



CERTIFICATE OF ANALYSIS

Name	GEVAXEL 4 G	Batch N°	C300159A3
Presentation	Vial 4 G		
Code list	C57720A	Manufacturing date	23-JUN-2013
		Expiry date	23-MAY-2015

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	White to off white powder	COMPLIES
Average fill mass	4.228 - 4.716 g	4.550
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	1.023
- pH	6.5 - 7.5	7.1
- Particulate contamination		
>= 10 µ	<=6000	773
>= 25 µ	<=600	32
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 344985

Batch Release date 17-FEB-2014

ACCEPTED by

Brice-Olivier PETTES
Head of Control Laboratory

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

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