
40 C.F.R. § 795.231

Pharmacokinetics of isopropanol.

(a) *Purpose.* The purposes of these studies are to:

- (1) Ascertain whether the pharmacokinetics and metabolism of the “test substance” are similar after oral and inhalation administration.
- (2) Determine bioavailability of the test substance after oral and inhalation administration.
- (3) Examine the effects of repeated dosing on the pharmacokinetics and metabolism of the test substance.

(b) *Definitions.* (1) “*Bioavailability*” refers to the rate and relative amount of administered test substance which reaches the systemic circulation.

(2) “*Metabolism*” means the study of the sum of the processes by which a particular substance is handled in the body, and includes absorption, tissue distribution, biotransformation, and excretion.

(3) “*Pharmacokinetics*” means the study of the rates of absorption, tissue distribution, biotransformation, and excretion.

(c) *Test procedures—(1) Animal selection—(i) Species.* The rat shall be used because it has been used extensively for metabolic and toxicological studies.

(ii) *Test animals.* For pharmacokinetics testing, adult male and female rats (Fischer 344 or strain used for major toxicity testing), 7 to 9 weeks of age, shall be used. The animals should be purchased from a reputable dealer and shall be identified upon arrival at the testing laboratory. The animals shall be selected at random for the testing groups and any animal showing signs of ill health shall not be used. In all studies, unless otherwise specified, each test group shall contain at least four animals of each sex for a total of at least eight animals.

(iii) *Animal care.* (A) Animal care and housing should be in accordance with DHEW Publication No. (NIH)-85-23, 1985, entitled “Guidelines for the Care and Use of Laboratory Animals.”

(B) The animals should be housed in environmentally controlled rooms with at least 10 air changes per hour. The rooms shall be maintained at a temperature of 22 ± 2 °C and humidity of 50 ± 20 percent with a 12-hour light/dark cycle per day. The animals shall be kept in a quarantine facility for at least 7 days prior to use and shall be acclimated to the experimental environment for a minimum of 48 hours prior to treatment.

(C) During the acclimatization period, the animals should be housed in suitable cages. All animals shall be provided with certified feed and tap water *ad libitum*.

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