



CERTIFICATE OF ANALYSIS

Name	CEVAXEL 4 G	Batch N°	C400021A2
Presentation	Vial 4 G	Manufacturing date	20-JAN-2014
Code list	C57720A	Expiry date	20-DEC-2015

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	White to off white powder	COMPLIES
Average fill mass	4.228 - 4.716 g	4.444
Loss on drying :	<=4.0 %	1.4
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	736
>= 25 µ	<=600	16
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 : Marine BREPSON

Batch Release number 352433

Batch Release date 19-JUN-2014

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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