

REPORT

Examination of an eluate of Blech mit Schicht ASOT® 7000
(Schichtdicke 0.5 - 2 µm),

on cytotoxic properties in a cell culture test

- according to USP, current edition and EN/ISO 10993-5

- Elution Test -

Sponsor:
Albrecht + Schumacher
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Study conducted by:
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and Toxicology GmbH & Co. KG
Redderweg 8
D-21147 Hamburg
Germany

Contact person:
P. Albrecht

Contact person:
Dr. phil. J. Leuschner

Test item:

Designation: Blech (21.0 cm x 30.0 cm) mit Schicht ASOT®7000
(Schichtdicke 0.5 - 2 µm)
Characteristics: light gold, solid, squarish
Receipt no.: 51434
Date of receipt: August 27, 2012

Method: Cytotoxicity Test - Elution Test

According to: USP, current edition and EN/ISO 10993-5

Eluant: Minimum essential Medium (MEM)
with Earle's salts containing 10% fetal calf serum
120 cm² material/10 ml eluant

Elution conditions: 37°C, 24 hours

Cell line: L - 929 cells
(mouse fibroblasts, ATCC CCL1, NCTC clone L 929)

Test period: calendar week 36

RESULTS

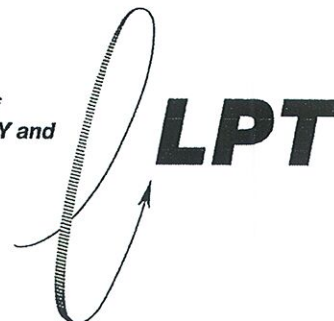
Under the present test conditions no signs of cytotoxicity (grade 0) were observed for an eluate obtained from Blech mit Schicht ASOT® 7000 (Schichtdicke 0.5 - 2 µm).

The sample meets the requirements of the USP, current edition and EN/ISO 10993-5.

The positive control resulted in severe signs of cytotoxicity (grade 4).

Hamburg, September 13, 2012

Dr. J. Leuschner



**Acute systemic toxicity of
eluates obtained from
Blech mit Schicht ASOT® 7000
(Schichtdicke 0.5 - 2 µm)
- according to EN / ISO 10993-11 -**

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INTRODUCTION

Aim of the experiment was to assess whether the intravenous and intraperitoneal administration of eluates obtained from Blech mit Schicht ASOT® 7000 (Schichtdicke 0.5 - 2 µm) in NMRI mice caused any mortality within 3 days (safety test according to EN / ISO 10993-11).

METHODS

This study was performed according to EN / ISO 10993-11 and based on the Good Laboratory Practice Regulations.

The eluates of the test item were prepared as follows:

- a) an equivalent of 120 cm²/20 mL was extracted in 0.9% NaCl solution[#] at 70°C for 24 h (polar eluate) for intravenous administration
- b) an equivalent of 120 cm²/20 mL was extracted in Sesame oil^{##} at 70°C for 24 h (unpolar eluate) for intraperitoneal administration

For this experiment 20 female mice (n = 5/eluate) with a body weight between 18 g and 23 g were used. 50 mL eluate obtained from Blech mit Schicht ASOT® 7000 (Schichtdicke 0.5 - 2 µm)/kg b.w. were administered by intravenous injection (polar) into a tail vein (injection speed: dose/15 sec) or by intraperitoneal administration (unpolar). During the following 3 days the mice were observed and the mortality determined. The test substance meets the requirements of EN / ISO 10993-11 if none of the mice dies within this period.

RESULTS

No signs of intolerance reactions, especially no mortality were observed following systemic administration of 50 mL eluate obtained from Blech mit Schicht ASOT® 7000 (Schichtdicke 0.5 - 2 µm)/kg b.w. (polar or unpolar) to mice. The test substance meets the requirements of EN / ISO 10993-11.

Hamburg, September 19, 2011


Dr. J. Leuschner

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