



Certificate of Analysis

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| | | | | |
|----------------------------|---|-------------------------|--------------------|-------------------------|
| Name of Product: | Betamox LA 150 mg/ml Szuszpenziós Injekció A.U.V. (Alpha Vet Hungary) | | | |
| Batch Number | Quantity | Manufacture Date | Expiry Date | Packaging |
| 6094-52A | 7,455 | March 2016 | March 2018 | 100 ml Clear Glass Vial |
| Active Ingredients: | * Amoxicillin as Trihydrate (150 mg/ml) | | | |

| Analytical | Results | Specifications |
|------------------|------------|-------------------------------------|
| Appearance | Conforms | An off white oily suspension. |
| Identification | Confirmed | Confirmed. |
| Fill Volume | 102 % | 100 to 108% of nominal fill. |
| Particle Size | Conforms | 99% less than 50 micron. |
| Sterility | Complies | Complies with BP test for sterility |
| Resuspendability | Conforms | Meets the test requirements. |
| Syringeability | Conforms | Passes 21 G needle. |
| Water Content | 2.5 % | Not more than 3.5 % |
| Assay: | | |
| * Amoxicillin | 15.32 %w/v | 14.25 to 15.75 %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:

Nadine Anderson
14-April-2016

Stephen Mitchell
Qualified Person
& Quality Advisor
PASSED

Step A Mitchell

APPROVED FOR THE HEAD OF QUALITY CONTROL