



## Certificate of Analysis

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<b>Name of Product:</b>	Amoxysol LA Injekcio A.U.V. [Bayer Hungary]			
<b>Batch Number</b>	<b>Quantity</b>	<b>Manufacture Date</b>	<b>Expiry Date</b>	<b>Packaging</b>
7373-50D	4,917	2017-09-13	2019-09-13	100 ml Clear Glass Vial
<b>Active Ingredients:</b>	• 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 21 G needle.
Particle Size	Conforms	99% less than 50 micron.
Resuspendability	Conforms	Meets the test requirements.
Water Content	2.3 %	Not more than 3.5 %.
Assay:		
• Amoxicillin	14.83 %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:

*Mahina Hegesh*  
06-November-2017

**Stephen Mitchell**  
Qualified Person  
& Quality Advisor  
**PASSED**

*Step A Mitchell*  
07 NOV 2017