

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.: PN1557
 Manufacturing Date: 12.2014
 Expiry Date: 11.2018
 Date of Analysis: 01.2015

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| | SPECIFICATION | RESULT |
|---------------------------------|--|--|
| APPEARANCE: | clear solution, free from visible impurities | clear solution, free from visible impurities |
| AVERAGE CONTENTS: | ≥ 10.0 ml | 10.5 ml |
| COLOUR OF SOLUTION: | not more intensely coloured than reference solution B9 | not more intensely coloured than reference solution B9 |
| pH: | 3.7 – 4.7 | 4.1 |
| DENSITY: | 0.990 – 1.030 g/ml | 1.015 g/ml |
| IDENTITY: | | |
| Butorphanol: HPLC | Retention time conforms to standard | conforms |
| UV | Absorption maximum at 279 ± 3 nm | 279 nm |
| | Absorption minimum at 245 ± 3 nm | 246 nm |
| Benzethonium chloride: HPLC | Retention time conforms to standard | conforms |
| ASSAY: | | |
| Butorphanol | HPLC: 9.50 – 10.50 mg/ml (95.0 – 105.0%) | 10.00 mg/ml |
| Benzethonium chloride | HPLC: 0.090 – 0.105 mg/ml (90.0 – 105.0%) | 0.095 mg/ml |
| KNOWN IMPURITIES: | | |
| 5.6-Dehydrobutorphanol tartrate | Σ ≤ 0.2% | < 0.1% |
| 6.7-Dehydrobutorphanol tartrate | | |

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| | SPECIFICATION | RESULT |
|----------------------------|--------------------------|-----------|
| UNKNOWN IMPURITIES: | individual: $\leq 0.2\%$ | $< 0.1\%$ |
| TOTAL IMPURITIES: | $\leq 1.0\%$ | $< 0.1\%$ |
| STERILITY: | sterile | sterile |

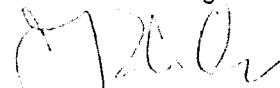
Certification

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.

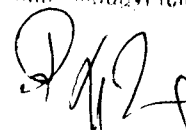
Neufeld/Leitha, 30.01.2015

Dr. Jan Rothenburger



Qualified Person

DR LENGYEL TAMÁS
minőségügyi felelős



KEHÉRSZEMÉLYI
FELELŐSÉGVÁLLÁS