



Certificate of Analysis

Norbrook Laboratories Ltd
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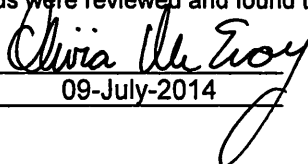
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Name of Product:	Betamox LA Injekcio A.U.V. [Alpha Vet Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
4211-52	1,847	May 2014	May 2016	250ml Clear Glass Vial
Active Ingredients:	• Amoxycillin as Trihydrate (150 mg/mL)			

Analytical	Results	Specifications
Appearance	Conforms	An off white oily suspension.
Identification	Confirmed	Confirmed.
Fill Volume	101% (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:		
• Amoxycillin	14.64 % 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:


09-July-2014

PASSED



APPROVED FOR THE HEAD OF QUALITY CONTROL

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