

Excipients Writer

Write the control of excipients: specifications and procedures for non-compendial excipients, justification, excipients of human or animal origin, and the full data set for a novel excipient (3.2.A.3).

WRITES

3.2.P.4.1
3.2.P.4.2
3.2.P.4.3
3.2.P.4.4
3.2.P.4.5
3.2.P.4.6
3.2.A.3

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

ICH M4Q(R1) 3.2.P.4
and 3.2.A.3; ICH
Q3C, Q3D; EMA
Guideline on
excipients in the
dossier
(EMA/CHMP/QWP/396
EMA/410/01 rev.3;
Ph. Eur. 5.15; USP
<1059>; FDA
Inactive Ingredient
Database

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

Compendial excipients are controlled by their monograph, but anything else needs its own specification, procedures, validation and justification (3.2.P.4.1 to 4.4). Excipients of human or animal origin need TSE and viral safety information (3.2.P.4.5), and a novel excipient needs a full data package (3.2.P.4.6 and 3.2.A.3).

The tool checks pharmacopoeia references for the region, TSE status, colourants such as titanium dioxide, and functionality-related characteristics of common excipients.

What you get

- Word or PDF files for 3.2.P.4.1 to 3.2.P.4.6 and 3.2.A.3.
- A summary file for the QOS Composer & Dossier Assembler.

2. Before you start

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

- Each excipient: function, quality standard (USP-NF, Ph. Eur., JP or in-house), supplier and grade, origin and whether it is novel.
- Tests, methods and acceptance criteria for in-house excipients, how the methods were validated and why the criteria are right.
- For a novel excipient: manufacturer and process, characterisation, stability, safety data and the regulatory route (DMF or full data).
- Statements on residual solvents, elemental impurities and nitrite in excipients.

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3. Step by step with the example

Open the tool at app.cmcfy.com/app/excipients.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 List the excipients

Enter one row per excipient. Write the quality standard as you will cite it (for example "USP-NF; Ph. Eur."), and "In-house" for anything without a monograph. The headline counts them: 6 excipients, 2 non-compendial, 1 novel, 1 of animal origin.

CMCfy Excipients & Novel Excipients Projects All modules Training Security

Runs entirely on this device Training guide Protocol builder

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

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3.2.P.4.1 3.2.P.4.2 3.2.P.4.3 3.2.P.4.4 3.2.P.4.5 3.2.P.4.6 3.2.A.3 Save project Open project Start blank Load example

Write the control of excipients sections: specifications and procedures for non-compendial excipients, justification, excipients of human or animal origin, and the full data set for a novel excipient (3.2.A.3). The tool checks pharmacopoeia references for the region, TSE status and functionality-related characteristics.

Guidance: ICH M4Q(R1) 3.2.P.4 and 3.2.A.3; ICH Q3C, Q3D; EMA Guideline on excipients in the dossier (EMA/CHMP/QWP/396951/2006); EMA/410/01 rev.3; Ph. Eur. 5.15; USP <1059>; FDA Inactive Ingredient Database

1 · EXCIPIENTS

Drug product

CMX-101 Tablets, 50 mg

Submission region

US: FDA (NDA, ANDA, BL)

Excipients

Columns: Excipient, Function, Quality standard (USP-NF / Ph. Eur. / JP / in-house), Supplier and grade, Origin (synthetic / plant / mineral / animal / human), Novel (yes/no)

Microcrystalline cellulose, Filler, USP-NF; Ph. Eur., Avicel
Lactose monohydrate, Filler, USP-NF; Ph. Eur., Supplier A
Croscarmellose sodium, Disintegrant, USP-NF; Ph. Eur., Ac-
Magnesium stearate, Lubricant, USP-NF; Ph. Eur., Ligamed M

RESULT

6 excipients · 2 non-compendial · 1 novel

1 of animal origin.

COMPENDIAL	IN-HOUSE SPECIFICATIONS	ANIMAL ORIGIN
4	2	1

NOVEL

1

EXCIPIENTS

EXCIPIENT	FUNCTION	STANDARD	ORIGIN	FLAGS
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2 Write the statements

The statements box covers all excipients: functionality-related characteristics, residual solvents (Q3C), elemental impurities (Q3D), nitrite and TSE. Missing topics raise minor alerts.

3 Specify the in-house excipients

For each non-compendial excipient enter its tests, methods and criteria, then how the methods were validated and why the criteria are justified.

EXCIPIENTS

EXCIPIENT	FUNCTION	STANDARD	ORIGIN	FLAGS
Microcrystalline cellulose	Filler	USP-NF; Ph. Eur.	plant	–
Lactose monohydrate	Filler	USP-NF; Ph. Eur.	animal	TSE
Croscarmellose sodium	Disintegrant	USP-NF; Ph. Eur.	plant	–
Magnesium stearate	Lubricant	USP-NF; Ph. Eur.	plant	–
Opadry II White 85F18422	Film coat	In-house	synthetic	in-house spec
CMX-Sol 200 (solubiliser)	Solubiliser	In-house	synthetic	in-house spec, novel

Excipients with their standard and origin.

4 Complete the novel excipient

Panel 3 collects the novel excipient package. Each empty field raises a major alert, because 3.2.A.3 needs all of it.

5 Preview and download

The example has no alerts. Preview each 3.2.P.4 section and 3.2.A.3, read the review and download.

Safety data Devices with AI Report to regulatory body

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.

1 to fix

REPORT CONTENT (1)

Placeholder left in the report: [State the TSE status.]

Replace the placeholder with the real information, or delete the sentence if it does not apply.

major Ignore

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.

3.2.P.4.1 Specifications

CMX-101 Tablets, 50 mg · US (FDA)

Excipient	Function	Quality standard	Supplier and grade
Microcrystalline cellulose	Filler	USP-NF; Ph. Eur.	Avicel PH-102
Lactose monohydrate	Filler	USP-NF; Ph. Eur.	Supplier A FlowLac 100
Croscarmellose sodium	Disintegrant	USP-NF; Ph. Eur.	Ac-Di-Sol
Magnesium stearate	Lubricant	USP-NF; Ph. Eur.	Ligamed MF-2-V (vegetable)
Opadry II White 85F18422	Film coat	In-house	Colorcon
CMX-Sol 200 (solubiliser)	Solubiliser	In-house	Excipient Co.

Opadry II White 85F18422

Test	Method	Acceptance criterion
Identification (IR)	In-house IR-OP-01	Conforms to reference
Loss on drying	Ph. Eur. 2.2.32 / USP <731>	NMT 5.0%
Components	Supplier composition statement	Polyvinyl alcohol, titanium dioxide, macrogol, talc each meet their monographs

CMX-Sol 200 (solubiliser)

Test	Method	Acceptance criterion
Identification (IR and HPLC)	In-house HPLC-CS-02	Conforms to reference
Assay	In-house HPLC-CS-02	95.0–105.0%
Related substances	In-house HPLC-CS-02	Any NMT 0.5%; total NMT 1.5%
Residual solvents	USP <467> / Ph. Eur. 2.4.24	Meets ICH Q3C
Elemental impurities	USP <233> / Ph. Eur. 2.4.20	Meets ICH Q3D option 1

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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.

1 · Excipients

FIELD	WHAT TO ENTER
Drug product	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Excipients	A table. Columns: Excipient Function Quality standard (USP-NF / Ph. Eur. / JP / in-house) Supplier and grade Origin (synthetic / plant / mineral / animal / human) Novel (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Statements covering all excipients	Type or paste text.

2 · Non-compendial excipient specifications (3.2.P.4.1–4.4)

FIELD	WHAT TO ENTER
Tests	A table. Columns: Excipient Test Method Acceptance criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Validation of in-house procedures	Type it in.
Justification of the specifications	Type it in.

3 · Novel excipient (3.2.P.4.6 and 3.2.A.3)

A novel excipient is one used for the first time in a drug product or by a new route.

FIELD	WHAT TO ENTER
Novel excipient	Type it in.
Manufacturer and manufacturing process	Type it in.
Characterisation	Type it in.
Stability	Type it in.
Safety data	Type it in.
Regulatory route	Type it in.

5. Checks and alerts

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

- Every excipient has a quality standard and a function.
- Non-compendial excipients have a specification with an identification test and acceptance criteria; in-house procedures are validated and the specifications justified.
- Excipients that may be of animal origin (lactose, gelatin, stearates, glycerol and others) need a TSE statement; human-origin excipients (albumin) are flagged; origin should be stated.
- Titanium dioxide (E 171) and colour additives are flagged for regional status.

- Functionality-related characteristics are addressed for common functional excipients (for example particle size of microcrystalline cellulose).
- Statements cover residual solvents, elemental impurities and nitrite.
- Every field of the novel excipient package is given.

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: Control of excipients. 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
3.2.P.4.1	Specifications
3.2.P.4.2	Analytical procedures
3.2.P.4.3	Validation of analytical procedures
3.2.P.4.4	Justification of specifications
3.2.P.4.5	Excipients of human or animal origin
3.2.P.4.6	Novel excipients
3.2.A.3	Novel excipients (full data)

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 mode cites USP-NF and the FDA Inactive Ingredient Database; a novel excipient is usually supported by a Type IV DMF with a letter of authorisation. EU mode cites Ph. Eur. (including 5.15 on functionality-related characteristics), the EMA guideline on excipients in the dossier and the TSE note for guidance (EMA/410/01 rev.3); a novel excipient needs full data in 3.2.A.3. Titanium dioxide is no longer authorised as a food additive in the EU, so its use in a medicine is flagged for justification.

8. Working with other modules

- The Specification Builder lists excipients in 3.2.P.4 briefly; use this module when you need the full sections.
- Composition and quantities come from the Composition & General Info.
- Elemental and nitrite contributions feed the Impurity & Risk Studio.

9. Common pitfalls

- Writing "compendial" without naming the pharmacopoeia.
- Treating a proprietary coating mix (for example Opadry) as compendial: it needs an in-house specification even if each component meets a monograph.

- Forgetting the TSE statement for lactose or magnesium stearate of animal origin.
- Leaving novel excipient fields empty because the data are in a DMF: say so in the field.

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. Remove a quality standard

In the excipients table, delete "USP-NF; Ph. Eur." from the croscarmellose sodium row.

EXPECTED RESULT

A major alert says croscarmellose sodium has no quality standard.

2. Remove the validation statement

Clear `Validation of in-house procedures`.

EXPECTED RESULT

A major alert says in-house procedures are not validated.

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.