



Certificate of Analysis

Norbrook Laboratories Ltd
Newry
BT35 6QQ
Northern Ireland

Tel: +44 (0) 28 3026 4435
Fax: +44 (0) 28 3026 1721
Email: enquiries@norbrook.co.uk
Web: <http://www.norbrook.com>

Name of Product:	Betamox LA 150 mg/ml Szuszpenziós Injekció A.U.V. (Alpha Vet Hungary)			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
7225-50C	2,979	May 2017	May 2019	100 ml Clear Glass Vial
Active Ingredients:	• Amoxicillin as Trihydrate (150 mg/mL)			

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	2.3 %	Not more than 3.5 %.
Assay: • Amoxicillin	15.61 %w/v	14.25 to 15.75 %w/v.

I hereby certify that the above information is authentic and accurate in so far that the specification information is available to us and we confirm that our scientific findings are true. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site (Manufacturing Authorisation Number: ManA 2000) in full compliance with GMP requirements and in accordance with the specification provided to us. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Prepared By:
Date of Issue:

Mahoe Hayes
04-July-2017

Ben Allen
Qualified Person
& Quality Advisor
PASSED