

LPT Report No. 24557/1

REPORT

**Examination of an eluate of Blech goldgelb 0,1 mm mit Schicht ASOT® 1000
(Schichtdicke 3 – 6 µm),
on cytotoxic properties in a cell culture test
- according to USP 29 and EN/ISO 10993-5 -
- Elution Test -**

Sponsor:
Albrecht & Schuhmacher
Oberflächentechnik GmbH
Graf-Zeppelin-Ring 15
D-27211 Bassum
Germany

Study conducted by:
LPT Laboratory of Pharmacology
and Toxicology GmbH & Co. KG
Redderweg 8
D-21147 Hamburg
Germany

Contact person:
P. Albrecht

Contact person:

Test item:

Designation: Blech goldgelb 0,1 mm mit Schicht ASOT® 1000
(Schichtdicke 3 – 6 µm)
Characteristics: golden yellow, solid, sheet
Receipt no.: 43067
Date of receipt: 03.07.2009

Method: Cytotoxicity Test - Elution Test

According to: USP 29 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 28

RESULTS

Under the present test conditions no signs of cytotoxicity (grade 0) were observed for an eluate obtained from Blech goldgelb 0,1 mm mit Schicht ASOT® 1000 (Schichtdicke 3 – 6 µm).

The sample meets the requirements of the USP 29 and EN/ISO 10993-5.

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

Hamburg, July 14, 2009



Dr. J. Leuschner

LPT Report No. 24558/1

**ACUTE SYSTEMIC TOXICITY OF
ELUATES OBTAINED FROM
BLECH GOLDGELB 0,1 MM MIT SCHICHT ASOT® 1000 (SCHICHTDICKE 3 – 6 µm)
- according to EN / ISO 10993-11 -**

Sponsor:
Albrecht & Schuhmacher
Oberflächentechnik GmbH
Graf-Zeppelin-Ring 15
27211 Bassum
Germany

Study conducted by:
LPT Laboratory of Pharmacology
and Toxicology GmbH & Co. KG
Redderweg 8
21147 Hamburg
Germany

Contact person:
P. Albrecht

Contact person:
Dr. phil. J. Leuschner

Test Item:

Designation: Blech goldgelb 0,1 mm mit Schicht ASOT® 1000
(Schichtdicke 3 – 6 µm)
Characteristics: golden yellow, solid, sheet
Receipt no.: 43067
Date of receipt: 03.07.2009
Test period: calendar week 30

INTRODUCTION

Aim of the experiment was to assess whether the intravenous and intraperitoneal administration of eluates obtained from Blech goldgelb 0,1 mm mit Schicht ASOT® 1000 (Schichtdicke 3 - 6 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 and the respective blank eluates 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

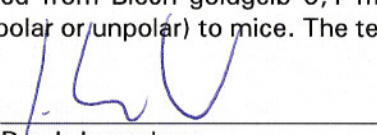
For this experiment 20 female mice (n = 5/eluate and 5/blank) with a body weight between 20 g and 22 g were used. 50 mL eluate obtained from Blech goldgelb 0,1 mm mit Schicht ASOT® 1000 (Schichtdicke 3 - 6 µm)/kg b.w. were administered by intravenous injection (polar) into a tail vein (injection speed: 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 goldgelb 0,1 mm mit Schicht ASOT® 1000 (Schichtdicke 3 - 6 µm)/kg b.w. (polar or unpolar) to mice. The test substance meets the requirements of EN / ISO 10993-11.

Hamburg, July 27, 2009


Dr. J. Leuschner

batch no. 05809201, DeltaSelect GmbH, 63303 Dreieich, Germany
batch no. 4434201, Henry Lamotte, 28197 Bremen, Germany