**PŘÍLOHA Č. 1**

**Benchtop Performance testing**

**Thermal Effects on Tissue**

|  |  |  |  |  |
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|  |  |  |  |  |
| Revision | Page | Change | Date | Signature |
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| Issued by | Expertly reviewed by | Approved by |
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| xxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxx |
| Valid from | xxxxxxxxxxxxxxxxxxxx |

Contents

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## Investigator

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| --- | --- |
| Principal Investigator Name, Title | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Date, Signature |  |

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| Co-investigator Name, Title | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Date, Signature |  |

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| --- | --- |
| Co-investigator Name, Title | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Institution | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Date, Signature |  |

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| --- | --- |
| Co-investigator Name, Title | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Date, Signature |  |

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| Co-investigator Name, Title | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Date, Signature |  |

## Sponsor

|  |  |
| --- | --- |
| Name, Title | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| Date, Signature |  |

# Study Aim

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# Period of Study

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# Type of Animal Testing

* 1. **Literature Review**
* xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	1. **3R Principles**

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# Laboratory Animals

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* 1. **Classification of Protocol according to Scientists Center for Animal Welfare (SCAW) Category**

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* 1. **Animal Testing Site**

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* 1. **Risk Factors and Substances**

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* 1. **Specific Procedures**

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# Test Article

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# Test Method and Procedures

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### Muscle Tissue

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Tab. 1

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **intensity** | **time [sec]** | **sample** | **time [sec]** | **sample** | **time [sec]** | **sample** |
| 0 |  0 0M0 |
| x |  |  |  |  |  |  |
| xxxxxxxxxxxxx |  | xxxxxxxxxxx |  | xxxxxxxxxxxx |  |
|  |  |  |  |  |  |
| x |  |  |  |  |  |  |
| xxxxxxxxxxxxx |  | xxxxxxxxxx |  | xxxxxxxxxxxx |  |
|  |  |  |  |  |  |
| x |  |  |  |  |  |  |
| xxxxxxxxxxx |  | xxxxxxxxx |  | xxxxxxxxxxxx |  |
|  |  |  |  |  |  |

### Liver

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Tab.2

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **intensity** | **time [sec]** | **sample** | **time [sec]** | **sample** | **time [sec]** | **sample** |
| 0 |  0 0L0 |
| xxxx |  |  |  |  |  |  |
| xxxxxxxxxxx |  | xxxxxx |  | xxxxxxxxxxxx |  |
|  |  |  |  |  |  |
| xxx |  |  |  |  |  |  |
| xxxxxxxxxx |  | xxxxxxx |  | xxxxxxxxxxxx |  |
|  |  |  |  |  |  |
| xxx |  |  |  |  |  |  |
| xxxxxxxxxx |  | xxxxxx |  | xxxxxxxxxxx |  |
|  |  |  |  |  |  |

### Kidney

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Tab.3

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **intensity** | **time [sec]** | **sample** | **time [sec]** | **sample** | **time [sec]** | **sample** |
| 0 |  0 0K0 |
| xxx |  |  |  |  |  |  |
| xxxxxxx |  | xxxxxxxxxxx |  | xxxxxxxxxx |  |
|  |  |  |  |  |  |
| xxx |  |  |  |  |  |  |
| xxxxxxx |  | xxxxxxxxxxx |  | xxxxxxxxxx |  |
|  |  |  |  |  |  |
| xxx |  |  |  |  |  |  |
| xxxxxxxxx |  | xxxxxxxxxx |  | xxxxxxxxxx |  |
|  |  |  |  |  |  |

# Study Endpoint

## Generaly

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|  |  |
| --- | --- |
| Intensity | Energy at set times and intensities |
| xxxxxxxxx | xxxxxxxxxxxxxx | xxxxxxxxxxx | xxxxxxxxxxx |
| xxxxxxxx | xxxxxxxxxxxxxx | xxxxxxxxxxx | xxxxxxxxxxx |
| xxxxxxxx | xxxxxxxxxxxxxx | xxxxxxxxxxx | xxxxxxxxxxx |

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# Statistical Analysis and Evaluation of Data

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# Circumstances That May Affect the Quality of the Data

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# Acceptance Criteria

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**Tab. 4**

|  |  |
| --- | --- |
| Criteria | Evaluation (YES/NOT) |
| xxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| xxxxxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |

# Pass/Fail Criteria

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