

Alpha-Vet Ltd. Pharmaceutical Plant Bábolna	MUT-6E002-M02	Page / total: 2/2	
Appendix (B type)	Certificate of Analysis	Valid from:	06.06.2016.
		Version:	V01

RECORD NO: MB-155/2018

½ page is approval page


Product Name:	Alphalben 100mg/mL oral suspension for cows and sheep A.U.V. (HU)		
Manufacturing Site:	Alpha-Vet Ltd., Bábolna, Hungary		
Batch No.:	0718004B	Manufacturing date:	23.04.2018.
Quality by:	MUT-6B-07 V02	Expiry date:	22.04.2020.
Quantity:	247 x 1 Litre	Analytical identification numbers:	AB-4/2018.04.25. 146/AHL31/18
Storage :	Does not require any special storage conditions. Do not freeze, protect from frost!		

**Test results:**

	Specification	Results
Appearance	White or almost white suspension	Conforms
Homogeneity	Homogenous suspension, without sediments	Conforms
Resuspendability	After shaking the suspension must be homogenous, no sediments must form for 60 min.	Conforms
Ph value	5.5 – 7.5	6.82
Particle size	NLT 40% < 10 µm NLT 60% < 30 µm	84.6 % < 10 µm 98.9 % < 30 µm
Albendazole Id 1 (RRt by HPLC) Id 2 (by UV) Assay	Positive Positive 100.0 mg/mL ± 5 % (95.0 – 105.0 mg/mL) 100.0 % ± 5 % (95.0 – 105.0 % related to the declared content)	Conforms Conforms 96.45 mg/mL
Benzyl Alcohol Id (RRt by HPLC) Assay	Positive 10.0 mg/mL ± 10 % (9.0 - 11.0 mg/mL) 100.0 % ± 10 % (90.0 – 110.0 % related to the declared content)	Conforms 10.258 mg/mL
Relative density	0.980 – 1.030	1.0228
Closure integrity	The closure system must be intact, no leakage must be observed	Conforms
Deliverable volume	NLT 1000 mL and NMT 1050 mL	Conforms

I hereby certify, that the quality control of the batch has been done in accordance with the EU GMP rules. The results conform to the product specification.

Date of issue (dd.mm.yyyy): 13.06.2018.

  
 András Gombos  
 Quality Assurance / QP

