Test Report

Sponsor	EnviteC-Wismar GmbH, Mr. Michael Schiffner, Alter Holzhafen 18, 23966 Wismar
Date of order	11-07-08
Test	Chemical analysis (characterization of organic leachables/extractables) EN ISO 10993-12, -18, LM P 8-01, LM SOP 8-01-01
Test material	T-adapter 22 mm/15 mm [Specified by the sponsor. Storage light-protected at 20-25 °C.]
Arrival of material	11-07-11/11-08-02
Study director	Dipl.-Ing. (FH) Ingrid Bierl
Beginning of study	11-07-21
End of study	11-08-11
Quality statement	Directive 93/42/EEC, 90/385/EEC, EN ISO/IEC 17025 (ZLG-P-870.96.08 accredited)
Data storage	All raw data of this study and a copy of this report in the archives of the supplier, samples of the test material by the sponsor.
Note	This report shall not be reproduced except in full without the written approval of Medical Device Services. The test results shown in this report relate only to the items tested.

Akkreditiert durch Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-P-870.96.08

Scope

The aim of this work was to determine the extent to which the organic constituents of the test material or additives used in the process of manufacture will be available under the actual conditions of use of the finished product. For this, extraction tests on the test material were performed. Appropriate extraction conditions were used to ensure that any organic constituent which is likely to be released during finished product use will be released into the extraction media: The test material was extracted with an organic solvent to maximize the migration of organic substances as well as with an aqueous solution that simulates product use. The extracts obtained were analysed qualitatively and quantitatively by gas chromatography to generate data that can then be used in the biological safety evaluation of the medical device.

Medical Device Services – DR. ROSSBERGER GmbH
Lilienthalstraße 4 · 82205 Gilching · Tel. +49 8105 7783-30 · Fax +49 8105 26152
www.mdservices.de · mds@mdservices.de
Geschäftsführer Dr. Stephan Roßberger · Handelsregister München HRB 107579
HypoVereinsbank München · Konto 2713660 · BLZ 700 202 70
Kreissparkasse München Starnberg · Konto 430037192 · BLZ 702 501 50 · Id.-Nr. DE811727131

Test method

Extraction

In order to remove superficial dirtying, the test material was cleaned with a common used detergent solution and tap water and placed for 10 min into 70 % v/v isopropanol. The isopropanol was allowed to evaporate for 15 min. Afterwards, the test material was rinsed with distilled water and extraction medium. Then, it was extracted light-protected with 5 % ethanol in distilled water and isopropanol, respectively, for 24 ± 2 h at 37 ± 1 °C. A surface area to volume ratio of 3 cm²/ml extraction medium was used. 5 % ethanol in distilled water and isopropanol, respectively, without test material were incubated 24 ± 2 h at 37 ± 1 °C as blanks.

Ethanol (REF 1.00983.1000) and isopropanol (REF 1.09634.1000) were purchased from Merck, Darmstadt, distilled water (Ampuwa, approval no. 40676.00.00) from Fresenius Kabi Deutschland, Bad Homburg.

Characterization and quantification

The ethanol/water and the isopropanol extract were measured by gas chromatography coupled with mass spectroscopy (GC-MS). The released organic compounds of the mass spectra were characterized by comparison with the NIST/EPA/NIH 2005 Mass Spectral Library. The ethanol/water extract was also measured by gas chromatography coupled with flame ionization detector (GC-FID) for the quantification of the released organic compounds. For this, guajacol in 5 % ethanol in distilled water solution was used as external standard. The sum of FID signals in the gas chromatogram was integrated and corrected by the blank.

Following equipment and settings were used:

- Gas chromatograph: TRACE GC Ultra, Thermo Fisher
- Column: TRACE TR-5MS, 30 m - 0.25 mm i.D., 0.5 µm film thickness
- Temperature program: 40 °C (5 min), heat rate 10 °C/min to 300 °C, 300 °C (10 min)
- Mass spectrometer: DSQ II, Thermo Fisher
- Scan range of mass spectrometer: 35 - 650 Dalton
- Scan rate of mass spectrometer: 0.5 s
- Flame ionization detector: trace detector, Thermo Fisher

Results

In the present investigation the test material was extracted with 5 % ethanol in water and isopropanol for 24 h at a physiological temperature of 37 °C. The released organic substances were quantified by GC-FID and characterized by GC-MS.

The test material showed no changes in colour or shape after ethanol/water and isopropanol extraction. The extracts did not differ optically from the blanks.

The amount of organic substances in the ethanol/water extract was below the limit of quantification (approx. 1 µg/cm² test material surface area, see gas chromatogram 1).

The isopropanol extract also did not contain detectable organic substances (see gas chromatogram 2). Peaks with a signal-to-noise ratio below 3 were disregarded.

I. Bierl

Dipl.-Ing. (FH) Ingrid Bierl
Study Director

p.p. Timme

Dr. Madlon Timme
Technical Manager BS-T

References

EN ISO/IEC 17025: 2005, General requirements for the competence of testing and calibration laboratories.

DIN EN ISO 10993-1: 2010-04, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system.

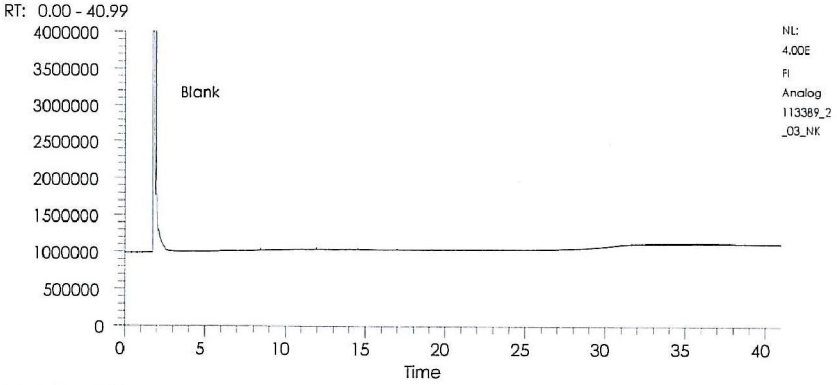
DIN EN ISO 10993-12: 2009-08, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

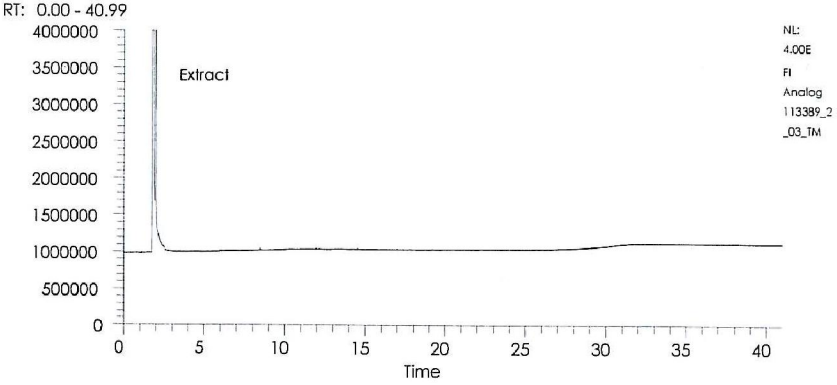
DIN EN ISO 10993-18: 2009-08, Biological evaluation of medical devices - Part 18: Chemical characterization of materials.

Gas chromatogram 1 Quantification of organic leachables by GC-FID

Test material T-adapter 22 mm/15 mm

Extraction 3 cm²/ml 5 % ethanol in water, 24 ± 2 h, 37 ± 1 °C





Gas chromatogram 2 Characterization of organic extractables by GC-MS
Test material T-adapter 22 mm/15 mm
Extraction 3 cm²/ml isopropanol, 24 ± 2 h, 37 ± 1 °C