



Certificate of Analysis

Norbrook Laboratories Ltd
Newry
BT35 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>

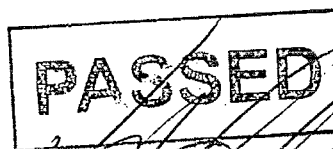
Name of Product:	Supraclox DC Tegyinfuzio A.U.V. [Ceva Hungary]			93048-018-02
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
4352-20	5,568	August 2014	August 2016	7ml Syringe
Active Ingredients:	<ul style="list-style-type: none"> • Cloxacillin as Benzathine (500 mg/tube) • Ampicillin as Trihydrate (250 mg/tube) 			

Analytical	Results	Specifications
Appearance	Conforms	An off-white cream.
Identification:		
• Cloxacillin	Confirmed	• Identity Confirmed.
• Ampicillin	Confirmed	• Identity Confirmed.
Fill Weight:		
• Mean	4.77 g	• 4.70 to 4.90 g.
• CV	0.4 %	• Not more than 4%.
Expressed Weight:		
• Mean	4.64 g	• 4.50 to 4.70 g.
• CV	0.6 %	• Not more than 4%.
Water Content	0.1 %	Not more than 2.0 %.
Sterility	Conforms	Meets the test requirements.
Particle Size	Conforms	90% ≤ 30µm.
Viscosity	112,000 cPs	50,000 to 150,000 cPs.
Assay:		
• Cloxacillin	513 mg/syringe	• 475 to 525 mg/syringe of average expressed weight.
• Ampicillin	247 mg/syringe	• 238 to 263 mg/syringe of average expressed weight.

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:

Chris McEvoy
22-September-2014



APPROVED FOR THE HEAD OF QUALITY CONTROL

Mr Ken Allen M.Sc., B.Sc., MRSC
Director of Compliance
Qualified Person