
Marketing Authorisation no.:	3007/1/11 MgSzH ATI (10 ml)
Marketing Authorisation no.:	LT/2/10/2048/001
Manufacturer:	Sanochemia Pharmazeutika AG, Landeggerstr. 7, 2491 Neufeld/L.
Batch No.:	PN0556
Manufacturing Date:	04.2014
Expiry Date:	03.2018
Date of Analysis:	05.2014

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	SPECIFICATION	RESULT
<b>APPEARANCE:</b>	clear solution, free from visible impurities	clear solution, free from visible impurities
<b>AVERAGE CONTENTS:</b>	≥ 10.0 ml	10.8 ml
<b>COLOUR OF SOLUTION:</b>	not more intensely coloured than reference solution B9	not more intensely coloured than reference solution B9
<b>pH:</b>	3.7 – 4.7	4.0
<b>DENSITY:</b>	0.990 – 1.030 g/ml	1.011 g/ml
<b>IDENTITY:</b>		
Butorphanol: HPLC UV	Retention time conforms to standard Absorption maximum at 279 ± 3 nm Absorption minimum at 245 ± 3 nm	conforms 277 nm 246 nm
Benzethonium chloride:HPLC	Retention time conforms to standard	conforms
<b>ASSAY:</b>		
Butorphanol	HPLC: 9.50 – 10.50 mg/ml (95.0 – 105.0%)	10.31 mg/ml
Benzethonium chloride	HPLC: 0.090 – 0.105 mg/ml (90.0 – 105.0%)	0.096 mg/ml
<b>KNOWN IMPURITIES:</b>		
5.6-Dehydrobutorphanol tartrate 6.7-Dehydrobutorphanol tartrate	Σ ≤ 0.2%	< 0.1%

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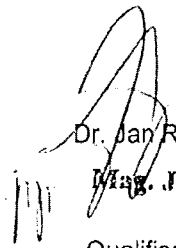
	SPECIFICATION	RESULT
<b>UNKNOWN IMPURITIES:</b>	individual: $\leq 0.2\%$	$< 0.1\%$
<b>TOTAL IMPURITIES:</b>	$\leq 1.0\%$	$< 0.1\%$
<b>STERILITY:</b>	sterile	sterile

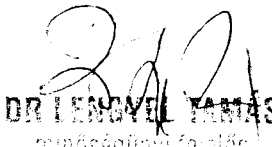
### Certification

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 in compliance with the specification in the Marketing Authorisation dossier. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

The product batch certified in this document is released for sale.

Neufeld/Leitha, 21.07.2014

  
Dr. Jan Rothenburger  
Mag. J. Gungl  
Qualified Person

  
DR. LENGYEL TAMÁS  
működőjele felhős

KERESKEDELMI CÉLRA  
FELSZABADÍTVA