



Certificate of Analysis

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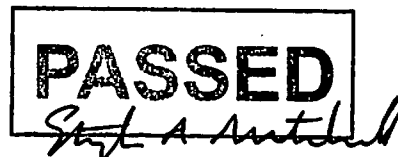
Name of Product:	Norodine 24 Injekcio A.U.V. [Alpha Vet Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
5135-604H	1,200	March 2015	March 2017	100ml Amber Glass Vial
Active Ingredients:	Sulphadiazine (200 mg/ml). Trimethoprim (40 mg/ml).			

Analytical	Results	Specifications
Appearance	Conforms	A clear, yellow solution.
Identification		
• Sulphadiazine	Confirmed	• Confirmed by HPLC.
• Trimethoprim	Confirmed	• Confirmed by HPLC.
Fill Volume	101% (102ml)	100 to 108% of nominal fill.
pH	10.1	10.0 to 10.2.
Sterility	Complies	Complies with test for sterility.
Assay:		
• Sulphadiazine	19.4 %w/v	• 19.0 to 21.0 %w/v.
• Trimethoprim	3.9 %w/v	• 3.8 to 4.2 %w/v.
• Chlorocresol	0.099 %w/v	• 0.095 to 0.11 %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:

Claire Teague
02-June-2015



APPROVED FOR THE HEAD OF QUALITY CONTROL

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