Alfasan INTERNATIONAL B.V.

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Holland
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CERTIFICATE OF ANALYSIS

product	**CEFTIOSAN, suspension for injection**			date of manufacture	07.2013
code	180	batch number	1306166.06	date of expiry	07.2016

specifications	results	requirements
Appearance	conform	creamy white to off-white oily suspension
Density	0.937	0.929 - 0.949 g/ml
Active ingredients: - Identification Ceftiofur HCL	positive	positive
- Quantitative analysis Cefiofur (as HCL)	50.2	47.5 – 52.5 mg/ml
Purity tests: -Individual impurities	0.2	≤ 0.7% of the area of the main ceftiofur peak
-Total impurities	0.5	≤ 3.0% of the area of the main ceftiofur peak
Sterility	sterile	sterile
Container	conform	injection vials, 100 ml
Closures	conform	bromobutylrubber stoppers and non re-usable aluminum closures

remarks

We hereby certify that the above mentioned information is authentic and accurate.This batch of product has been manufactured, including packaging / labeling and quality control in full compliance with the GMP-requirements of the local regulatory authority and with the specifications as agreed with the marketing authorization holder/contract giver of the importing country. The batch processing, packaging and analyses records were reviewed and found to be in compliance with GMP.

date of report

2-9-2013

Quality Control Alfasan INTERNATIONAL B.V. P.O. Box 78 3440 AB Woerden Holland

Woerden, Date: 03-09-2013

Drs. A van Drunen, QP
Manager QA/QC