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TEST REPORT

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SPONSOR:

InterHealth AB
Kungsängsvägen 27
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Sweden

ECOMER ALKYLGLYCEROLS

COAGULATION TEST IN BLOOD FROM PIGS

AUTHOR:

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

The investigation described in this report "Ecomer Alkylglycerols - Coagulation Test in Blood from Pigs" was carried out under my supervision and responsibility and in accordance with the OECD Principles of Good Laboratory Practice (as revised in 1997), which are essentially in conformity with:

EEC Principles of Good Laboratory Practice, Directive 87/18/EEC,
United States Food and Drug Administration, Title 21, CFR, Part 58, and
Japanese Ministry of Health and Welfare, PAB Notification No. 424.

The report is a complete and accurate account of the methods employed and the data obtained.

SCANTOX
27 May 1999



C Nicholas Edwards, BSc, PhD
Study Director

QUALITY ASSURANCE STATEMENT

The Quality system at Scantox complies with the OECD principles of Good Laboratory Practice and the European Standards EN45001.

Short term routine studies of the type described in this report "Ecomer Alkylglycerols - Coagulation Test in Blood from Pigs" are inspected by the Quality Assurance Unit in compliance with the principles of Good Laboratory Practice. Process-based inspections are carried out regularly. Inspection reports have been communicated to the Study Director and to the management of Scantox.

Date of most recent inspection:

8 April 1999

Date of report to Study Director and management:

8 April 1999

This report has been audited by the Quality Assurance Unit and was found to be an accurate description of the methods and procedures used during the conduct of the study and an accurate reflection of the raw data.

Date of final audit:

27 May 1999

27 May 1999



Susanne B Nissen, MSc
QA Auditor

PERSONNEL RESPONSIBLE FOR THE STUDY

Study Director

C N Edwards
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Quality Assurance

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SUMMARY

Ecomer Alkylglycerols was tested for its ability to affect the rate of coagulation of samples of pig blood *in vitro*.

Aliquots of the test article oil (0.5 g each) were covered with fresh pig blood (2.5 ml) in a plastic tube, immediately placed in a water bath at 37°C, and shaken regularly. The time taken for total coagulation of each sample was recorded. Blind controls (no treatment), negative controls (treated with pieces of negative control plastic), and positive controls (treated with Fuller's Earth) were tested concurrently. All control and test treatments were replicated using blood from four pigs.

Results from the control treatments demonstrated the efficacy and sensitivity of the test system.

It is concluded that the test article, Ecomer Alkylglycerols, did not reduce the mean coagulation time of blood compared to the blind (untreated) control time in this study.

INTRODUCTION

The objective of the Coagulation test was to evaluate the effect of the test article on the rate of coagulation of blood samples from pigs.

The experimental work was performed on 27 May 1999.

This report describes the procedures used and the results obtained.

MATERIALS AND METHODS

Test article

Ecomer Alkylglycerols

Synonym: Ecomer shark liver oil

Chemical name: Diesters of alkylglycerols

Batch No: 990106

Expiry: 01/2002

Intended use: Immune system stimulator

Description: A light yellow oil

The test article was received from the Sponsor on 12 May 1999. Two blister cards were supplied, each with 30 transparent soft gelatine capsules, each containing 250 mg of the test article.

Test article characterization (purity, solubility and stability etc.) was the responsibility of the Sponsor. The test article was labelled with the laboratory number of this study and kept at room temperature in the dark. The test results relate to the above mentioned test article supplied by the Sponsor.

Control materials

USP Reference Standard Negative Control: high density polyethylene rod
Fuller's Earth; Surrey Finest Grade, JCJ, England

Coagulation test procedure

Aliquots of the test article oil (0.5 g/tube), USP Reference Standard Negative Control (2 pieces/ tube) and Fuller's Earth (100 mg/tube) were placed in separate 10 ml plastic tubes (Nunc, Denmark). A fourth tube was left empty.

A fresh blood sample was obtained by venipuncture (Bijugular trunc) of a pig using a Vacutainer (plain glass). Aliquots (2.5 ml) of the blood were added to each of the four tubes. Immediately, the tubes were placed in a water bath at 37°C and shaken regularly until coagulation occurred. The time taken between the start of the test and complete coagulation was recorded for each tube.

The test was performed a total of four times using blood samples taken from four pigs.

The ratio of the weight of the test article to the volume of blood was 0.2 g/ml. This ratio was selected on the basis of guidance given in the US Pharmacopeia (23rd edition, <88> Biological reactivity tests, *in vivo*) for the preparation of extracts.

Archives

For a period of 10 years the following material relating to the study will be retained in the archives of Scantox:

- Protocol and correspondence
- Test material receipts
- All original data
- Final report

At the end of the storage period Scantox will contact the Sponsor for instructions whether the material should be transferred, retained or destroyed.

RESULTS

The results are presented in Table 1.

The test article did not cause a reduction in the mean coagulation time compared to the blank (untreated) control value.

The negative control plastic caused only a slight reduction in the mean coagulation time.

The positive control treatment with Fuller's Earth caused a reduction in the mean coagulation time to 55% of the blank control value.

CONCLUSION

It is concluded that the test article, Ecomer Alkylglycerols, did not reduce the mean coagulation time of blood compared to the blind (untreated) control time in this study.

Ecomer Alkylglycerols

Coagulation Test

Pig No.	Time for total coagulation						
	Blind control	Negative control		Positive control		Test article	
	T (sec)	T (sec)	%	T (sec)	%	T (sec)	%
1	239	225	94	155	65	239	100
2	385	303	79	180	47	285	74
3	318	314	99	168	53	385	121
4	295	265	90	159	54	309	105
Mean	309	277	91	166	55	305	100
SD	60	40	9	11	8	61	20

Key:

T (sec) Time taken for total coagulation (in seconds)
% Coagulation time as a percentage of corresponding blind control time
SD Standard deviation

Blind control No treatment
Negative control Treatment with negative control plastic
Positive control Treatment with Fuller’s Earth
Test article Treatment with test article