



Certificate of Analysis

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Name of Product:	Tylowerfit LA Injekcio A.U.V. [Alvetra Werfit Hungary]			90643-999-01
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
5234-01G	1,224	June 2015	June 2017	100ml Clear Glass Vial
Active Ingredients:	• Tylosin (150 mg/ml)			
Storage Conditions:	Do not store above 25°C			

Analytical	Results	Specifications
Appearance	Conforms	An oily, cream suspension, which resuspends easily.
Identification	Confirmed	Identity confirmed.
Volume of Fill	102% (102ml)	100 to 108% of nominal fill.
Syringeability	Conforms	Passes freely through an 18G needle.
Resuspendability	Conforms	Not more than 20 seconds.
Sedimentation Rate	Conforms	Not more than 10% in 24 hours.
Specific Gravity	0.95 g/ml	0.94 to 0.96 g/ml.
Viscosity	37 cPs	30 to 80 cPs.
Particle Size	Conforms	95% less than or equal to 25 µm.
Water Content	0.3 %w/w	Not more than 1 %w/w.
Tyramine	Conforms	Meets the Ph. Eur test requirements.
Factor Analysis:		
• Tylosin A	93 %w/w	• Not less than 80 %w/w.
• Tylosin A, B, C & D	100 %w/w	• Not less than 90 %w/w.
Sterility	Conforms	Meets the sterility test requirements.
Assay:		
• Tylosin	155,600 iu/ml	• 149,625 to 165,375 iu/ml.

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: Claire Teague
Date: 09-July-2015
Goods Invoice Number:

PASSED

APPROVED FOR THE HEAD OF QUALITY CONTROL

Steph A Mitchell

Mr Stephen Mitchell B.Sc.
Director of Technical Compliance
Qualified Person

KERESKEDELMI CÉLRA
FELSZABADÍTVA

[Handwritten signature]

DR LENGYEL TAMÁS
minőségügyi felelős