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ACUTE ORAL TOXICITY SIGHTING STUDY OF MEGA BAC 10% IN THE RAT

FINAL REPORT

Date: 08 March 2004

Submitted to: **NeuMedix Biotechnology Pty Ltd**
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1.0. SUMMARY

The acute oral toxicity of **Mega Bac 10%** was investigated in groups of 2 Sprague Dawley Specific Pathogen Free (SPF) rats at a single dose level.

The test item was administered orally by intragastric gavage to one (1) group of 2 rats (1/sex) at the maximum administerable volume of 10 mL/kg. A control groups of 2 rats (1/sex) was dosed with the vehicle alone (water). Body weights were determined immediately before test item administration and daily thereafter. All animals were observed at frequent intervals on the day of test item administration, and then daily for signs of toxicity over the 7-day experimental period. At the end of the experimental period, on Day 8, all surviving animals were sacrificed and subjected to a gross necropsy examination.

There were no deaths or abnormal clinical signs in any animal during the experimental period.

Overall body weight gains occurred in all animals.

There were no gross abnormalities found in the major organs of any animal treated with the vehicle or test item at autopsy.

Under the conditions of this study, the test item, **Mega Bac 10%**, produced no signs of toxicity when administered at a volume of 10 mL/kg.

2.0. INTRODUCTION

2.1. Sponsor

Gelair Pty Ltd
PO Box 20
Tweeds Heads, NSW 2485
AUSTRALIA.

2.2. Study number

ICPQN410.A
ICP Firefly protocol ICPQN410.A, Schedule 2.

2.3. Study director

Miaofen Shen, B.Med.

2.4. Rationale for the study

In the assessment and evaluation of the toxic characteristics of a substance, determination of acute intravenous toxicity is useful where exposure by the intravenous route is likely. The aim of the study was to obtain information on the dose-toxicity relationship at various doses and to determine the maximum tolerated dose for the main study. The experimental procedure was based on OECD guidelines for the testing of chemicals, No. 401.

2.5. Study timetable

Protocol acceptance date	23 October 2003
Study initiation date	24 October 2003
Animal arrival date	26 November 2003
Experimental start date	1 December 2003
Experimental completion date	9 December 2003
Study completion date	16 December 2003

2.6. Study integrity

Deviations from the Study Plan:

1. The test item and vehicle were administered at concentrations supplied by the sponsor. The maximum dose is 10 mL/kg at 1000 ppm.
2. Originally 5 different dose levels were intended to be administered at one dose level per group, with a sixth group acting as the control vehicle group. However, in this study, only two dose levels were administered at concentrations of 500 ppm (Group 2) and 1000 ppm (Group 3), respectively, and the control vehicle group (Group 1). This was because no toxic signs were observed at the maximum dose (group 3). The volumetric dose equivalent was 10 mL/kg. Animals in Groups 4 to 6 were not treated and they were sacrificed at completion of study.
3. Organs and carcasses were frozen and sent to Sponsor as per Sponsor's requirements.

Deviations from the Study Plan are presented in Appendix E.