

GLP Toxicology Study Report

Write the final report of a GLP repeat-dose toxicity study: design, findings by dose, unscheduled deaths, toxicokinetics and deviations, with the NOAEL set from the adverse findings and the GLP and QA statements checked.

WRITES

4.2.3.2

PRODUCT TYPE

Small molecule and
biologics

**GUIDANCE IT
FOLLOWS**

21 CFR Part 58;
OECD Principles of
GLP; OECD TG 407,
408, 409; ICH
M3(R2); ICH S3A
(toxicokinetics)

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/glp-toxicology-report.html>. This guide is also online at <https://cmcfy.com/guides/glp-toxicology-report.html>

1. What this module does

You enter the groups with their doses and animal numbers, the findings by dose with the change versus control, any unscheduled deaths and the deviations.

The tool sets the NOAEL as the highest dose with no adverse finding at that or any lower dose, compares it with the NOAEL the study director proposes, and checks group sizes, dose selection, recovery and toxicokinetics, deviations and the GLP compliance and QA statements.

What you get

- A Word or PDF report: GLP toxicology study report (Module 4.2.3.2).

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- Groups, doses and animal numbers.
- Findings by dose with the change versus control.
- Deviations with their impact assessment.

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/glp-toxicology-report.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1 Describe the study

Enter the study number, title, facility and study director, the species type and the dosing and recovery periods.

CMCfy GLP Toxicology Study Report Projects All modules Training Security Runs entirely on this device [Training guide](#)

PROJECTS Keep this work in a project, with version history and your company logo on every report. [Choose projects folder](#) [Keep in this browser](#)

- Network requests since load: 0**
Counted live by your browser. Your data never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

4.2.3.2 [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the final report of a GLP repeat-dose toxicity study from the study design, findings and deviations. The tool sets the NOAEL from the adverse findings by dose, and checks the group sizes, dose selection, recovery and toxicokinetic groups, deviations and the GLP compliance and quality assurance statements.

Guidance: 21 CFR Part 58; OECD Principles of GLP; OECD TG 407, 408, 409; ICH M3(R2); ICH S3A (toxicokinetics)

1 - STUDY

Test item
CMX-101 hydrochloride

Submission region Study number
US: FDA (INDA, ANDA, BL) TX-001

Study title
13-week oral (gavage) toxicity study in the Sprague-Dawley

Test facility
Acme Preclinical Services, Durham NC USA

Study director Species type
Dr. J. Rivera Rodent

RESULT

NOAEL 30 mg/kg/day · report complete

4 groups (10, 30, 100 mg/kg/day and control); 5 findings, 1 adverse; 1 unscheduled death; 2 deviations.

NOAEL	GROUPS	ADVERSE
30 mg/kg/day	4	1

DEVIATIONS
2

GROUPS AND NOAEL

GROUP	DOSE (MG/KG/DAY)	MAIN / SEX	RECOVERY / SEX	TK / SEX	ADVERSE FINDING:
1	0	10	5	3	control

2 Enter groups and findings

One row per group and per finding. Write "yes" in Adverse for each adverse finding.

3 Read the result

The headline gives the NOAEL: "NOAEL 30 mg/kg/day · report complete".

GROUPS AND NOAEL					
GROUP	DOSE (MG/KG/DAY)	MAIN / SEX	RECOVERY / SEX	TK / SEX	ADVERSE FINDINGS
1	0	10	5	3	control
2	10	10	0	9	no
3	30	10	0	9	no
4	100	10	5	9	yes

Groups, findings and the NOAEL.

4 Resolve alerts and download

A missing GLP or QA statement and test item related deaths are critical. A proposed NOAEL that differs from the findings, body weight loss of 10% or more marked not adverse, and deviations without an impact assessment are flagged. Then preview and download.

Preview and review before download

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

No open gaps

No open gaps: the data, the report and the protocol (if given) match every rule checked, or you accepted the rest. Read the preview before you sign.

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol file

Compare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before anything leaves this device. Results and pass/fail are not changed.

Run AI review

GLP toxicology study report

CMX-101 hydrochloride · TX-001 · 13-week oral (gavage) toxicity study in the Sprague-Dawley rat with a 4-week recovery period · US (FDA)

Study	TX-001
Test item	CMX-101 hydrochloride
Test facility	Acme Preclinical Services, Durham NC USA
Study director	Dr. J. Rivera
Archive	Acme Preclinical Services GLP archive, Durham NC

GLP compliance statement

This study was conducted in compliance with 21 CFR Part 58. Exceptions: DEV-01, DEV-02 (no impact on the study integrity).

Quality assurance statement

The study was inspected by quality assurance; the dates of inspections and of reports to management and the study director are listed in the QA statement.

Study design

Group	Dose (mg/kg/day)	Main per sex	Recovery per sex	TK per sex
1	0	10	5	3
2	10	10	0	9
3	30	10	0	9
4	100	10	5	9

Download Word (.docx)

Download PDF

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies”

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appear only for the choices that need them.

1 - Study

FIELD	WHAT TO ENTER
Test item	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Study number	Type it in.
Study title	Type it in.
Test facility	Type it in.
Study director	Type it in.
Species type	Choose one: Rodent; Non-rodent.
Dosing period (weeks)	Type a number.
Recovery period (weeks)	Type a number.
High-dose justification	Choose one: Maximum tolerated dose; Limit dose (1000 mg/kg/day); 50-fold exposure margin; Saturation of exposure; Not stated.
GLP compliance statement signed by the study director	Tick the box if it applies.
Quality assurance statement (inspections and dates reported)	Tick the box if it applies.
Archive location of raw data, specimens and report	Type it in.

2 - Groups

One row per group. Dose 0 is the control. Recovery and toxicokinetic (TK) animals per sex.

FIELD	WHAT TO ENTER
Groups	A table. Columns: Group Dose (mg/kg/day) Main animals per sex Recovery animals per sex TK animals per sex. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Findings

One row per finding and dose group. Change versus control in % where it applies. Adverse: yes when the finding is adverse; Reversible: yes when it recovered.

FIELD	WHAT TO ENTER
Findings	Give the change versus control with its sign, for example -12 for a 12% decrease. A table. Columns: Dose (mg/kg/day) Finding Change vs control (%) Adverse (yes/no) Reversible (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Unscheduled deaths	A table. Columns: Dose (mg/kg/day) Animal Cause Test item related (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Protocol and SOP deviations	A table. Columns: Deviation Description Impact assessed (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Toxicokinetics (AUC at each dose, ng-h/mL)	Type it in.
NOAEL proposed by the study director (mg/kg/day)	Type a number.

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- NOAEL from the adverse findings.
- Group sizes, dose levels, high-dose justification, recovery and toxicokinetics.
- GLP and QA statements, deviations and archive.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press **Record**.
- **Major** alerts block the download until you fix them or type a justification and press **Accept justification**.
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an **Apply fix** button that makes the change for you. **Reopen** undoes a justification.

Narratives

This module writes: Conclusion. Each narrative is written by fixed rules from your data. You can edit it in the box. **Rewrite with AI** (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. **Reset to rule-based text** brings back the original.

6. Preview, gap review and download

1. Press **Preview** next to a section, or **Preview and download all**. The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
4.2.3.2	GLP toxicology study report

Use **Save project** to keep your work as a file on your computer, and **Open project** to continue later. **Start blank** clears every field; **Load example** brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

US: 21 CFR Part 58. EU: OECD Principles of GLP (Directive 2004/10/EC). The OECD test guidelines apply to both.

8. Working with other modules

- The study is summarised in the Nonclinical Overview & Summaries.
-

9. Common pitfalls

- A NOAEL set at a dose with an adverse finding.
 - Deviations listed without an impact assessment.
-

10. Practice exercises

Each exercise starts from the example (press **Load example** to reset). We run these on every update of this guide, so the result you see should match.

1. **Make a finding adverse**

Mark the liver weight increase at 30 mg/kg/day as adverse.

EXPECTED RESULT

The headline shows the proposed NOAEL differs from the findings.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.