

CERTIFICATE OF ANALYSIS

Product:	ALVEGESIC 10 mg/ml <i>Injectable solution, 10 ml</i>		
Product code:	IN-BUTOR-0010-A2258 (ROU)		
Batch N°:	PR0807		
Manufacturing date:	28/08/2018	Expiry date:	08/2022
Quantity:	1500 vials		

TESTS	REQUIREMENTS	RESULTS
<u>Appearance:</u>	Clear solution, free from visible impurities Not more intensely coloured than ref B9	complies
<u>Extractable volume:</u>	Not less than 10.0 ml	complies 10.6 ml
<u>Density:</u>	0.990 – 1.030 g/ml	1.013 g/ml
<u>pH:</u>	3.7 -4.7	4.1
<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 %)	10.23 mg/ml (102.3 %)
- Benzethonium chloride	0.090 – 0.105 mg/ml (90.0 – 110.0 %)	0.093 mg/ml (93 %)
<u>Impurities</u>		
- Known impurities	$\Sigma \leq 0.20 \%$	< 0.1 %
5.6-Dehydrobutorphanol tartrate		
6.7-Dehydrobutorphanol tartrate		
- Unknown impurities (single)	$\leq 0.2 \%$	0.1 %
- Total	$\leq 1.0 \%$	0.1 %

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: 25/11/2020

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

