



Certificate of Analysis

Norbrook Laboratories Ltd
Newry
BT38 6QQ
Northern Ireland

Tel: +44 (0) 28 3026 4435
Fax: +44 (0) 28 3026 1721
Email: enquiries@norbrook.co.uk
Web: <http://www.norbrook.com>

Name of Product: Amoxysol LA injekció A.U.V Szuszpenziós injekció (Bayer Hungary)				
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
6242-51A	7,074	2016-06-14	2018-06-14	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 % (102 mL)	100 to 108% of nominal fill		
Sterility	Conforms	Meets the test requirements		
Syringeability	Conforms	Passes Z1 G needle.		
Particle Size	Conforms	99% less than 50 micron.		
Resuspendability	Conforms	Meets the test requirements.		
Water Content	2.5 %	Not more than 3.5 %.		
Assay:				
• Amoxicillin	15.37 %w/w	14.25 to 15.75 %w/w.		

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:

Stephen Mitchell
18 July 2016

Stephen Mitchell
Qualified Person
& Quality Advisor
PASSED

Stephen Mitchell

18 JUL 2016

Diszpó: 5928023662 Vev: ALPHA-VET File név: BA00001951 Egyedi sorszám: BA000002132 52 másolat
Szállító: Bayer Állat gyógyászati Üzletág Oldal/Lap 1 / 1 AnyagLap: 500187425
Az eredetivel megegyez elektronikus másolat a(z): Gyriné dr. min.bízt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.09.28 CertEx v 3.03a