



Certificate of Analysis

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Name of Product:	Amoxysol LA Injekcio A.U.V. [Bayer Hungary]			90454-QA10-02(386)
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
8172-52A	6,912	2018-04-24	2020-04-24	100 ml Clear Glass Vial
Active Ingredients:	• Amoxicillin as Trihydrate			

Analytical	Results	Specifications
Appearance	Conforms	An off-white oily suspension
Identification: • Amoxicillin	Confirmed	• Identity: Confirmed
Volume of Fill	102 % (102 mL)	100 to 108 % of nominal fill
Sterility	Conforms	Complies with Ph. Eur. test for sterility
Syringeability	Conforms	Passes through 21 G needle
Particle Size	Conforms	99 % <50 micron
Resuspendability	Conforms	Should resuspend within 15 seconds of shaking
Water Content	2.1 %	Less than 3.5 %
Specific Gravity	0.983 g/mL	0.965 to 0.99 g/mL at 20°C
Assay: • Amoxicillin	15.01 %w/v	• 14.25 to 15.75 %w/v

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Prepared By:
Date of Issue:

Emilie Worsleand
23-May-2018

Stephen Mitchell
Qualified Person
& Quality Advisor
PASSED

Stephen A Mitchell

24 MAY 2018