

APPENDIX III



THE DEPARTMENT OF HEALTH OF THE GOVERNMENT
OF THE UNITED KINGDOM

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE
IN ACCORDANCE WITH DIRECTIVE 88/320 EEC

LABORATORY
SafePharm Laboratories Limited
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Derby
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DATE OF INSPECTION

17 March 1992

A general inspection for compliance with the Principles of Good Laboratory Practice was carried out at the above laboratory as part of the UK GLP Compliance Programme.

At the time of the inspection no deviations were found of sufficient magnitude to affect the validity of studies performed at these facilities.

11/6/92.

D. F. Moore
Director
UK GLP Monitoring Unit

CONFIDENTIAL

CODE NUMBER: 329179 (50 ppm):

ACUTE EYE IRRITATION

TEST IN THE RABBIT

PROJECT NUMBER 28/6

AUTHOR: P.P. Tomlinson

STUDY SPONSOR:

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QUALITY ASSURANCE REPORT

The routine inspection of short term studies at Safepharm Laboratories is carried out as a continuous process designed to encompass all major phases of each study type once per month. Dates of the most recently completed series of monthly inspections relevant to the study type(s) in this report are given below.

Date(s) of Inspection and Reporting:

02/12/92, 15/12/92

This report has been audited by Safepharm Laboratories Quality Assurance Unit. It is considered to be an accurate account of the data generated and of the procedures followed.

Date of Report Audit:

14/01/93

J.R. Pateman C. Biol., M.I. Biol.
FOR SAFEPHARM QUALITY ASSURANCE UNIT

J.R. Pateman.....

DATE:

..... 20/01/93

GLP COMPLIANCE STATEMENT

I, the undersigned, hereby declare that the objectives laid down in the protocol were achieved and as nothing occurred to adversely affect the quality or integrity of the study, I consider the data generated to be valid. This report fully and accurately reflects the procedures used and data generated in the study, and the work described was performed in compliance with the following principles of Good Laboratory Practice.

Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health 1989.

Organisation for Economic Co-operation and Development, ISBN 92-64-12367-9, Paris 1982.

.....*P. Tomlinson*..... DATE:*18.1.93*.....

P.P. Tomlinson B.Sc. (Hons)
Study Director
for Safepharm Laboratories

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S U M M A R Y

STUDY SPONSOR : CENTRILAB

PROJECT NUMBER : 28/6

TEST MATERIAL : CODE NUMBER: 329179 (50 ppm)

1. A study was performed to assess the irritancy potential of the test material to the eye of the New Zealand White rabbit. The method used followed that described in the OECD Guidelines for Testing of Chemicals (1987) No. 405 "Acute Eye Irritation/Corrosion" referenced as Method B5 in Commission Directive 84/449/EEC (which constitutes Annex V of Council Directive 67/548/EEC).

The results may be used as a basis for classification and labelling under Annex VI of Council Directive 67/548/EEC (as adapted to technical progress by Commission Directive 91/325/EEC).

2. A single instillation of the test material to the non-irrigated eye of three rabbits produced no adverse ocular effects.

3. The test material produced a maximum group mean score of 0.0 and was classified as non-irritating (Class 1 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.

The test material was also classified as non-irritant according to EEC labelling regulations. No symbol and risk phrase are required.

