

# CERTIFICATE OF ANALYSIS

<b>product</b>	<b>VITAMINE K 10 MG/ML, solution for injection</b>	<b>date of manufacture</b>	12.2015
<b>code</b>	900	<b>batch number</b>	1512362.04
		<b>date of expiry</b>	06.2017

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	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**

10-3-2016

Quality Control Department

  
 INTERNATIONAL B.V.

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Woerden:


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