



# Certificate of Analysis

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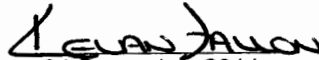
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<b>Name of Product:</b>	Supraclox LC Togyinfuzio A.U.V. [Ceva Hungary]			93002-000-01
<b>Batch Number</b>	<b>Quantity</b>	<b>Manufacture Date</b>	<b>Expiry Date</b>	<b>Packaging</b>
4425-20	4,800	October 2014	October 2016	7ml Syringe
<b>Active Ingredients:</b>	<ul style="list-style-type: none"> <li>• Cloxacillin as Sodium (200 mg/syringe)</li> <li>• Ampicillin as Sodium (75 mg/syringe)</li> </ul>			

Analytical	Results	Specifications
Appearance	Conforms	An off-white suspension.
Identification	Conforms	Confirmed by HPLC.
Fill Weight:		
• Mean	5.3 g	• 5.2 to 5.4g
• C.V.	1 %	• Not more than 4%.
Expressed Weight:		
• Mean	5.2 g	• 5.0 to 5.2g.
• C.V.	1 %	• Not more than 4%.
Expression	Complies	Complies with approved test.
Water Content	0.0 %	Not more than 1.0 %.
Sterility	Complies	BP test.
Assay:		
• Cloxacillin	4.1 %w/w	• 3.8 to 4.2 %w/w.
• Ampicillin	1.76 %w/w	• 1.43 to 1.89 %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:

04-December-2014

Goods Invoice Number:

**PASSED**

APPROVED FOR THE HEAD OF QUALITY CONTROL

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