



CERTIFICATE OF ANALYSIS

Name **CEVAXEL 4 G**  
Presentation **Vial 4 G**  
Code list **C57720A**

Batch N° **C400212A2**  
Manufacturing date **15-SEP-2014**  
Expiry date **15-AUG-2016**

Tests	Specifications	Results
<b>GENERAL CHARACTERISTICS</b>		
Appearance :	White to off white powder	COMPLIES
Average fill mass	4.228 - 4.716 g	4.497
Loss on drying :	<=4.0 %	1.2
Solution injectable :		
- Reconstituted time	Once the solvent addition is completed, should dissolve within 90 sec. with vigorous shaking	COMPLIES
- Appearance	Solution is clear and not more intensely coloured than reference solution Y2	COMPLIES
- Relative density (at 20°C)	1.010 - 1.030	1.020
- pH	6.5 - 7.5	7.0
- Particulate contamination		
>= 10 µ	<=6000	731
>= 25 µ	<=600	32
Uniformity of dosage units :	Complies to Ph.Eur. 2.9.40	COMPLIES
<b>IDENTIFICATIONS</b>		
Ceftiofur sodium :		
- HPLC	Concordant with the Rt of reference substance	COMPLIES

This batch has been tested in reference to the dossier in force and has been found to meet the specification requirements

**COMPLIES / NOT COMPLIES**

Checked by : **Maureen MAYENC**

Batch Release number **368109**

Batch Release date **13-MAR-2015**

**ACCEPTED by**

**Stéphanie ZEBST**  
Quality Assurance Manager

The undersigned certifies this is a true copy of the results of tests and assays



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<b>IDENTIFICATIONS</b>		
- IR	IR spectrum of the test is concordant with IR spectrum of the reference Ceftiofur sodium	COMPLIES
<b>ASSAYS</b>		
Related substances :		
- CFSRC-1	<=0.30 %	0.10
- CFSRC-2	<=0.30 %	0.00
- CFSRC-3	<=0.30 %	0.00
- CFSRC-4	<=0.30 %	0.10
- CFSRC-5	<=1.00 %	0.13
- CFSRC-6	<=0.30 %	0.07
- CFSRC-7	<=0.30 %	0.00
- CFSRC-8	<=0.30 %	0.15
- CFSRC-9	<=1.00 %	0.00
- CFSRC-10	<=0.30 %	0.00
- CFSRC-11	<=0.30 %	0.00
- CFSRC-12	<=0.30 %	0.00
- CFSRC-13	<=0.30 %	0.00

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<b>ASSAYS</b>		
- CFSRC-14	<=0.30 %	0.00
- CFSRC-15	<=0.30 %	0.00
- Unknown impurity (each)	<=0.50 %	0.28
- Total	<=2.50 %	1.23
Ceftiofur: (as sodium)	3800.0 - 4200.0 mg/flacon	4060.4
<b>STERILITY</b>		
According to Ph. Eur.	Sterile	COMPLIES

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