



CERTIFICATE OF ANALYSIS

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

Batch N° **C400193A3**
Manufacturing date **15-SEP-2014**
Expiry date **15-AUG-2016**

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	White to off white powder	COMPLIES
Average fill mass	4.228 - 4.716 g	4.461
Loss on drying :	<=4.0 %	0.9
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	1.022
- pH	6.5 - 7.5	7.0
- Particulate contamination		
>= 10 µ	<=6000	1179
>= 25 µ	<=600	48
Uniformity of dosage units :	Complies to Ph.Eur. 2.9.40	COMPLIES
IDENTIFICATIONS		
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 364973

Batch Release date **27-JAN-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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IDENTIFICATIONS		
- IR	IR spectrum of the test is concordant with IR spectrum of the reference Cefotiofur sodium	COMPLIES
ASSAYS		
Related substances :		
- CFSRC-1	<=0.30 %	0.13
- CFSRC-2	<=0.30 %	0.00
- CFSRC-3	<=0.30 %	0.00
- CFSRC-4	<=0.30 %	0.17
- CFSRC-5	<=1.00 %	0.00
- CFSRC-6	<=0.30 %	0.09
- CFSRC-7	<=0.30 %	0.00
- CFSRC-8	<=0.30 %	0.00
- 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 %	0.13

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COMPLIES / NOT COMPLIES

Checked by : **Maureen MAYENC**

Batch Release number **364973**

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ASSAYS		
- CFSRC-14	<=0.30 %	0.00
- CFSRC-15	<=0.30 %	0.00
- Unknown impurity (each)	<=0.50 %	0.33
- Total	<=2.50 %	1.57
Ceftiofur: (as sodium)	3800.0 - 4200.0 mg/flacon	3956.3
STERILITY		
According to Ph. Eur.	Sterile	COMPLIES

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