

CERTIFICATE OF ANALYSIS

Product: **Alvegesic vet. 10 mg/ml
Injectable solution, 10 ml**

Product code: **IN-BUTOR-0010-A2258 (ROU)**

Batch N°: **PU0016**

Manufacturing date: **01/2021** Expiry date: **01/2025**

Quantity: **1500 vials**

TESTS	REQUIREMENTS	RESULTS
<u>Appearance:</u>	Clear solution, free from visible impurities Not more intensely coloured than ref B9	complies complies
<u>Extractable volume:</u>	Not less than 10.0 ml	10.6 ml
<u>Density:</u>	0.990 – 1.030 g/ml	1.011 g/ml
<u>pH:</u>	3.7 – 4.7	4.0
<u>Sterility:</u>	Sterile	sterile
<u>Identification:</u>		
- Butorphanol	positive	positive
- Benzethonium chloride	positive	positive
<u>Assay:</u>		
- Butorphanol	9.50 – 10.50 mg/ml (95.0 – 105.0 %)	10.37 mg/ml (103.7 %)
- Benzethonium chloride	0.090 – 0.105 mg/ml (90.0 – 110.0 %)	0.094 mg/ml (94 %)
<u>Impurities</u>		
- Known impurities	$\Sigma \leq 0.20 \%$	< 0.2 %
5.6-Dehydrobutorphanol tartrate		
6.7-Dehydrobutorphanol tartrate		
- Unknown impurities (single)	$\leq 0.2 \%$	complies
- Total	$\leq 1.0 \%$	< 0.2 %

Conclusion: The product meets the requirements

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Name and signature of the Qualified Person:

Date: 23/03/2021

L. Aerden
Qualified Person
V.M.D. nv

