



CERTIFICATE OF ANALYSIS

Name **CEVAXEL RTU**
Presentation 100 ml
Code list **C58110E**

Batch N° **152A1**
Manufacturing date 3-FEB-2015
Expiry date 3-FEB-2018

Tests	Specifications	Results
CHARACTERS		
Appearance :	After a vigorous shaking, an oily beige suspension is obtained	COMPLIES
Average fill volume :	100 - 110 %	102
Relative density :	0.935 - 0.955	0.948
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	16
Water content (KF):	<=1.0 %	0.1
Extractable volume :	>= 100 % of nominal volume	COMPLIES
Degradation products :		
- Anticeftiofur	<=1.0	0.3

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 : **Isabelle BERNALEAU**

Batch Release number **367774**

Batch Release date **17-MAR-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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Tests	Specifications	Results
TESTS		
- Known impurity (each)	<=1.0	0.0
- Other individual impurity (each)	<1.0	0.0
- Total	<=2.5	0.3
ASSAYS		
Ceftiofur (as hydrochloride): (HPLC)	4.75 - 5.25 % m/v	5.22
STERILITY		
According to Ph. Eur.	Sterile	COMPLIES

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