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Certificate of analysis

P000180

Alvegesic vet 10 mg/mL, 10 mL

Batch number : 24052103

Expiry date : 08/2028

Manufacturing date : 01/09/2024

Control number : COA006857

Quality order : QO023684/Pass

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Test	Requirements	Results
Appearance	CF Clear solution, free from visible impurities. No more intensely coloured than ref B9	CF
Density	0.990 - 1.030 g/ml	1.011 g/ml
pH :	3.7 - 4.7 .	4.1 .
Extractable volume :	CF Not less than 10,0 ml	CF
Sterility (bacterial and fungal)	CF Sterile	CF
Identification of butorphanol (HPLC)	Positive Retention time conforms to standard, absorption max at 279 +- 3nm, absorption min at 245 +- 3nm	Positive
Identification of benzethonium chloride (HPLC)	Positive Retention time conforms to standard	Positive
Assay of Butorphanol (HPLC)	9.50 - 10.50 mg/ml	10.20 mg/ml
Assay of benzethonium chloride (HPLC)	0.090 - 0.105 mg/ml	0.101 mg/ml
Known impurities : $\sum \leq 0.20 \%$	CF	CF
Unknown (single) impurity: RRT 0,32: $\leq 0,2\%$	CF	CF
Total impurities: $\leq 1,0 \%$	CF	CF

Remarks :

Test results digitally approved by Jo Wouters, on 28/11/2024
Batch disposition code RELEASED on : 29/11/2024
Electronically signed by : Leo Aerden: Qualified Person