



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 150mg/ml Szuszpenzios injekcio A.U.V. [Alpha Vet Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
5162-03B	2,748	April 2015	April 2017	250ml 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	100% (252ml)	100 to 108% of nominal fill.
Particle Size	Conforms	99% less than 50 micron.
Sterility	Complies	Complies with BP test for sterility
Resuspendability	Conforms	Meets the test requirements.
Syringeability	Conforms	Passes 21 G needle.
Water Content	2.3 %	Not more than 3.5 %
Assay:		
• Amoxicillin	15.68 % 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:
Goods Invoice Number:

Nadine Anderson
26-May-2015

PASSED

APPROVED FOR THE HEAD OF QUALITY CONTROL

Mr Ken Allen M.Sc., B.Sc., MRSC
Director of Compliance
Qualified Person