

Method Validation Studio

Write a validation protocol, then calculate linearity, accuracy, precision, LOD/LOQ, specificity and robustness from your data and write the validation report against ICH Q2(R2).

WRITES

3.2.S.4.3

3.2.P.5.3

Validation
protocol and
report

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

ICH Q2(R2), ICH
Q14, USP <1225>,
Ph. Eur. 2.2.46

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/method-validation-studio.html>. This guide is also online at <https://cmcfy.com/guides/method-validation-studio.html>

1. What this module does

The module covers the whole validation of an analytical procedure. Section 1 holds the protocol: write a new one with the protocol writer, paste one, or upload it. Section 2 takes the raw data. The tool calculates every characteristic, compares it with your acceptance criteria and writes the report.

With AI available, it can also review the protocol against ICH Q2(R2) and draft the narrative; numbers and pass/fail always come from the calculations, and any number in the AI draft that is not in your data is flagged.

What you get

- A validation protocol (.docx) from the protocol writer.
- A validation report in Word or PDF: scope, each characteristic with data, results and discussion, a summary table, resolved alerts and blank sign-off lines.

2. Before you start

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

- Product, method name and number, concentration unit, report number and protocol reference.

- The protocol, or the facts to write one: method type (assay, impurities, dissolution, identification), technique, analyte, nominal concentration and acceptance criteria.
- Linearity data (concentration, response), accuracy data (level %, theoretical, found), repeatability results, intermediate precision series, and specificity and robustness results.

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/method-validation-studio.html. The example (HPLC assay AM-0142 v2) is loaded in every section when the page opens. The example protocol contains a few deliberate gaps so you can see what the protocol review finds.

1 Describe the method

Enter product, method, report number, concentration unit and the protocol reference at the top.

The screenshot shows the CMCfy Method Validation Studio interface. At the top, there's a navigation bar with 'CMCfy', 'Method Validation Studio', and links to 'Projects', 'All modules', 'Training', and 'Security'. Below this is a status bar indicating 'Runs entirely on this device', 'Training guide', and 'Protocol builder'. The main content area is divided into several sections:

- PROJECTS:** A section with a note 'Keep this work in a project, with version history and your company logo on every report.' and buttons for 'Choose projects folder' and 'Keep in this browser'.
- Network requests since load: 0:** A section indicating that calculations never leave the device.
- Works offline:** A section stating that everything the tool needs is inside the page and can be disconnected from the internet.
- Locked offline copy:** A section explaining that a single file can be saved to open from a local computer with all network access blocked.
- METHOD:** A section with input fields for:
 - Product: CMX-101 Tablets, 50 mg
 - Method: HPLC assay, method AM-0142 v2
 - Report number: MVR-2026-031
 - Concentration unit: µg/mL
 - Protocol reference: MVP-2026-031
- 3 - ALERTS TO RESOLVE:** A section stating 'No data alerts. Run the protocol review to check the protocol against ICH Q2(R2).'.
- VALIDATION SUMMARY:** A section showing a 'Pass' result. It states 'All 11 acceptance criteria are met. The method is suitable for its intended use as a HPLC assay, method AM-0142 v2.' Below this is a table with the following data:

CHARACTERISTIC	CRITERION	RESULT
Linearity	$r \geq 0.999$; $ y\text{-intercept} \leq 2\%$ of 100% response	$r = 0.99997$; $y\text{-intercept} 0.14$
Range	Linearity, accuracy and precision acceptable across range	80 to 120 µg/mL (80–120%)
Accuracy	Mean recovery 98–102% at each level	80%: 99.9%; 100%: 100.0%
Repeatability	%RSD $\leq 2\%$ (n = 6)	Mean 100.03; %RSD 0.33%
Intermediate precision	Overall %RSD $\leq 2\%$; difference of means $\leq 2\%$	Overall %RSD 0.42%; difference of means 0.03%
LOD / LOQ	Reported (calibration-curve approach)	LOD 1.00 µg/mL; LOQ 3.03 µg
- 1 - PROTOCOL:** A section with a note 'Write a new protocol, paste an existing one, or upload it (Word, PDF, scan or text)' and a button for 'VALIDATION PROTOCOL MVP-2026-031'.

2

Write or load the protocol

Press **Write a new protocol** to open the protocol writer: choose the method type, enter the technique, analyte, nominal concentration and criteria, then **Generate protocol** and **Download protocol (.docx)**. Or paste the approved protocol, or press **Upload protocol** (Word, PDF, scan or text).

WRITE A NEW PROTOCOL

Method type
Assay (content or potency) ▼

Protocol number
MVP-2026-031

Technique
HPLC-UV

Analyte
CMX-101

Nominal concentration
100

Unit
µg/mL

Impurity specification limit (%)
0.5

Min. correlation r
0.999 ▲ ▼

Max. y-intercept (% of 100%)
2.0

Recovery from (%)
98.0

Recovery to (%)
102.0

Max. %RSD
2.0

Max. difference of series means (%)
2.0

Prepared by
Name, title

Criteria defaults are typical for this method type. Change them to match your SOPs.

Generate protocol

Download protocol (.docx) Close

The protocol writer.

3

Enter the data

Paste each data set in its box. The criteria next to each box are editable and are used for pass/fail. For linearity give concentration and response; for accuracy the level, theoretical and found; for precision one result per line, and series and result for intermediate precision.

2 · DATA: LINEARITY

CSV: concentration, response

concentration, response

50, 625210

50, 621480

75, 937880

75, 941120

100, 1250430

100, 1243870

125, 1562110

Min. correlation r

0.999

Max. y-intercept, % of
100% response

2.0

Nominal (100%) concentration

100

Linearity data with its criteria.

4**Read the summary**

The validation summary shows "Pass": all 11 acceptance criteria are met. Linearity $r = 0.99997$ with y-intercept 0.14%; accuracy 99.9–100.0%; repeatability %RSD 0.33%; LOD 1.00 µg/mL and LOQ 3.03 µg/mL by the calibration-curve approach.

VALIDATION SUMMARY

Pass

All 11 acceptance criteria are met. The method is suitable for its intended use as a HPLC assay, method AM-0142 v2.

CHARACTERISTIC	CRITERION	RESULT
Linearity	$r \geq 0.999$; $ y\text{-intercept} \leq 2\%$ of 100% response	$r = 0.99997$; $y\text{-intercept} 0.14$
Range	Linearity, accuracy and precision acceptable across range	80 to 120 µg/mL (80–120%)
Accuracy	Mean recovery 98–102% at each level	80%: 99.9%; 100%: 100.0%;
Repeatability	%RSD $\leq 2\%$ (n = 6)	Mean 100.03; %RSD 0.33%
Intermediate precision	Overall %RSD $\leq 2\%$; difference of means $\leq 2\%$	Overall %RSD 0.42%; differen
LOD / LOQ	Reported (calibration-curve approach)	LOD 1.00 µg/mL; LOQ 3.03 µg
Specificity	Placebo injection	No peak at analyte retention ti
Specificity	Forced degradation (acid/base/oxidative/heat/light)	Peak purity passes; resolution
Robustness	Flow rate 0.9 and 1.1 mL/min	Assay 99.7% and 100.2%; sy:
Robustness	Column temperature 28 and 32 °C	Assay 100.1% and 99.8%; sy:
Robustness	Mobile phase pH ± 0.2	Assay 99.6% and 100.3%; sy:
Solution stability	Standard and sample at 25 °C for 48 h	Change 0.4% and 0.6%

5

Resolve alerts

Section 3 lists data alerts (for example fewer than five linearity levels, too few accuracy determinations, no second precision series) and, after the protocol review, protocol findings. Fix them or accept a justification.

3 · ALERTS TO RESOLVE

No data alerts. Run the protocol review to check the protocol against ICH Q2(R2).

6

Preview, review and download

Press [Preview and download report](#). The review compares the report with the protocol in section 1 and lists data and report gaps. Download Word or PDF.

99.8 All intermediate precision 12 100.26 0.423 0.42

Preview and review before download Close

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 review before you sign.

Compare with the protocol

The protocol from section 1 is compared with the report. Edit it here to compare a different version.

VALIDATION PROTOCOL MVP-2026-031
Validation of HPLC assay method AM-0142 v2 for CMX-101 Tablets, 50 mg

1. Objective

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

Analytical Method Validation Report

HPLC assay, method AM-0142 v2 - CMX-101 Tablets, 50 mg

Report number	MVR-2026-031
Protocol	MVP-2026-031
Product	CMX-101 Tablets, 50 mg
Method	HPLC assay, method AM-0142 v2
Guideline	ICH Q2(R2), Validation of Analytical Procedures
Date drafted	2026-10-29

1. Purpose and scope

This report presents the validation of HPLC assay, method AM-0142 v2 for CMX-101 Tablets, 50 mg, executed per protocol MVP-2026-031. The characteristics evaluated are specificity, linearity, range, accuracy, precision (repeatability and intermediate precision), detection and quantitation limits, robustness and solution stability, following ICH Q2(R2).

2. Summary of results

Characteristic	Acceptance criterion	Result	Outcome
Linearity	$r \geq 0.999$; $ y\text{-intercept} \leq 2\%$ of 100% response	$r = 0.99997$; $y\text{-intercept} 0.14\%$	Pass
Range	Linearity, accuracy and precision acceptable across range	80 to 120 $\mu\text{g/mL}$ (80–120% of nominal); linearity shown from 50 to 150 $\mu\text{g/mL}$, accuracy only from 80% to 120%	Pass
Accuracy	Mean recovery 98–102% at each level	80%: 99.9%; 100%: 100.0%; 120%: 99.9%	Pass
Repeatability	%RSD $\leq 2\%$ (n = 6)	Mean 100.03; %RSD 0.33%	Pass
Intermediate precision	Overall %RSD $\leq 2\%$; difference of means $\leq 2\%$	Overall %RSD 0.42%; difference 0.45%	Pass

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” appear only for the choices that need them.

Method

FIELD	WHAT TO ENTER
Product, Method, Report number	Type them in; they appear on the report.
Concentration unit	For example $\mu\text{g/mL}$; used for LOD and LOQ.
Protocol reference	The protocol number the report refers to.

1 - Protocol

FIELD	WHAT TO ENTER
Protocol text	Paste, upload (Word, PDF, scan or text) or write with Write a new protocol .

FIELD	WHAT TO ENTER
Protocol writer	Method type, protocol number, technique, analyte, nominal concentration and unit, impurity specification limit (impurity methods), the acceptance criteria and the author. Generate protocol , optionally Improve wording with AI , then Download protocol (.docx) .

2 · Data

FIELD	WHAT TO ENTER
Linearity	Rows of concentration, response. Criteria: minimum correlation r, maximum y-intercept as % of the 100% response, nominal concentration.
Accuracy	Rows of level %, theoretical, found. Criteria: recovery from and to (%).
Precision	Repeatability: one result per line. Intermediate precision: rows of series, result. Criteria: maximum %RSD and maximum difference of series means.
Specificity and robustness	Rows of test, condition, result, meets criterion (yes/no).

5. Checks and alerts

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

- Linearity by least squares: slope, intercept, r, r^2 , residual SD and y-intercept as % of the 100% response; at least five levels (critical if fewer).
- Range covered by linearity, accuracy and precision.
- Accuracy: recovery = found / theoretical × 100 at each level, with enough determinations (at least nine over three levels).
- Repeatability %RSD with at least six determinations; intermediate precision needs a second series (analyst, day or instrument).
- LOD = $3.3\sigma/S$ and LOQ = $10\sigma/S$ from the residual SD of the calibration line.
- Specificity results present; each robustness and specificity result judged by its criterion.
- Any criterion entered in the form that differs from the protocol is flagged. The AI protocol review, where available, adds findings against ICH Q2(R2).

How to resolve alerts

- **Critical** alerts must be fixed in the data; they cannot be justified.
- **Major** and **minor** alerts can be fixed, or justified: type the reason and press **Accept justification**. The report lists every justification.
- The report download is blocked while a critical or unjustified major alert is open. The preview still opens, so you can see the draft.

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
Protocol	Validation protocol (.docx) from the protocol writer
Report	Validation report for 3.2.S.4.3 or 3.2.P.5.3

7. US and EU submissions

ICH Q2(R2) and Q14 apply in both regions. US reports also cite USP <1225> and <1226>; EU reports cite Ph. Eur. 2.2.46 and the relevant general chapters. Write the protocol for the region where the method will be filed.

8. Working with other modules

- Method summaries in the specification are written by the Specification Builder.
- An invalid run or failing result during validation can be recorded in the Investigation Studio (OOS, deviation, CAPA).
- Upload a validation report written elsewhere to the Report Reviewer for a gap check.

9. Common pitfalls

- Criteria in the form that differ from the approved protocol: the tool flags them, and the protocol wins.
- Pasting accuracy data as recoveries only: give theoretical and found so recovery is calculated.
- Only one precision series, so intermediate precision cannot be shown.
- Reading LOD/LOQ from the calibration line for an impurity method without confirming them experimentally.

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. Tighten the linearity criterion

Change `Min. correlation r` under linearity to 0.99999.

EXPECTED RESULT

The summary changes to Fail, with linearity not met.

2. Remove intermediate precision

Clear the intermediate precision box.

EXPECTED RESULT

A major alert says there is no second series in the data.

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.