**V1.1 Nonclinical Study Report Template for Repeat‑Dose Toxicology Studies**

**About This Template & Template Disclaimer**

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**Components of the Study Report Template**

* **Individual Sections** contain study report information common to most standard single-dose or repeat-dose toxicity.

**Core Backbone Headings**

* For reference and mapping purposes, Level 1 and 2 headings are generally intended to be consistent across study reports that use the template.
* The headings and order of sections are designed to generally align with and link to the companion protocol template; however, only relevant sections should be maintained in the report.

**Formatting and Text Conventions**

* Common Text: Black font is common or suggested language that can be harmonized across the protocol and the report templates. This text can be used as written to maintain consistency across template users but can be adapted if required.
* Instructional Text: Red italicized text is intended to aid in authoring of the study report in this template. At times, example variables may be provided within instructional text for illustration purposes. All language should be reviewed to ensure it is appropriate for the specific study, and if not, be customized or altered as necessary.

Study Report

|  |  |
| --- | --- |
| Study Title: | *Copy and paste the title from the protocol*  |
| Test Facility Name: | *NameAddress* |
| Study Number: | *Number* |
| Sponsor:Sponsor Reference ID:*(optional)* | *Name* *Address**Unique Study ID* |

GLP Status [GLPFL]: *[GLP/Non GLP]*

*Note: Title page may be updated to include company specific information, headers, footers and logo. Internal SOP reference and company statement may also be included as appropriate.*

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Approval

*Delete or add signature lines based on company specific requirements.*

The signature below <OR on the last page of the document> acknowledges the Study Director’s responsibility to the study as defined by the relevant GLP regulations.

The signature below <OR on the last page of the document> indicates that the Study Director approves the study report.

 Date:

*[Insert Name, Credentials]*
Study Director

Summary

*The summary defines the basic/high level elements of the study objectives, study design, and all test article-related effects, typically introducing the most impactful findings first and organizing information in an integrated manner based on organ systems and correlating effects. This section should include important findings across the study that are relevant to risk assessment (for example, all deaths and other non-test article-related findings potentially important to the MOA or requiring extensive consideration) and clarify interpretations and/or significance of findings in relationship to one another. Where applicable and where feasible, a determination of and supporting justification for whether the finding is adverse should be provided in this section. This section should contain sufficient detail to allow the reader to understand the identified target organs or effects and which findings are considered adverse or non-tolerated, leading the reader to understand the basis for setting of the NOAEL. A conclusion statement should be included that is short and concise and identifies the no-observed-adverse-effect-level (NOAEL) and may include the following: Mortality/lethal dose, target organ toxicities, the Cmax and AUC at the NOAEL*

Discussion *(optional)*

*The Discussion Section is optional**and should provide information to further contextualize the study findings, the MOA/pharmacology of the test article, and/or may include references to literature to support this. The Discussion Section should not be a copy/paste of the Summary Section.*

# Objective

*Restate the study objective section from the protocol, change tense as appropriate.*

# Experimental Design

C*opy Experimental Design table from protocol*

| **Group No.** | **Test Article or Vehicle** | **Dose Level (mg/kg/day)** | **Dose Volume (mL/kg)** | **Concentration (mg/mL)** | **No. of Animals** |
| --- | --- | --- | --- | --- | --- |
| **Dosing Phase** | **Recovery Phase** | **Toxicokinetics** |
| **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
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| - = not applicable. |

# Study Schedule

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| --- |
| *[Update to include the actual study dates rather than proposed]* *Schedule detail may vary based on study/sponsor/CRO needs.*  |
| Study Initiation Date (date protocol signed):  | *Date* |
| Experimental Start Date (date of first data collection): | *Date* |
| Dosing Start Date: | *Date* |
| Dosing End Date: | *Date* |
| Experimental Completion Date (date of last data collected):  | *Date* |

#  Sponsor/Test Facility/Test Site Information

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Key Personnel

[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol. There may be variations as to the amount of personal identifiable information that is included based on CRO/Sponsor agreements]

**Materials and Methods**

*For the Level 1 headers, copy corresponding section from Protocol and change tense as appropriate OR a link to the corresponding protocol section (current protocol including amendments) will be included and the link to the Level 1 headers for each section will be used to navigate to the Level 2 or Level 3 headers that fall within that section. If there are changes to the study not reflected in the amended protocol, be sure to bring them forward in the appropriate section of the report (e.g., animal replacement, notes to file, deviations, etc.).*

# Test Item/Article and Vehicle Control Item/Article

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol. Link to Certificate of Analysis and/or other test item/article information as appropriate.]*

# Dose Formulation

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Test System and Husbandry

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Experimental Design

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# In-life Observations and Procedures

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Clinical Pathology

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Bioanalysis

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Toxicokinetic Evaluation

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Other Testing

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Terminal Procedures

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Histology and Histopathology

[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]

# Pathology Peer Review

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Data Evaluation and Statistical Analysis

[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]

# Regulatory Information

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Quality Assurance

*[*Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol*]*

# Animal Welfare

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# Major Computer Systems

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

*or*

*populate table below with computer systems used in the study if different from protocol*

List the major computerized systems were used in the study.

|  |  |
| --- | --- |
| **System Name** | **Description of Data Collected and/or Analyzed** |
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# Deviations

*Include impactful deviations as appropriate. Deviations may also be added to the appropriate section when it provides value to the reader in more easily reconstructing the study.*

|  |  |
| --- | --- |
| **Deviation**  | **Impact to Study**  |
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# Retention of Records, Samples and Specimens

*[Copy corresponding section from Protocol and change tense as appropriate OR include a hyperlink to corresponding section of Protocol]*

# RESULTS

*For each section below, the author will link directly to the applicable Contributing Report Results Section and may also include a high-level summary. Repetition of text from the Contributor Report should be avoided.*

*For those results that are interpreted by the Study Director and not accompanied by a Contributing Report, a summary and link to the results tables/figures will be included.*

*The Results section should provide an understanding of the results observed for each protocol endpoint and the supporting detail that facilitates the further integration and interpretation of the study data in the Summary (and Discussion, if used) sections. Include the relationship of findings or lack thereof to the test article and provide the interpretation of the findings relevant to the study objective as appropriate.*

*Content should adequately convey the information that provides the basis for interpretations (e.g., target organ identification), and establish correlations to any companion parameters or endpoints that are clearly interrelated (i.e., food consumption and body weight reductions, ALT increases and liver necrosis, etc.).*

*When a summary of results is included from Contributor Reports, text should ideally be selected from these reports directly and not re-written (when possible).*

*Delete the results sections that are not applicable to your study and add sections if appropriate.*

## Test Item/Article Formulation and Analyses Verification

*[Link to applicable Contributor Report]*

*AND/OR*

*Include summary of results*

## In-life Observations/Measurements

### Mortality

*Include summary of results.*

Mortality data are presented in Table <> OR included in Appendix <>.

### Clinical Observations

*Include summary of results.*

An incidence summary of clinical observations is presented in Table <>. Individual animal clinical observations are included in Appendix <>.

### Body Weight

*Include summary of results.*

Group mean body weight data are presented in Table <>. Group mean body weight change data are presented in Table <>. Individual animal body weight data are included in Appendix <>. Individual animal body weight change data are included in Appendix <>.

### Food Consumption

*Include summary of results.*

Group mean food consumption data are presented in Table <>. Individual animal food consumption data are included in Appendix <>.

### Ophthalmic Examinations

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Ophthalmic findings are presented in Table <>. Individual data are included in Appendix <>.

### Veterinary Examinations

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Veterinary examination findings are presented in Table <>. Individual data are included in Appendix <>.

### Veterinary Treatments

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Individual veterinary treatment data are included in Appendix <>.

### Safety Pharmacology (Cardiovascular, Respiratory, CNS)

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

## Clinical Pathology

### Hematology

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Group mean hematology data are presented in Table <>. Individual hematology data are included in Appendix <>.

### Coagulation

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Group mean coagulation data are presented in Table <>. Individual coagulation data are included in Appendix <>.

### Clinical Chemistry

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Group mean clinical chemistry data are presented in Table <>. Individual clinical chemistry data are included in Appendix <>.

### Urinalysis

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

Group mean urinalysis data are presented in Table <>. Individual urinalysis data are included in Appendix <>.

## Bioanalytical

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

## Toxicokinetics

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

## <Other Testing>

*Use this section to describe other, non‑standard testing and results (e.g. Micronucleus testing, Toxicogenomics, Biomarkers, Immunotoxicology, ADA).*

 *[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

## Anatomic Pathology

### Organ Weight

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

### Macroscopic Observations

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

### Microscopic Findings

*[Link to applicable Contributor Report and/or Tables within the Contributor Report]*

*AND/OR*

*Include summary of results.*

# References

Insert numbered references cited elsewhere within this document in a generally accepted format.

# Abbreviations

*The Abbreviation Table is considered optional. Terms may be abbreviated, and acronyms may be used to avoid repeating a phrase or long word many times in a document. If an abbreviation is used 3 or fewer times, consider spelling it out instead of abbreviating it.*

|  |
| --- |
| **LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS** |
| **Abbreviation** | **Definition** |
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# QUALITY ASSURANCE STATEMENT

*Update the QA Statement to fit the needs of the specific organization.*

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| **Phase Inspected** | **Audit/Inspection Date** | **Reporting Date** |
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The signature below indicates that the Quality Assurance personnel approves the Quality Assurance Statement.

 Date:

*[Insert Name, Credentials]*
<Quality Assurance>

# Tables

*Tables generally will include summary data tables that are appended to the Study Report such as clinical observations, body weight, and food consumption.*

# Appendices

*Appendices generally will include the following:*

* *The most current version of the protocol*
* *Individual animal data listings such as clinical observations, body weight, and food consumption*
* *Contributing Scientist Reports including relevant summary data tables and individual animal listings*
* *Test Article documentation (e.g., certificate of analysis)*