Certificate of Analysis

Norbrook Laboratories Ltd
Newry
BT35 6QQ
Northern Ireland

Tel: +44 (0) 28 3026 4436
Fax: +44 (0) 28 3026 1721
Email: enquiries@norbrook.co.uk
Web: http://www.norbrook.com

Name of Product:	Alamycin LA Injekcio A.U.V. (Alpha Vet Hungary)			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
7132-603F	1,224	March 2017	March 2019	100 ml Amber Glass Vial
Active Ingredient:	• Oxytetracycline as Dihydrate (200 mg/ml)			

Analytical	Results	Specifications
Appearance	Conforms	A clear amber liquid, free from visible particulates.
Identification:		
• Oxytetracycline Base	Confirmed	• Identity confirmed.
• Sodium Formaldehyde Sulphoxylate	Confirmed	• Identity confirmed.
Fill Volume	102 % (102 ml)	100 to 108% of nominal fill.
pH	8.6	8.3 to 8.8.
Sterility	Conforms	Meets the test requirements.
Light Absorbing Impurities:		
• 430nm	0.17 AU	• Not more than 0.75 absorbance units.
• 490nm	0.17 AU	• Not more than 0.40 absorbance units.
Assay:		
• Oxytetracycline Base	19.3 %w/v	• 19.0 to 21.0 %w/v.
• Sodium Formaldehyde Sulphoxylate	0.00 %w/v	• Not more than 0.44 %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: Mona Heaty
Date of Issue: 23-May-2017

Ian Allen
Technical Person
Quality Advisor
(QP)