



## Certificate of Analysis

Material Name: ADVOCIN 180 INJ 100ML B1 HUN  
Material Code: 0522HUN

Lot Number: A389110

Specification: 00RS08057(17-05-2007)-100ML

Date of Manufacture: SEP. 25, 2013

Expiration Date: AUG-2015

TEST	Limit	Result
Identity (HPTLC)	MEETS TEST	MEETS TEST
Sterility	MEETS TEST	MEETS TEST
Appearance	Medium yellow to amber solution essentially free from foreign matter.	MEETS TEST
pH	7.2-7.8	7.6
Monothioglycerol content	4.5-5.5 mg/ml	4.9 mg/ml
Bacterial endotoxins	<=150 IU/ml	<= 113 IU/ml
Extractable volume	MEETS TEST	MEETS TEST
Danofloxacin content (HPLC)	171-189 mg/ml	182 mg/ml
Identity (HPLC)	MEETS TEST	MEETS TEST
Phenol content	2.38-2.63 mg/ml	2.56 mg/ml
Specified Degradation Products: CP-74,416	MAX 0.6 %	0.0 %
Specified Degradation Products: CP-83.088	MAX 0.4 %	0.0 %
Specified Degradation Products: CP-102.446	MAX 0.4 %	0.0 %
Unspecified Degradation Product	MAX 0.4 %	0.0 %
Total Degradation Products	MAX 1.0 %	0.0 %

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of Hungary or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

### QUALIFIED PERSON ASSESSMENT.

Electronic Signature: Beatrice CAZEAUX Lot Release Local Timestamp: 06-JAN-2014 09:55:31