



THE OTC TOPICAL MANUFACTURING GUIDE

Right formula. Right fill. Your quality unit decides.

Creams, gels and ointments under 21 CFR 211, for brands and contract makers

A practical evaluation guide for teams that make OTC topical drug products, for their own brands or for customers: how intended use decides which rules apply, what the batch record should hold from component to carton, and what to ask any software before you rely on it.



21 CFR 210 / 211

DRUG FACTS 201.66

QUALITY UNIT DECIDES

U.S. edition / October 2026

v5ultimate.com

Scope: practical orientation, not legal or regulatory advice. Photos are staged; batches, weights and results are worked examples.

INSIDE THE GUIDE

One cream batch, component to carton.

A topical batch joins an active ingredient, a base, water, tubes and printed labels in a few hours of mixing and filling. This guide follows one contract batch and shows what the CGMP rules expect the record to hold.

01 / FRAME

pp. 03–04

Drug, cosmetic or both

Intended use, the OTC monograph route, registration and listing, and the CGMP rules.

02 / CONTROL

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Components and master record

Quarantine and testing, the master production record and verified dispensing.

03 / MAKE

pp. 07–10

Phases, equipment, fill, labels

In-process checks, cleaning, fill weights, Drug Facts and label reconciliation.

04 / DECIDE

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Test, date, review

Finished product testing, stability and expiry, and the quality unit's review.

05 / PARTNER

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Contracts, complaints, software

Quality agreements, complaints and distribution, and the software you rely on.

06 / APPLY

pp. 17–22

V5 fit, worksheets, sources

Where V5 fits and does not, two worksheets, a four-week evaluation and ten sources.

Who it is for. Quality unit leads, production and compounding managers, QC laboratory leads, contract manufacturing account teams, brand owners who audit their makers, and anyone choosing a production and quality system for a topical operation.

How to read it. Operational pages end with a teal Where V5 fits panel. Everything above it is regulation and practice; practice is labelled as such. Statements cite numbered sources; always check the current text.

THREE TAKEAWAYS

01 Settle drug, cosmetic or both from intended use before designing the record.

02 Verify every component, weight and label against the approved master record.

03 Only your quality unit releases a batch; V5 keeps the evidence together.

WHERE V5 FITS

V5 records the receiving, dispensing, mixing, filling, labeling, testing and quality work your procedures define. It does not classify products, confirm monograph conformity, approve labels or release batches. Those decisions stay with your quality unit and regulatory team.

FRAME / 01

Drug, cosmetic or both?

Whether a product is a cosmetic or a drug under U.S. law is determined by its intended use, shown by claims, labeling, marketing and ingredients. Different rules then apply [4].



- Cosmetic

Intended for cleansing, beautifying, promoting attractiveness or altering appearance (FD&C Act 201(i), paraphrased) [4].
- Drug

Intended to diagnose, cure, mitigate, treat or prevent disease, or to affect the structure or function of the body [4].

EXAMPLE PRODUCT	CATEGORY	WHAT APPLIES
Moisturiser for appearance	Cosmetic	Cosmetic rules
Sunscreen, skin protectant	Drug (FDA examples)	Drug rules [5]
Acne, eczema or rosacea treatment	Drug (FDA examples)	Drug rules [5]
Moisturiser with sun protection	Both	Both sets of rules [5]

- Claims decide

A cream does not become a cosmetic by calling itself one. A therapeutic claim on the label or website makes it a drug [4].
- Both means both

A product that is both must meet drug CGMP, Drug Facts and cosmetic requirements. Plan the record for the stricter set.
- Keep cosmetics separate

Pure cosmetic lines are covered by V5's cosmetics page and guide; this guide is about drug products.

WHERE V5 FITS

V5 product master data can carry the product category, intended-use statement and your regulatory notes, so the right master record, tests and label template follow. V5 does not classify products or decide which rules apply.

FRAME / 02

The OTC route and the rules that follow.

Most OTC topicals reach the market under an OTC monograph rather than an approved application. Section 505G of the FD&C Act, added by the CARES Act in 2020, governs that route [6][7].

FD&C Act 505G	OTC monograph drugs may be marketed without an approved application if they meet 505G and the applicable monograph	Route
OTC monograph	Conditions such as active ingredients, uses, doses, routes, labeling and testing; changed by administrative order	Route
Part 207	Establishment registration and drug listing, including for contract manufacturers	Register
Parts 210, 211	Current good manufacturing practice for finished pharmaceuticals, OTC included	Make
201.66	Drug Facts labeling: content, order and format of the OTC label	Label
211.22	A quality control unit with responsibility to approve or reject components and drug products	Decide
211.188, 211.192	Batch production records and their review before release	Review
Quality agreement	FDA guidance on documenting who does what in contract manufacturing (nonbinding)	Partner

Check the current monograph. Monographs now live as administrative orders on OTC Monographs@FDA and can change. Confirm the current order for each product rather than relying on an older CFR monograph citation [7].

WHERE V5 FITS

V5 keeps procedures, specifications and master records as controlled documents and links each batch to the revisions it used. V5 does not interpret monographs, check label claims against them or register establishments.

Sources: [2], [3], [6], [7], [8], [9] (linked on pages 21–22)

CONTROL / 01

Components wait until they are released.

Components, containers and closures are held in quarantine until tested or examined and released by the quality control unit. Each lot is tested for identity; a supplier's certificate can be relied on for other attributes only with periodic validation of the supplier's results (211.84) [2].

COMPONENT LOT (WORKED EXAMPLE)	EVIDENCE	RELEASE FOR USE?
Active ingredient AI-204	Identity test + supplier certificate	YES
Emollient base EB-881	Identity test + certificate	YES
Purified water	Daily monitoring results	YES
Tubes TB-3307 (printed)	Inspection awaited	HOLD
Thickener TK-119	Identity test failed	NO

Identity every lot

At least one identity test on each component lot is the baseline in 211.84(d)(1). Record the test and the result per lot.

Certificates with checks

Relying on a supplier's analysis for other attributes needs your own periodic verification of that supplier's results [2].

Containers count too

Tubes, jars and closures are components of the finished product's control. Printed tubes are also labeling.

PRACTICE: MAKE QUARANTINE A STATUS, NOT A SHELF

A quarantine cage helps, but the record should stop a pending lot being dispensed even if it is picked up by mistake. Status, not location, is what the scanner should check.

WHERE V5 FITS

V5 receiving records supplier and internal lots, holds each lot as pending until released, attaches certificates and issues only released lots. AI certificate extraction can draft values from supplier PDFs for a person to check. Test methods and acceptance stay with your quality unit.

CONTROL / 02

Dispense to the approved master record.

Each product has a master production record with components, quantities, instructions and limits (211.186). Each component added to a batch is weighed or measured as written and verified, by a second person or, where automated equipment is used under 211.68, by one person checking it (211.101) [2].

COMPONENT (BATCH TP-6130, MPR REV 7) TARGET		ACTUAL	TOLERANCE	IN LIMIT?
Active ingredient AI-204	1.200 kg	1.204 kg	±0.006 kg	YES
Emollient base EB-881	18.40 kg	18.43 kg	±0.10 kg	YES
Preservative PV-07	0.120 kg	0.128 kg	±0.004 kg	HOLD
Purified water	39.6 kg	39.6 kg	±0.2 kg	YES



Out of tolerance

The preservative reads 8 g over target. The entry is flagged and held; your procedure decides whether to adjust, and the deviation is reviewed.

Right revision

The batch record shows master record revision 7. A change of base supplier would be change control, not a dispensing note.

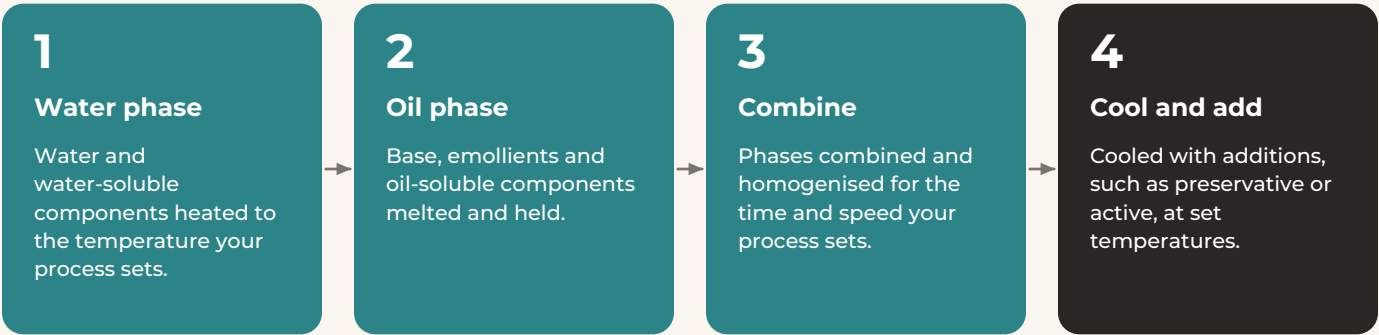
WHERE V5 FITS

V5 master and batch records carry components and quantities by revision; dispensing steps check the scanned lot, scale and tolerance, record the verifying person, flag out-of-limit entries and raise a deviation. V5 does not design formulas or set limits.

MAKE / 01

Phases, heat and time, as your process defines.

Topicals are often made in phases: an oil phase and a water phase heated, combined, homogenised and cooled, with additions at set temperatures. Written procedures and in-process controls cover each step (211.100, 211.110) [2].



IN-PROCESS STEP (WORKED EXAMPLE)	LIMIT	RECORDED	OK?
Water phase temperature	Your range	In range	YES
Homogenise time	Your range	Extended by 6 min	HOLD
Active added below	Your temperature	Confirmed	YES
Appearance, pH, viscosity (in-process)	Your limits	In limits	YES

WORKED EXAMPLE: A LONGER MIX

Homogenising ran six minutes past the limit while a seal was checked. The step records the actual time, deviation DV-2214 opens, and the quality unit reviews it before the batch can be approved.

WHERE V5 FITS

V5 batch records guide each step, record times, temperatures and checks you define, and raise deviations when a value is outside its limit. Process parameters and their validation are your team's; V5 does not control vessels.

Sources: [2] (linked on pages 21–22)

MAKE / 02

Clean equipment, identified on the record.

Equipment is cleaned and maintained to written procedures (211.67), major equipment is identified in the batch record (211.105), and a cleaning and use log is kept (211.182). Topicals can leave hard-to-clean residues, so cleaning evidence matters [2].

EQUIPMENT (WORKED EXAMPLE)	STATUS BEFORE TP-6130	USE?
Vessel V-03 (500 L)	Cleaned after TP-6122; checked	YES
Homogeniser H-01	Cleaned; inspection recorded	YES
Tube filler F-02	Cleaned; line clearance done	YES
Scale S-11	Calibration current	YES
Scale S-14	Calibration expired	NO

Clean between products

When a vessel moves from one product, or one customer, to another, the cleaning record should show the previous use, the method and who checked it.

Calibration where it counts

Scales, thermometers and viscometers used for release-relevant values need current calibration on the day of use.

Look back on failure

If a scale fails calibration, list the batches weighed on it since its last pass so your team can evaluate them.

WHERE V5 FITS

V5 records equipment cleaning, use and maintenance, calibration with certificates, and can gate devices whose calibration is out of date. It lists batches that used an instrument after a failed calibration. Cleaning validation and limits stay with your team.

MAKE / 03

Fill, check weights, clear the line.

Packaging and labeling operations prevent mix-ups and cross-contamination: products are physically separated, lines are inspected before use, and the inspection is recorded in the batch record (211.130) [2].

PACKAGING STEP (WORKED EXAMPLE)	RESULT	OK?
Line clearance before TP-6130	Previous materials removed; checked by two people	YES
Fill weight start-up checks	Within your limits, 10 of 10	YES
Hourly fill checks	Within your limits, 40 of 40	YES
Crimp lot and expiry	Verified at start-up and hourly	YES



WHERE V5 FITS

V5 records line clearance, fill-weight checks against your limits and packaging steps, and blocks the next step when a check fails where configured. Filler settings and sampling plans are your team's.

Sources: [2] (linked on pages 21–22)

MAKE / 04

Drug Facts, issued and reconciled.

OTC labels follow the Drug Facts format in 201.66. Labeling is issued in controlled quantities and reconciled: issued, used and returned, with discrepancies outside narrow preset limits investigated (211.125) [2][3].

LABEL RECONCILIATION (TP-6130)	COUNT	NOTES
Labels issued	2,060	From printed lot LB-7710
Applied to tubes	2,000	Matches tubes filled
Destroyed at start-up and set-up	42	Counted and recorded
Returned to stores	18	Counted and recorded
Unexplained	0	Within your preset limit

Drug Facts content

Active ingredients, purpose, uses, warnings, directions, other information and inactive ingredients, in the set order and format [3].

Check the printed piece

Verify a printed sample from the line against the batch record and approved artwork: lot, expiry and Drug Facts version.

Customer artwork

In contract work the brand owner usually approves artwork; record which approved version was printed.

WHERE V5 FITS

V5 prints labels from approved templates and the batch record, records label checks and reconciles issued, used, destroyed and returned counts per batch. V5 does not write Drug Facts content or check claims against a monograph.

DECIDE / 01

Test the batch, keep pending visible.

Each batch is tested against its specifications, including identity and strength of each active ingredient, before release (211.165). Topicals commonly add appearance, pH, viscosity and microbial limits, as your specification sets [2].



- Identity and strength**

Each active ingredient's identity and strength are tested before release (211.165(a)) [2].
- Microbial limits**

Where your specification includes them, results often arrive last. Show them as pending, not missing.
- Out of specification**

An OOS result is investigated and documented before any decision (211.192) [2].

FINISHED PRODUCT TEST (TP-6130)	RESULT	COMPLETE?
Assay, active ingredient	In specification	YES
Identity	Confirmed	YES
Appearance, pH, viscosity	In specification	YES
Microbial limits	Awaiting lab	PENDING

WHERE V5 FITS

V5 laboratory sample plans carry your finished product tests, record results against your specifications, keep pending tests visible and escalate out-of-specification results to a deviation. Methods and acceptance criteria stay with your lab and quality unit.

DECIDE / 02

Stability supports the date on the crimp.

A written stability programme supports storage conditions and expiration dates (211.166), and the expiration date on the label is based on it (211.137). Check 211.137 for the narrow exemptions that can apply to some OTC products [2].

STUDY (WORKED EXAMPLE)	SCHEDULE	STATUS	CURRENT?
Long-term, labelled storage	0, 3, 6, 9, 12, 18, 24, 36 months	Month 6 due	PENDING
Accelerated	0, 3, 6 months	Complete	YES
Annual batch enrolment	One batch per year per your plan	TP-6130 enrolled	YES
Container closure	Per your protocol	Ongoing	PENDING

In the marketed pack

Stability is tested in the same container-closure system as the marketed product, so a tube change is a stability question [2].

Pulls on schedule

A missed pull is missing evidence. Keep the schedule where quality can see it, not only in the lab.

Trend, then decide

Your team reviews trends and decides whether dating still holds; record the decision with the data.

WHERE V5 FITS

V5 stability management schedules pulls, records results against your specification and escalates out-of-specification results. Study design, shelf life and expiration dating are your quality unit's decisions.

DECIDE / 03

Review the record, then decide.

The quality control unit reviews and approves batch production and control records before release, and investigates any unexplained discrepancy or failure to meet specifications (211.22, 211.192) [2].



WHAT THE BATCH RECORD SHOWS (211.188, PARAPHRASED)

Who and what

Dates, equipment, component lots, weights and the people who performed and checked each step.

Checks and results

In-process and laboratory results, yields, and the packaging and labeling inspection.

Labels and deviations

Specimens or copies of labeling used, reconciliation, and every investigation.

Yield is a question. Actual yield against theoretical is recorded at the end of each phase where your process sets it (211.103). A low yield in a cream batch is a reason to ask, before it is a reason to explain [2].

WHERE V5 FITS

V5's QC release queue shows each batch's results, open deviations, yields and label reconciliation in one view, and a named reviewer records the decision with an electronic signature. V5 never releases product automatically and never makes the disposition decision.

PARTNER / 01

Contract work: write down who decides.

FDA's quality agreements guidance describes how owners and contract facilities can document their CGMP responsibilities. It is nonbinding, but the owner's quality unit stays responsible for approving or rejecting the product made for it [8].

ACTIVITY (EXAMPLE ALLOCATION)	TYPICAL OWNER	NOTE
Approve master record and specifications	Owner	Contract maker executes
Component supplier qualification	As agreed	Record who did it
Batch manufacture and record	Contract maker	Owner may review
Testing	As agreed	Contract maker or owner's lab
Disposition for the market	Owner's quality unit	After contract maker's review
Changes and deviations	Notify per agreement	Both keep records
Complaints	Owner usually leads	Contract maker investigates

Two releases, one product

In many contract arrangements the contract maker releases the batch to the owner and the owner's quality unit releases it to market. Record both.

Separate customers

When several brand owners share a plant, each customer's records, documents and portal access should stay separate.

WHERE V5 FITS

V5 records the contract maker's batch and review, notes the customer's release step your agreement sets, and gives customers their orders and documents through the portal where enabled. Your quality agreement, not the software, allocates responsibilities.

Sources: [8] (linked on pages 21–22)

PARTNER / 02

From one active lot to every customer.

Written complaint procedures (211.198) and distribution records that let you find every shipment of a lot (211.196) are what make a fast response possible [2].

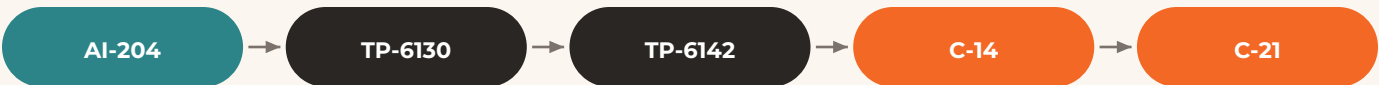


Trace forward

From active lot AI-204: batches, finished lots, customers and shipments, with dates. Then back from a tube's lot to every component.

Complaints with lots

Record the lot from the crimp with every complaint, so investigations and trends follow the batch.



WORKED EXAMPLE: ONE ACTIVE LOT, TWO BATCHES, TWO CUSTOMERS

BATCH	MADE	SHIPMENT	CONSIGNEE
TP-6130	2,000 tubes	SHP-5120	Customer C-14, 2,000 tubes
TP-6142	1,500 jars	SHP-5133	Customer C-21, 1,500 jars
In stock	0	None	No finished stock from AI-204

WHERE V5 FITS

V5 records complaints against lots, routes investigations and CAPA, and traces from a component lot to batches, shipments and customers and back. Reportability decisions, recall strategy and notices stay with your people.

Sources: [2] (linked on pages 21–22)

PARTNER / 03

Your software is part of your controls.

Computers and related systems used in manufacturing are routinely checked, with controls over changes and access, and records kept (211.68). Part 11 applies to electronic records and signatures used to meet these rules [2][10].

01 Define intended use
What the system does in your process, which records it holds and which decisions it supports.

02 Assess risk
Scale validation effort to the risk of each use, as your procedure describes.

03 Validate before use
Plan, test and approve before relying on it; keep the evidence.

04 Control change
Assess each change, including supplier releases, and revalidate as needed.

WHO DOES WHAT

You, the manufacturer, decide the intended use, assess risk, plan and approve validation, including performance qualification, and decide when a change needs revalidation. **A supplier** can provide documentation and, where agreed, installation and operational qualification support. In V5's case, IQ/OQ and validation support are part of the Enterprise plan, scoped in the accepted quote or statement of work.

WHERE V5 FITS

V5 records configuration and record changes in an audit trail and releases software in versions, so you can see what changed. V5 is not validated for your use until you validate it, and it does not make a product or plant compliant on its own.

Sources: [2], [10] (linked on pages 21–22)

APPLY / 01

Where V5 fits, and where it does not.

A plain map from each rule to the V5 capability that keeps its record, and the decision that stays with you. Capabilities are from the V5 product reference reviewed 1 October 2026 and depend on plan and configuration.

RULE OR AREA	V5 KEEPS THE RECORD	YOUR PEOPLE DECIDE
Components (211.84)	Receiving, quarantine status, certificates	Tests and acceptance
Master record (211.186)	Master records by revision	Formula and limits
Dispensing (211.101)	Weigh steps, verifier, tolerance	Adjustment decisions
In-process (211.110)	Step records, times, deviations	Process parameters
Equipment (211.67, .182)	Cleaning, use, calibration logs	Cleaning validation
Packaging (211.130)	Line clearance, fill checks	Sampling plans
Labeling (211.125)	Label print, reconciliation	Drug Facts content
Testing (211.165)	Sample plans, results, OOS	Methods, specifications
Stability (211.166)	Schedules, results	Dating
Review (211.192)	QC release queue, e-signature	The disposition
Distribution (211.196)	Shipments, lot trace, portal	Recall decisions

Not offered: product classification, monograph conformity checks, label claim review, establishment registration or submissions to FDA. **Coming soon:** AI demand and yield forecasting and process anomaly detection. **Plan-dependent:** IQ/OQ and validation support are Enterprise only.

WHERE V5 FITS

Nothing in V5 releases a batch, decides a disposition, classifies a product or approves a label. It keeps the evidence connected so the quality unit that makes those decisions can see it.

WORKSHEET 01

Batch review readiness for one cream batch.

Use with a real (or test) batch record. Tick what the record shows today without asking anyone.

	SHOWN	PARTLY	NOT SHOWN
Components released Each lot tested for identity and released before use	☐	☐	☐
Master record revision The batch shows which approved revision it followed	☐	☐	☐
Dispensing verified Each weight in tolerance, with the verifying person	☐	☐	☐
Phase steps Times, temperatures and additions recorded as defined	☐	☐	☐
Equipment Cleaning, identification and calibration shown	☐	☐	☐
Fill and line clearance Fill checks and line clearance recorded	☐	☐	☐
Label reconciliation Issued, used, destroyed and returned accounted	☐	☐	☐
Tests complete No required result still pending; OOS investigated	☐	☐	☐
Deviations closed Each reviewed, with a recorded decision	☐	☐	☐
Quality unit decision Who decided, when, with what evidence	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Questions for any software demo.

Ask the vendor to show, not tell, using test data. Record what you saw.

	SHOWN	PARTLY	NOT SHOWN
Quarantined lot Try to dispense an active ingredient still in quarantine.	☐	☐	☐
Wrong revision Show how the batch is tied to the current master record.	☐	☐	☐
Tolerance Enter an out-of-tolerance weight; show the hold.	☐	☐	☐
Verifier Show the second-person check on a dispensed weight.	☐	☐	☐
Expired scale Try to weigh on a scale whose calibration has lapsed.	☐	☐	☐
Label count Enter a label count that does not reconcile.	☐	☐	☐
Missing result Try to approve with a microbial result pending.	☐	☐	☐
Customer split Show one contract customer's records without another's.	☐	☐	☐
Trace From one active lot, list batches and customers, timed.	☐	☐	☐
Audit trail Show who changed a value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

A fair evaluation in four weeks.

A practical way to test any system with your own people and one real product, without touching live records.

WEEK 1

Agree one product and the five questions that matter most. Load its master record, specifications, tests and label template.

WEEK 2

Run a batch end to end with test data: receipt, dispensing, phases, fill, labels, tests and the review.

WEEK 3

Break it on purpose: quarantined lot, out-of-tolerance weight, long mix, lapsed scale, unreconciled labels.

WEEK 4

Run a timed trace from one active lot. Review with quality, lab, production, customers and IT; plan validation.

Rules for the evaluation. Use test data only. Keep your current records and release process live until a validated change is approved. Record what was shown, not what was promised.

ASK V5

“We make [OTC creams / gels / ointments] for [our own brands / contract customers]. Our hardest moment is [e.g. label reconciliation]. Which workflows should we evaluate first?”

Start a 7-day free trial, no card required, or ask V5 on v5ultimate.com.

WHERE V5 FITS

Try V5 with your own product in a trial workspace using test data. The assistant answers questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked 3 October 2026. Click a title to open the publisher's page.

- | | | |
|---|--|---------------------------|
| [1] | U.S. eCFR, 21 CFR Part 210: CGMP in manufacturing drugs, general | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210 | | |
| [2] | U.S. eCFR, 21 CFR Part 211: CGMP for finished pharmaceuticals | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211 | | |
| [3] | U.S. eCFR, 21 CFR 201.66: Drug Facts labeling for OTC drugs | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/section-201.66 | | |
| [4] | U.S. FDA, Is it a cosmetic, a drug, or both? (Or is it soap?) | FDA INFORMATION PAGE |
| https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-bo... | | |
| [5] | U.S. FDA, Soaps and lotions: cosmetics, drugs or both | FDA INFORMATION PAGE |
| https://www.fda.gov/cosmetics/cosmetic-products/soaps-lotions | | |
| [6] | U.S. FDA, OTC monograph reform in the CARES Act (505G) | FDA INFORMATION PAGE |
| https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-o... | | |
| [7] | U.S. FDA, OTC drug review process and OTC Monographs@FDA | FDA INFORMATION PAGE |
| https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs | | |
| [8] | U.S. FDA, Quality agreements for contract drug manufacturing | FDA GUIDANCE (NONBINDING) |
| https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contra... | | |

SOURCES

Sources, continued.

[9] [U.S. eCFR, 21 CFR Part 207: establishment registration and drug listing](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207)

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207>

[10] [U.S. eCFR, 21 CFR Part 11: electronic records and electronic signatures](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11>

How to read the status labels. Binding regulations are law. FDA guidance documents describe FDA's current thinking and are not binding. FDA information pages explain and announce. OTC monographs are administrative orders published on OTCMonographs@FDA; check the current order for each product.

SCOPE AND LIMITS

This guide is practical orientation for evaluating OTC topical drug manufacturing operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. It covers U.S. rules for OTC drug products; it does not cover prescription products, cosmetic-only products or other markets. Regulatory text was checked on eCFR and FDA pages on 3 October 2026; confirm the current text before relying on it. V5 capability statements reflect the V5 product reference reviewed on 1 October 2026 and depend on plan, configuration, devices and permissions. AI forecasting and anomaly detection are coming soon. V5 does not classify products, check monograph conformity, approve labels, release batches, decide dispositions or report to FDA; it is not validated for your use until you validate it and does not by itself make a product or plant compliant. Photography is illustrative; batches, weights and results are worked examples, not customer data.



Right formula. Right fill. Your quality unit decides.

See OTC topical workflows at v5ultimate.com · U.S. edition · October 2026