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 ÁTI (10 ml)
Marketing Authorisation no.:	LT/2/10/2048/001
Manufacturer:	Sanochemia Pharmazeutika AG, Landeggerstr. 7, 2491 Neufeld/L.
Batch No.:	PO0598
Manufacturing Date:	05.2015
Expiry Date:	04.2019
Date of Analysis:	05.2015

	SPECIFICATION	RESULT
APPEARANCE:	clear solution, free from visible impurities	clear solution, free from visible impurities
AVERAGE CONTENTS:	≥ 10.0 ml	10.3 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	1.011 g/ml
IDENTITY:		
Butorphanol: HPLC	Retention time conforms to standard	conforms
UV	Absorption maximum at 279 ± 3 nm	278 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%)	9.94 mg/ml
Benzethonium chloride	HPLC: 0.090 – 0.105 mg/ml (90.0 – 105.0%)	0.094 mg/ml
KNOWN IMPURITIES:		
5.6-Dehydrobutorphanol tartrate 6.7-Dehydrobutorphanol tartrate	∑ ≤ 0.2%	< 0.1%

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	SPECIFICATION	RESULT
UNKNOWN IMPURITIES:	individual: ≤ 0.2%	0.2%
TOTAL IMPURITIES:	≤ 1.0%	0.2%
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 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, 26.08.2015

Dr. Jan Rothenburger

Qualified Person

KERESKEDELMI CÉLRA
FELSZABADÍTVA

DR LENGYEL TAMÁS