Alfasan INTERNATIONAL B.V.

Kuipersweg 9 - 3449 JA Woerden, Holland
P.O. Box 78 - 3440 AB Woerden, Holland
Tel. +31 348 41 69 45
Fax +31 348 42 35 77
E-mail: alfasan@wxs.nl

CERTIFICATE OF ANALYSIS

product	**VITAMIN K, solution for injection**		date of manufacture 06.2014
code 900	batch number 1406171.07		date of expiry 12.2015

specifications	results	requirements
Appearance	conform	limpid, colourless solution
Density	1.011	1.003 - 1.023 g/ml
Acidity	3.5	2.0 - 5.0 pH units
Active ingredients: - Identification Menadione sodium bisulfite	positive	positive
- Quantitative analysis Menadione sodium bisulfite	9.8	9.5 – 10.5 mg/ml
Preservatives	conform	within limits
Sterility	sterile	sterile
Container	conform	injection vials, 10 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

11-12-2014

Quality Control Department

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

Woerden, Date: 11-12-2014

Drs. A van Drunen, QP
Manager QA/QC