



Certificate of Analysis

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Name of Product:	Betamox LA 150 mg/ml Szuszpenziós injekció A.U.V. [Alpha Vet Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
8172-55D	1,512	April 2018	April 2020	100 ml Clear Glass Vial
Active Ingredients:	• Amoxicillin as Trihydrate			

Analytical	Results	Specifications
Appearance	Conforms	An off white oily suspension
Identification	Confirmed	Confirmed
Fill Volume	102 % (102 mL)	100 to 108% of nominal fill
Sterility	Complies	Complies with BP test for sterility
Syringeability	Conforms	Passes 21 G needle
Particle Size	Conforms	99% less than 50 micron
Resuspendability	Conforms	Meets the test requirements
Water Content	2.2 %	Not more than 3.5 %
Assay: • Amoxicillin	15.02 %w/v	14.25 to 15.75 %w/v

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 [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Prepared By:
Date of Issue:

[Signature]
12-June-2018

[Signature]

Dr Lillian Cromie
Director of Science
& Qualified Person

PASSED