



Norbrook®

Certificate of Analysis

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Name of Product:	Alamycin LA 300 Injekcio A.U.V. [Alpha Vet Hungary]			90125-000-04
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
5302-92C	1,872	July 2015	July 2017	100ml Amber Glass Vial
Active Ingredients:	• Oxytetracycline as Dihydrate (300 mg/mL)			

Analytical	Results	Specifications
Appearance	Conforms	A clear, dark amber liquid free from visible particles.
Identification	Confirmed	Confirmed by HPLC.
Fill Volume	102% (102ml)	100 to 108% of nominal fill.
pH	8.6	8.4 to 9.2.
Sterility	Conforms	Meets the test requirements.
Light Absorbing Impurities	Conforms	Meets the BP (Vet) 1988 test requirements for Oxytetracycline injection
Assay:		
• Oxytetracycline Base	29.2 %w/v	• 28.5 to 31.5 %w/v
• Sodium Formaldehyde Sulphoxylate	0.02 %w/v	• Not greater than 0.48 %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:

[Signature]
30-September-2015

Stephen Mitchell
 Qualified Person
 & Quality Advisor
PASSED

[Signature]

APPROVED FOR THE HEAD OF QUALITY CONTROL