

SANOCHEMIA PHARMAZEUTIKA AG

A-2491 Neufeld/Leitha, Landeggerstr. 7, Tel.: +43-2624-52342-0. Fax: +43-2624-52342-143

BATCH CERTIFICATE

NAME OF PRODUCT

CAROFERTIN

Solution for Injection

Packaging Size: 100 ml
No. of packages: 8345
Presentation: International
Manufacturer: Sanochemia Pharmazeutika AG, Landeggerstr. 7, 2491 Neufeld/Leitha
Batch No.: PM1046
Manufacturing date: 09.2013
Expiry Date: 08.2015
Date of Analysis: 09.2013

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	SPECIFICATION	RESULT
APPEARANCE:	dark-red solution, free of visible impurities	dark-red solution, free of visible impurities
AVERAGE CONTENTS:	100 – 104 ml	104 ml
DENSITY:	0.995 – 1.005 g/ml	1.000 g/ml
pH:	5.0 – 6.0	5.7
IDENTITY:		
β-Carotene HPLC	retention time conforms to standard	conforms
Ascorbyl Palmitate HPLC	retention time conforms to standard	conforms
D,L- α –Tocopherol HPLC	retention time conforms to standard	conforms
Benzyl Alcohol GC	retention time conforms to standard	conforms
ASSAY:		
β-Carotene HPLC	9.50 – 10.50 mg/ml (95.0 – 105.0%)	9.59 mg/ml 95.9%
Ascorbyl Palmitate HPLC	≤ 0.100 mg/ml	0.015 mg/ml
D, L- α –Tocopherol HPLC	0.090 – 0.110 mg/ml (90.0 – 110.0%)	0.091 mg/ml
Benzyl Alcohol GC	9.50 – 10.50 mg/ml (95.0 – 105,0%)	9.93 mg/ml 99.3 %
STERILITY:	sterile (Ph.Eur.)	sterile

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Certification

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and in compliance with the specification in the Marketing Authorisation dossier. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

The product batch certified in this document is released for sale.

Neufeld/Leitha, 20.01.2014

Dr. Jan Rothenburger



Qualified Person

DR LENCYEL TAMÁS
primáris orvosi felelős
KERESKEDELMI CÉLRA
FELSZABADÍTVA