



Certificate of Analysis

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Name of Product:	Duofast Togyinfuzio A. U. V. [Alpha Vet Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
4464-20	4,896	November 2014	November 2016	12ml Syringe
Active Ingredients:	<ul style="list-style-type: none"> • Sulphadiazine (200 mg/syringe) • Trimethoprim (40 mg/syringe) 			

Analytical	Results	Specifications
Appearance	Conforms	A white to off-white suspension.
Identification:		
• Sulphadiazine	Confirmed	• Identity confirmed.
• Trimethoprim	Confirmed	• Identity confirmed.
Express Weight:		
• Mean	8.0 g	• 8.0 to 8.2g.
• CV	0.4 %	• Not more than 3.0%.
Water Content	0.1 %	Not more than 1.0 %.
Particle Size:	Complies	• At least 95% less than 100 µm.
	Complies	• At least 75% less than 60 µm.
	Complies	• At least 50% less than 40 µm.
	Complies	• At least 25% less than 10 µm.
	Complies	• At least 5% less than 5 µm.
Stenility	Conforms	Meets the test requirements.
Assay:		
• Sulphadiazine	201 mg/syringe	• 190 to 210 mg/syringe
• Trimethoprim	40 mg/syringe	• 38 to 42 mg/syringe.

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: KELAN JAYON
 Date: 17-December-2014
 Goods Invoice Number:

PASSED

APPROVED FOR THE HEAD OF QUALITY CONTROL

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