

Container Closure & E&L

Describe the container closure system and show it is suitable: protection, compatibility, safety and performance, with compendial tests, light and moisture protection, leachable thresholds and container closure integrity checked by rule.

WRITES

3.2.S.6

3.2.P.7

3.2.P.2.4

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

FDA Container Closure Systems for Packaging Human Drugs and Biologics (1999); USP <660>; USP <661.1>; USP <661.2>; USP <381>; USP <671>; USP <1207>; USP <1663>; USP <1664>; PQRI thresholds

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

The module writes 3.2.P.7 (container closure system) and 3.2.P.2.4 (its suitability) for a drug product, or 3.2.S.6 for a drug substance.

It sets the degree of concern from the dosage form (FDA 1999 container closure guidance), calculates the safety concern threshold (SCT) and the analytical evaluation threshold (AET) from the units used per day, and checks each component for the compendial tests its material needs.

What you get

- Word or PDF files for 3.2.P.7 and 3.2.P.2.4 (or 3.2.S.6).

- A summary file for the QOS Composer & Dossier Assembler, which checks light and moisture protection against the storage statement.

2. Before you start

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

- Every component: material, whether it contacts the product, compendial tests, supplier and DMF, and drawing or specification reference.
- Photostability (ICH Q1B) outcome and moisture sensitivity, with water vapour transmission data if moisture sensitive.
- Extractables and leachables results with estimated daily exposure and any toxicological limit.
- Container closure integrity data for sterile products.

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/container-closure-studio.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 Choose the section and route

Choose drug product or drug substance, the dosage form and route, and [Units used per day](#). The headline gives the degree of concern (low for an oral solid) and the result panel shows SCT 1.5 µg/day and AET 0.75 µg per unit for 2 units a day.

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Container Closure & E&L

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

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.

3.2.S.6

3.2.P.7

3.2.P.2.4

Save project

Open project

Start blank

Load example

Describe the container closure system and show it is suitable: protection, compatibility, safety and performance. Compendial tests, light and moisture protection, leachable thresholds and container closure integrity are checked by rule.

Guidance: FDA Container Closure Systems for Packaging Human Drugs and Biologics (1999); USP <660>; USP <661.1>; USP <661.2>; USP <381>; USP <671>; USP <1207>; USP <1663>; USP <1664>; PQRI thresholds

1 · PRODUCT AND ROUTE

Section

Submission region

Drug product (3.2.P.7 an

US: FDA (NDA, ANDA, BL

Product or substance name

CMX-101 Tablets, 50 mg

Dosage form and route

Units used per day (for the AET)

Oral solid

2

Pack presentations

30 tablets per bottle; 90 tablets per bottle

RESULT

4 components · 3 in direct contact

Degree of concern for oral solid products: low (FDA 1999 guidance, Table 1).

SECTIONS

SCT

AET

3.2.P.7, 3.2.P.2.4

1.5 µg/day

0.75 µg per unit

LEACHABLES

0 reported

COMPONENTS

COMPONENT	MATERIAL	CONTACT	COMPENDIAL TESTS	DMF
			USP <661.1>; USP	Acme

2 Enter the components

One row per component. Mark direct product contact, and give the compendial tests (USP <661.1> for plastics, <660> for glass, <381> for elastomers; Ph. Eur. 3.1 and 3.2 in EU mode).

COMPONENTS				
COMPONENT	MATERIAL	CONTACT	COMPENDIAL TESTS	DMF
Bottle 75 cc	HDPE (white)	Direct	USP <661.1>; USP <671>	Acme Packaging; DMF 12345
Cap	Polypropylene child-resistant	No	–	Acme Packaging; DMF 12345
Induction seal liner	Aluminium foil / PET / LDPE (LDPE product side)	Direct	missing	Seal Co.; DMF 23456
Desiccant canister	Silica gel 1 g in HDPE canister	Direct	USP <670>	Desi Co.; DMF 34567

Components with material and contact.

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3 Enter protection data

Say whether the product is light or moisture sensitive and whether the pack protects it. Give WVTR data for a moisture-sensitive product.

4 Enter E&L and integrity

Enter extractables and leachables with exposures; the tool compares them with the SCT and any toxicological limit. For sterile products, enter container closure integrity methods and results.

5 Resolve alerts

In the example, two plastic components in product contact do not cite USP <661.1>. Add the test to the component row to clear each alert.

ALERTS TO RESOLVE
2 alerts to fix, justify, or proceed without before export. It is your call: "Proceed without it" lets you continue when the information is not available.

MAJOR Induction seal liner is plastic and in product contact, but USP <661.1> is not cited.
Components · USP <661.1>
Test the material to USP <661.1> (or give the DMF that covers it).

Justification

Accept justification

Proceed without it

MAJOR Desiccant canister is plastic and in product contact, but USP <661.1> is not cited.
Components · USP <661.1>
Test the material to USP <661.1> (or give the DMF that covers it).

Justification

Accept justification

Proceed without it

6 Preview and download

Preview 3.2.P.7 and 3.2.P.2.4, read the review, and download.

Canister), closed with cap (Polypropylene child-resistant). Presentations: 30 tablets per bottle.

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.

2 to fix 1 recommended

MISSING INFORMATION (1)

"Extractables and leachables" is empty.

Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Extractables, leachables and integrity

Ignore

DATA AND INPUTS (2)

Induction seal liner is plastic and in product contact, but USP <661.1> is not cited.

Test the material to USP <661.1> (or give the DMF that covers it).

major · Components · USP <661.1>

Ignore

Desiccant canister is plastic and in product contact, but USP <661.1> is not cited.

Test the material to USP <661.1> (or give the DMF that covers it).

major · Components · USP <661.1>

Ignore

Compare with the protocol

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

Fix or justify the 2 blocking alerts before downloading. Or choose "Download anyway".

Download anyway Download Word (.docx) Download PDF

3.2.P.7 Container closure system

CMX-101 Tablets, 50 mg · US (FDA)

CMX-101 Tablets, 50 mg is packaged in bottle 75 cc (HDPE (white)), induction seal liner (Aluminium foil / PET / LDPE (LDPE product side)), desiccant canister (Silica gel 1 g in HDPE canister), closed with cap (Polypropylene child-resistant). Presentations: 30 tablets per bottle; 90 tablets per bottle.

Components in direct contact with the product comply with USP <661.1>, USP <671>, USP <670>. Specifications and drawings for each component are listed in Table 1. Supplier information is referenced in the DMFs listed, with letters of authorisation in Module 1.

Table 1. Components

Component	Material	Product contact	Compendial tests	Supplier / DMF	Specification
Bottle 75 cc	HDPE (white)	Yes	USP <661.1>; USP <671>	Acme Packaging; DMF 12345	DWG-075-B rev 3
Cap	Polypropylene child-resistant	No	-	Acme Packaging; DMF 12345	DWG-CAP-33 rev 2
Induction seal liner	Aluminium foil / PET / LDPE (LDPE product side)	Yes	-	Seal Co.; DMF 23456	SPEC-IS-01
Desiccant canister	Silica gel 1 g in HDPE canister	Yes	USP <670>	Desi Co.; DMF 34567	SPEC-DES-1

Review notes

Area	Issue	Resolution
Components	Induction seal liner is plastic and in product contact, but USP <661.1> is not cited.	Open
Components	Desiccant canister is plastic and in product contact, but USP <661.1> is not cited.	Open

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 · Product and route

FIELD	WHAT TO ENTER
Section	Choose one: Drug product (3.2.P.7 and 3.2.P.2.4); Drug substance (3.2.S.6).
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Product or substance name	Type it in.
Dosage form and route when it applies	Choose one: Oral solid; Oral liquid; Topical; Ophthalmic; Parenteral (injection); Inhalation.
Units used per day (for the AET) when it applies	Used with the SCT to set the AET per unit. Type a number.

FIELD	WHAT TO ENTER
Pack presentations	Type it in.

2 · Components

FIELD	WHAT TO ENTER
Components	Write "yes" in the contact column only for components that touch the product. A table. Columns: Component Material Direct product contact (yes/no) Compendial tests Supplier and DMF Specification or drawing. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Protection

FIELD	WHAT TO ENTER
Photostability (ICH Q1B)	Choose one: Not light sensitive; Light sensitive; Not tested yet.
The container protects from light	Tick the box if it applies.
Moisture sensitivity	Choose one: Moisture sensitive; Not moisture sensitive; Not known.
Water vapour transmission data (USP <671>)	Type it in.
Stability support	Type it in.

4 · Extractables, leachables and integrity

FIELD	WHAT TO ENTER
Extractables and leachables	A table. Columns: Compound Study (extractable / leachable) Estimated daily exposure (µg/day) Toxicological limit (µg/day, if assessed). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Food-contact compliance statement for plastics (oral solids)	Type it in.

FIELD	WHAT TO ENTER
Container closure integrity when it applies	A table. Columns: Method Result Samples tested. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

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

- Components have materials; plastics in contact cite USP <661.1> (Ph. Eur. 3.1); glass cites USP <660> and Type I where needed; elastomers cite USP <381>; a packaging-system test to USP <661.2> is present.
- Supplier or DMF and a drawing or specification for each component.
- Photostability tested; a light-sensitive product needs a light-protective pack; a moisture-sensitive product needs WVTR data; stability in the proposed pack is cited.
- Leachables data for products with a higher degree of concern; extractables data; a food-contact statement for plastics in oral solids.
- Leachables against the toxicological limit (critical above) and against the SCT without an assessment (major).
- Sterile products: container closure integrity data; probabilistic methods are flagged in favour of deterministic ones (USP <1207>).

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: Description of the container closure system; Suitability (protection, compatibility, safety, performance). 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.7 / 3.2.S.6	Container closure system
3.2.P.2.4	Container closure system (suitability)

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 uses the FDA 1999 container closure guidance, USP <661.1>, <661.2>, <660>, <381>, <671> and 21 CFR 174–186 for food contact. EU mode uses Ph. Eur. 3.1 and 3.2, the EMA guideline on plastic immediate packaging materials, and Regulation (EU) 10/2011 for food contact.

8. Working with other modules

- Photostability and storage conditions come from the Stability Studio or Biologics Stability Studio.
- Nitrocellulose in blister lidding is a nitrosamine risk factor in the Impurity & Risk Studio.

- The QOS Composer & Dossier Assembler checks that a light-sensitive product says "protect from light" on the storage statement.

9. Common pitfalls

- Listing the material but no compendial test.
- Marking a component as "no contact" when it is a liner or seal that touches the product.
- Using units per day for a different dose than the maximum daily dose.
- Relying on dye ingress (probabilistic) alone for container closure integrity of a sterile product.

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 the product light sensitive in a clear pack

Set [Photostability \(ICH Q1B\)](#) to "Light sensitive" and untick [The container protects from light](#).

EXPECTED RESULT

A major alert says the product is light sensitive but the container does not protect from light.

2. Switch to an injection

Set [Dosage form and route](#) to "Parenteral (injection)".

EXPECTED RESULT

A major alert says there are no container closure integrity data for a sterile product.

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.