

CERTIFICATE OF ANALYSIS

product	VITAMINE K, solution for injection	date of manufacture	12.2015
code	900	batch number	1512362.02
		date of expiry	12.2017

specifications	results	requirements
Appearance	conform	limpid, colourless solution
Density	1.012	1.003 - 1.023 g/ml
Acidity	3.6	2.0 - 5.0 pH units
Active ingredients:		
- Identification		
Menadione sodium bisulfite	positive	positive
- Quantitative analysis		
Menadione sodium bisulfite	10.3	9.5 – 10.5 mg/ml
Preservatives	conform	within limits
Sterility	sterile	sterile
Container	conform	injection vials, 10 ml
Closures	conform	bromobutyrrubber 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

8-2-2016

Quality Control Department


 P.O. Box 78
 3440 AB Woerden
 Holland

Woerden:

 Drs. A. van Drunen
 Ir. A.P.F. Philipsen
 Qualified Person