

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 10 mg/ml Solution for Injection

Packaging Size 100 ml
No. of packages: 3090
Countries: Hungary, Czech Republic, Slovakia
Marketing Authorization No.: Hungary 3375/1/13
Czech Rep.: 96/1342/97-C
Slovakia.: 06/007/04-S
Manufacturer: Sanochemia Pharmazeutika AG, Landeggerstr. 7, 2491 Neufeld/Leitha
Batch No.: PP0600
Manufacturing date: 04.2016
Expiry Date: 03.2018
Date of Analysis: 05.2016

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	SPECIFICATION	RESULT
APPEARANCE:	clear dark-red solution (microemulsion), free of visible impurities	clear dark-red solution (microemulsion), free of visible impurities
AVERAGE CONTENTS:	≥ 100 ml	103 ml
DENSITY:	0.995 – 1.005 g/ml	1.000 g/ml
pH:	5.0 – 7.0	5.5
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%)	9.55 mg/ml 95.5%
Ascorbyl Palmitate HPLC	≤ 0.100 mg/ml	0.013 mg/ml
D, L- α –Tocopherol HPLC	0.090 – 0.110 mg/ml (90.0 – 110.0%)	0.104 mg/ml
Benzyl Alcohol GC	9.50 – 10.50 mg/ml (95.0 – 105,0%)	10.14 mg/ml 101.4%
MICROBIOLOGY:		
Sterility	sterile	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, 16.06.2016

Dr. Jan Rothenburger



Qualified Person



KERESKEDELMÉI CÉLRA
FELSZABADÍTVA

DR LENGYEL TAMÁS
minőségügyi felelős