

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 31-R-0091

2. Number 4 total, 1 in Column E of animals used in this study.

3. Species (common name) Dog of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Animal dosed orally with test article. Single dose, for rising dose study caused death overnight. The animal was found dead in its cage the morning following dosing.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Had the animal been found to be in distress at the evening observation, appropriate measures would have been taken to relieve the animal. As the animal was found dead in its cage the next morning, there was no way to relieve distress.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

NP 12-22-2010

NOV 24 2010

Obtained by Rise for Animals.

Uploaded to Animal Research Laboratory Overview (ARLO) on 09/03/2020

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1. Registration Number: 31-R-0091

2. Number 32 total, 1 in Column E of animals used in this study.

3. Species (common name) Cyno Monkey of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Animal dosed orally with test article. Test article was inadvertently instilled into the lungs, which was confirmed by histopathology following necropsy.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The animal, although test article had been placed in the lungs, showed no outward signs of distress following dosing. The animal was then found dead in its cage at cageside observations. Therefore, no relief of pain or distress could be administered.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

NP 12 - 22 - 2013

NOV 24 2013

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