Toxikon Corporation
14-R-0101
Annual Report of Research Facility
2020-2021

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part or in full), the animal room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by laypersons as well as scientists.

---

1. **Registration Number:** 14-R-101
2. **Number of animals used in the study(s):** (b) (4)
3. **Specie (common name) of animals used in this study(s).** Guinea Pig
4. **Explain the procedure producing pain and/or distress.**

(b) (4)

5. **Attach or include with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used.** (For Federally mandated testing, see question 6 below)

(b) (4)

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):**

ISO 10993-10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation Sensitization.

ISO 10993-12, 2012 & 2021, Biological Evaluation of Medical Devices – Part 12: Sample Preparation Reference Materials

OECD 406, Organization for Economic Co–Operation and Development (OECD), Guidelines for the Testing of Chemicals, “Skin Sensitization”, adopted 17 July, 1992, corrected 14 June 2021.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

FDA, CDRH, June 16, 2016, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluations and testing within a risk management process"

Toxikon Corporation
14-R-0101
Annual Report of Research Facility
2019-2020

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part or in full), the animal room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by laypersons as well as scientists.

---

1. **Registration Number:** 14-R-101
2. **Number of animals used in the study(s):** (b) (4)
3. **Specie (common name) of animals used in this study(s).** Rabbits
4. **Explain the procedure producing pain and/or distress.**

(b) (4)

5. **Attach or include with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used.** (For Federally mandated testing, see question 6 below)

(b) (4)

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):**

ISO 10993-11, 2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

ISO 10993-12, 2012 & 2021, Biological Evaluation of Medical Devices – Part 12: Sample Preparation Reference Materials

USP 43, National Formulary 38, 2020. <151> Pyrogen Test. & USP-NF 2021. <151> Pyrogen Test

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

FDA, CDRH, June 16, 2016, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluations and testing within a risk management process"