



CERTIFICATE OF ANALYSIS

Name **CEVAXEL RTU** Batch N° **151A2**
Presentation **100 ml**
Code list **C58110E** Manufacturing date **18-DEC-2014**
Expiry date **18-DEC-2017**

Tests	Specifications	Results
CHARACTERS		
Appearance :	After a vigorous shaking, an oily beige suspension is obtained	COMPLIES
Average fill volume :	100 - 110 %	100
Relative density :	0.935 - 0.955	0.943
IDENTIFICATIONS		
Ceftiofur (as hydrochloride):		
- by HPLC	Concordant with the Rt of reference substance	COMPLIES
- by UV diode array	UV spectra superimposable	COMPLIES
TESTS		
Particles size distribution:		
D (0.5)	<5 µm	4
D (0.9)	<10 µm	7
Viscosity at 20°C:	15 - 21 mPa.s	17
Water content (KF):	<=1.0 %	0.2
Extractable volume :	>= 100 % of nominal volume	COMPLIES
Degradation products :		
- Anticeftiofur	<=1.0	0.0

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 **366714**

Batch Release date **4-MAR-2015**

ACCEPTED by

Stéphanie ZEBST
Quality Assurance Manager

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



CERTIFICATE OF ANALYSIS

Name **CEVAXEL RTU** Batch N° **151A2**
Presentation **100 ml** Manufacturing date **18-DEC-2014**
Code list **C58110E** Expiry date **18-DEC-2017**

Tests	Specifications	Results
TESTS		
- Known impurity (each)	<=1.0	0.0
- Other individual impurity (each)	<1.0	0.4
- Total	<=2.5	0.4
ASSAYS		
Ceftiofur (as hydrochloride): (HPLC)	4.75 - 5.25 % m/v	5.08
STERILITY		
According to Ph. Eur.	Sterile	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 **366714**

Batch Release date **4-MAR-2015**

ACCEPTED by

Stéphanie ZEBST
Quality Assurance Manager

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