

FINAL REPORT

SR-53929i: 35 Day Oral (Capsule Administration) Tolerance Study in the Monkey with a 2 Week Treatment-free Period

Report for: Symphar
243 route des Fayards
1290 Versoix
Geneva
Switzerland

Author: N M Shepherd

Test facilities:	Corning Hazleton (Europe) Otley Road Harrogate North Yorkshire HG3 1 ENGLAND	Symphar 243 route des Fayards 1290 Versoix Geneva Switzerland
------------------	---	---

CHE study number: 267/31

Report issue date: February 2002

Page number: 1 of 10

4.4 Achieved concentration

Not appropriate on a capsule study.

5 TEST SYSTEM

5.1 Species, strain and supplier

Fifteen male purpose-bred cynomolgus monkeys (*Macaca fascicularis*) were obtained from Consort Bioservices, Steyning, UK and were bred by Del Mundo Trading, Mandaluyong, Metro Manila, Philippines. The animals on this study were used on previous studies conducted at CHE (Study Numbers 267/18, 20, 22, 23, 24, 26, 27, 28, 29 and 30).

5.2 Specification

The animals will be young adults in a weight range 3.0 to 6.0 kg at the start of the study.

5.3 Environment

The animals will be housed in a single room, air-conditioned to provide a minimum of 10 air changes/hour. Routinely the temperature and relative humidity ranges will be 18 to 25°C and 40 to 80% respectively. Fluorescent lighting will be controlled automatically to give a cycle of 12 hours light (0700 to 1900) and 12 hours dark.

The animals will be housed singly during the day in cages 1.1 m high with a minimum floor area of 0.8 square metres. Where possible, animals of the same group will be group housed overnight to allow social contact.