CERTIFICATE OF ANALYSIS

Name	**CEVAXEL 4 G**	Batch N°	**C500022A6**
Presentation	Vial 4 G		
Code list	**C57720A**	Manufacturing date	3-JAN-2015
		Expiry date	3-DEC-2016

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	White to off white powder	COMPLIES
Average fill mass	4.228 - 4.716 g	4.442
Loss on drying :	<=4.0 %	0.8
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	7.1
- Particulate contamination		
>= 10 µ	<=6000	229
>= 25 µ	<=600	11
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 378359

Batch Release date **28-AUG-2015** **ACCEPTED by**

Brice-Olivier PETTES
Head of Control Laboratory

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

Ceva **Santé Animale**
Siège **social : 10, av. de La Ballastière - 33500 Libourne - France**
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SA **au capital de 40 682 182 Euros - RCS Libourne B 301 763 405**

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Tests	Specifications	Results
IDENTIFICATIONS		
- IR	IR spectrum of the test is concordant with IR spectrum of the reference Ceftiofur sodium	COMPLIES
ASSAYS		
Related substances :		
- CFSRC-1	<=0.30 %	0.00
- CFSRC-2	<=0.30 %	0.00
- CFSRC-3	<=0.30 %	0.00
- CFSRC-4	<=0.30 %	0.08
- CFSRC-5	<=1.00 %	0.00
- CFSRC-6	<=0.30 %	0.00
- 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 %	0.00

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Tests	Specifications	Results
ASSAYS		
- CFSRC-14	<=0.30 %	0.00
- CFSRC-15	<=0.30 %	0.00
- Unknown impurity (each)	<=0.50 %	0.27
- Total	<=2.50 %	1.02
Ceftiofur: (as sodium)	3800.0 - 4200.0 mg/flacon	4088.6
STERILITY		
According to Ph. Eur.	Sterile	COMPLIES

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COMPLIES / NOT COMPLIES

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