Analytical or product-testing laboratory

Focus on testing the material: identity, purity, content, activity, contamination and stability. Work through a hypothetical certificate, then connect the result to sampling, provenance and the limits of the claim made from it.



Owen / fictional visitor

YOUR LEARNING JOURNEY

Create a certificate-scope review that distinguishes measured attributes from assumptions about an entire product or batch.

Define the measurement question, work through method limits and sampling, then read the report in that context.

FDA manufacturing guidance discusses supplier reliability and identity testing in its own CGMP context. This worksheet is not laboratory accreditation, batch release or proof of suitability for human use.

Open the current online guide

Sources and related guides remain accessible on the website. All role paths are open to every reader.

Portrait: fictional illustration, not a real patient, professional reviewer or endorsement. This handbook provides education, not individual medical or legal advice.

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Read in order for a foundation, or use the linked contents to find a specific topic. Page numbers refer to this edition.

SUGGESTED START

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Testing the material: seven different questions

An analytical laboratory studies the material submitted to it. Start with the question you want answered, then ask which method can answer it. A report about identity cannot silently stand in for a report about amount, contamination or clinical effectiveness. The sample, formulation, analytical method and acceptance criteria all shape what the result means.

Identity asks whether the material matches its stated identity. Laboratories may compare molecular mass, amino acid sequence, structural features or chromatographic behavior with a suitable reference. A matching mass alone does not establish every structural detail. Ask which features the method can distinguish, and whether additional methods are needed for the particular material.

Purity asks what else a method detected. A chromatographic purity percentage describes separated signals under specified conditions. It is not automatically the proportion of all powder that is peptide. Water, counterions, residual solvents and impurities outside the method’s detection capability can require separate measurements. Two methods may produce different descriptions because they observe different properties.

Content, sometimes called assay or strength, asks how much target substance was measured. Read the units and calculation basis: mass per container, concentration or percentage of a stated claim. Biological potency asks a different question: whether the material produces specified biological activity in an appropriate assay. Chemical content alone does not establish biological activity, and an activity assay does not establish effectiveness in patients.

Sterility testing looks for viable microorganisms using a defined method and sample plan. A reported result concerns the material and conditions tested; it is not a universal guarantee covering every container or every contamination risk. Bacterial endotoxin testing is separate. Read its method, units, limit and sample-suitability information. Endotoxin testing does not cover every pyrogen. USP includes both Chapter 85 and Chapter 86 approaches; the latter uses recombinant reagents.

Stability asks whether specified qualities are maintained over time under defined conditions. A fresh COA is a snapshot, not a shelf-life study. Expiry support depends on the formulation, packaging and storage conditions studied. A reference standard is characterized material used for comparison. Traceability is a documented measurement chain to a reference, not a blanket endorsement of a laboratory or supplier. Measurement uncertainty describes uncertainty associated with a result; it should not be confused with permission to ignore a failed criterion.

One result cannot answer every question

A fictional sample has high chromatographic purity but no content, sterility or endotoxin results. The supported statement is that the submitted sample met the stated chromatographic criterion. Its amount and those microbiological properties remain unassessed. Nothing in that limited result establishes clinical benefit or suitability for human use.

READ THE SOURCE

USP authors: Reference Standards to Support Quality of Synthetic Peptide Therapeutics

FDA: Pyrogen and Endotoxins Testing-Questions and Answers, March 2026

USP Chapter 1085: Guidelines for Bacterial Endotoxins Testing

FDA: Expiration Dates-Questions and Answers

NIST: Metrological Traceability

Read a certificate of analysis without filling in the blanks

A certificate of analysis, or COA, records analytical findings for an identified material or sample. It is useful evidence only when its scope is understood. It is not interchangeable with a manufacturing history, clinical study, regulatory approval or guarantee about every item bearing a similar label. Begin with the identifiers rather than the biggest percentage on the page.

Match the laboratory name, report number, sample identifier and stated lot or batch. Check receipt, testing and issue dates, and whether the report was revised. Establish who selected and submitted the sample and what material the laboratory actually received. A report cannot establish the history of material it never handled. A seller’s screenshot may omit pages, qualifications or revisions; report authenticity can be checked through independently located contact details for the issuing laboratory.

For each result, read four things together: the property measured, the method, the units and the acceptance criterion. A specification describes tests and criteria used to judge the material. A pass means the reported finding met that stated criterion; it does not make unmeasured properties pass too. The appropriateness of the criterion is a separate question. If the report does not explain its basis, ask what standard or specification was used.

Read purity and content separately. Chromatographic peak-area purity describes signals separated by a particular analytical method. A content assay measures an amount using its own method and calculation basis. A product can have a high chromatographic percentage while containing less target substance than its stated claim. Water, counterions and other components are reasons that the mass of powder and the mass of target peptide are not necessarily identical.

Not tested means no result for that question; it is neither a pass nor a demonstrated failure. Not detected means the method did not detect the substance under its conditions and detection capability; it does not necessarily mean zero. A result below a quantification limit cannot automatically be treated as a precise amount. When relevant, ask about method suitability, the reference standard and measurement uncertainty rather than comparing bare numbers across unlike methods.

Keep the conclusion as narrow as the evidence. A chemical report without microbiological testing cannot establish sterility or endotoxin status. A single test date does not establish shelf life. A certificate for one submitted sample also does not show that a treatment works in humans. The practical reading question is: which test, on which sample, against which criterion, and what remains unknown?

Invented COA exercise: high purity, failed amount

This is an invented learning example, not a real product or report. Teaching Material A, lot EDU-001: identity is consistent with the stated sequence under the named method. HPLC purity is 99.2% area against an invented criterion of at least 98.0%, so that criterion passes. Content is 8.1 mg per container against a nominal 10.0 mg claim and an invented acceptance range of 9.0-11.0 mg, so content fails: 8.1 divided by 10.0 equals 81% of the claim. Biological potency, sterility and endotoxin were not tested; no stability study was supplied. Those questions remain unanswered. All limits here are fictional educational values, not product standards or use instructions.

READ THE SOURCE

USP authors: Peptide reference standards, purity and content

NIST: Reference materials and certified values

NIST: Traceability and uncertainty

FDA: Expiration Dates-Questions and Answers

Worked method review: identity, purity and amount

A fictional report records an expected intact mass and 99% HPLC peak-area purity. A mass match supports a limited identity comparison; it does not distinguish every structural variant. Isobaric amino acids share a mass, and stereochemical differences may require additional methods. HPLC area purity is not automatically peptide content: quantitative content assessment needs an appropriate reference standard and method, with non-peptide contributions addressed.

For this report, write “consistent with the tested identity criterion” rather than “fully characterized,” and ask which additional identity methods were performed. Record whether the reported percentage is peak area or an independently established content value. The cited research illustrates why several complementary methods are used.

Sampling questions: who selected the containers, how many were sampled, what lot do they represent, and what sampling plan supports that inference? Custody questions: who transferred the sample, when was it received, what seal and identifiers were recorded, and were transport or storage deviations documented? Separate observed receipt details from the submitter’s assertions. An accurate measurement cannot establish representativeness that was never documented.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

Peer-reviewed original research - Reference standards for synthetic peptides

API provenance: trace the ingredient, not just the logo

An active pharmaceutical ingredient, or API, is the ingredient intended to provide a medicine’s pharmacological activity. An excipient serves another formulation role. A manufacturer makes material; a distributor moves it through commerce; a repackager transfers material into another container. One organization may perform several roles, but a reseller’s name does not identify the original manufacturing site. This distinction matters when interpreting records and investigating a quality problem.

FDA urges compounders to understand their API and excipient suppliers, the quality of the material and what testing has been performed. It also urges repackagers to identify the original API manufacturer clearly and maintain supply-chain transparency. The agency describes patient harm associated with component-quality problems. A useful document review therefore connects the chemical identity, original manufacturer, manufacturing site, intermediaries, batch identifiers and document dates instead of collecting unrelated certificates.

A certificate of analysis, or COA, reports specified test results for an identified sample or batch. Start by asking what was measured and how the report connects to the material. Identity, purity, content, microbial quality and other attributes answer different questions. A percentage without its method and meaning is easy to overinterpret. A purity result alone cannot establish sterility, clinical benefit, FDA approval or eligibility for a particular compounding use. Those are different conclusions requiring different evidence.

In its drug-manufacturing guidance, FDA discusses representative sampling, identity testing and establishing the reliability of supplier analyses. That context matters: a manufacturing quality system cannot be reduced to downloading a COA. Nor is every CGMP provision automatically a universal checklist for every research laboratory. The educational task is to recognize missing information and the applicable context, not to declare a batch released or independently certify a laboratory.

Keep three conclusions separate: what the organization says it does, what documents establish about this material, and what rules apply to the proposed use. Registration is not FDA approval. A sound provenance record can reveal unanswered questions without promising that a product is safe, legally eligible or appropriate for a patient.

Illustrative case: a report with no batch connection

A brochure displays a high-purity result but the report identifier cannot be linked to the item being discussed. The result may describe a tested sample; it does not establish that the item shares those results. Record the gap rather than filling it with an assumption about the entire supplier.

READ THE SOURCE

FDA - Know Your Bulks and Excipients Suppliers

FDA - CGMP Questions and Answers: Components, Containers and Closures

FDA - Is It Really FDA Approved?

Bachem - Vista Manufacturing Site

CordenPharma - API Manufacturing

What “gray market” leaves unexplained

“Gray market” is a loose conversational label, not a quality grade or a legal conclusion. It can blur several different issues: an unapproved product promoted for human use, an authentic product outside a documented supply chain, a counterfeit identity, misleading research labeling, or a preparation that does not meet a compounding pathway’s conditions. Name the actual question before deciding what a document or testimonial proves.

A research-use statement describes a claimed purpose; it does not automatically settle intended use. In a March 31, 2026 warning letter to Gram Peptides, FDA explained that website evidence established intended human use despite research-only and not-for-human-consumption disclaimers. This is an example of FDA's stated enforcement findings, not a final court judgment or a claim about the company's later status. The broader lesson is to read the surrounding claims and presentation, not a disclaimer in isolation.

Counterfeit and unapproved are also different concepts. Counterfeit identity concerns a product falsely represented as authentic. Unapproved status concerns the absence of applicable approval. Lawfully compounded medicines are themselves not FDA-approved, so "unapproved" alone does not describe every applicable legal condition. Conversely, calling something compounded does not establish that it meets those conditions. Classification requires the exact product, source, claims and regulatory context.

Chemical names require precision. On its current GLP-1 concerns page, FDA states that retatrutide and cagrilintide cannot be used in compounding under federal law. The same page distinguishes semaglutide sodium and acetate from the active ingredient in approved medicines and says the agency is unaware of a lawful basis for their compounding use. These are product-specific statements, reviewed October 31, 2026; do not generalize them to every peptide, salt or jurisdiction.

A separate FDA clarification dated April 1, 2026 discusses restrictions on preparations that are essentially copies of commercially available drugs. It explains that adding another active ingredient does not automatically avoid those restrictions. That dated statement should remain dated: it is not an independently checked live shortage-database result. An April 30, 2026 announcement proposing exclusion of three GLP-1 substances from the 503B bulks list was a proposal, not a final decision.

For an educational review, record exactly what is known: the named item, original source, date, claimed use and unresolved identity or quality questions. Distinguish a reported adverse event from proven causation and a compelling anecdote from a controlled study. Neither a disclaimer nor a dramatic personal story turns an uncertain product into a verified clinical option.

Illustrative case: "research only" beside human promises

A page says research only while its surrounding language promises personal recovery or weight loss. A reader should record the tension between those messages and examine the applicable rules. The footer alone cannot answer whether the product is being marketed for human use.

READ THE SOURCE

FDA - Gram Peptides Warning Letter, March 31, 2026

FDA - Concerns with Unapproved GLP-1 Drugs

FDA - Compounding Questions and Answers

FDA - Compounding Clarification, April 1, 2026

FDA - Proposed 503B Exclusions, April 30, 2026

Read a study as a complete record

Begin with the primary paper and registry where available. A registry describes a planned or reported study; its presence does not prove benefit. Compare the registered population, outcomes and timing with the published account. Preserve publication date, study period and later update date as different facts.

Write the research question using population, intervention, comparator and outcome. Include species, formulation, route and duration. A comparison against placebo answers a different question from a comparison against an active medicine. A study in one population may leave other groups unrepresented.

Look at how participants entered the analysis. An estimate based on everyone assigned may differ from one describing participants who remained on treatment. Missing observations and treatment discontinuations can affect interpretation. Record the paper’s stated analysis and assumptions instead of merging estimates from different methods.

Check whether an outcome was primary, secondary or exploratory. Multiple measurements increase the opportunity for chance findings; the analysis plan and adjustments matter. A confidence interval describes uncertainty under the analysis assumptions. Statistical significance does not by itself establish a meaningful improvement in daily life.

Read withdrawals, adverse events and serious events alongside benefits. Retain reported causality assessments and comparator counts. Distinguish no event observed from evidence that an event cannot occur. Small studies and short follow-up may have limited ability to characterize uncommon or delayed harms.

Finally, separate the result from its interpretation. Note sponsor involvement, available methods and missing details. A sponsor release can report a development before full results are public; attribute it clearly and leave unresolved methods visible until the paper or registry supplies them.

Worked learning example

A headline reports one percentage while a paper supplies two estimates under different analysis assumptions. Label each estimate with its population and method; do not choose the larger number simply because it makes a stronger headline. The comparison is only meaningful when the definitions travel with the numbers.

READ THE SOURCE

Testing Treatments - evaluating treatment evidence

Reading path and books

1. Separate evidence categories

Analytical identity and purity are different questions from clinical safety and effectiveness.

2. Check product context

Connect a report to the named product, provenance and regulatory category.

3. Keep research status visible

A laboratory result does not change an investigational compound into an approved medicine.

Continue in the Church Library

Choose the level that fits your background. Book links lead to the Library, where reading options and any affiliate disclosures are shown.

Testing Treatments - Evans, Thornton, Chalmers and Glasziou

Start with fair comparisons and uncertainty. The library entry includes an official free reading option. Published in 2011; use current official sources for regulatory questions.

The Art of Statistics - David Spiegelhalter

Go deeper into denominators, uncertainty and interpreting data. Read alongside the actual study rather than using a statistical slogan as a verdict.

Bad Blood - John Carreyrou

A reporting case study in laboratory claims and organizational accountability. It is not a laboratory method or accreditation standard.

Browse all Library rooms

Examples in practice

These examples identify published resources and their uses; they are not evaluated services.

Intertek - peptide characterization

Analytical example: provider-published descriptions of identity, impurity analysis, stability and biological activity assays. Read to compare the questions different methods answer; this is not an endorsement or independent accreditation verification.

Eurofins - peptide characterization and development

Analytical example: describes complementary separation, structural, impurity and stability methods. Published capabilities do not guarantee acceptance of a particular sample or suitability for a particular project.

Bachem - Vista peptide API manufacturing

Company-described example of clinical-to-commercial peptide API manufacturing in Vista, California. The page lists GMP and non-GMP capabilities, illustrating why a company name alone does not establish a specific item’s grade. Reviewed October 31, 2026; not an endorsement, current inspection assessment, purchase direction or finding of compounding eligibility.

CordenPharma - API manufacturing and peptide services

Company-described example of peptide API development, cGMP manufacturing, analytical services and clinical/commercial supply. Reviewed October 31, 2026. This illustrates an industry role; it does not establish availability, approval, suitability or legal eligibility of a particular product or transaction.

Questions and explanations

Does this test answer the claim being made from it?

Match the asserted property to the method’s measurand: what the assay actually measures. Identity, chromatographic purity, content, biological activity and microbiological properties are different targets. For example, a mass consistent with the expected molecule does not establish biological potency or exclude every structural variant. Phrase the conclusion in terms of the method’s demonstrated capability and identify the additional claim it cannot answer.

Is the tested sample demonstrably connected to the item under discussion?

The connection depends on documented sample identifiers, submission details and the relationship between the submitted material and the claimed lot. An accurate result cannot repair an undocumented sampling chain. For example, a laboratory can correctly report on a customer-submitted vial while lacking evidence that it represents other vials sold under the same name. Distinguish what the laboratory observed from what the submitter asserted about provenance.

Which uncertainties remain even if the reported analytical result is accurate?

An accurate result can leave unmeasured attributes, sampling representativeness, stability and clinical relevance unresolved. Method accuracy addresses the reported measurement, not every possible conclusion someone might draw from it. For example, a reliable content measurement today does not establish that the formulation retains that content throughout a claimed shelf life. State the remaining uncertainties explicitly so the report is not reused as a broader guarantee.

Who originally manufactured this material, and how does this report connect to this batch?

Original manufacture is a provenance question that may require records beyond the laboratory’s own receipt log. Distinguish the sample submitter, distributor, repackager and original manufacturing site, and avoid implying the laboratory verified relationships it did not investigate. For example, receiving a container from Distributor X establishes receipt from that submitter, not that Manufacturer Y made its contents. Report the source of any manufacturer attribution and the limits of the batch linkage.

Which attributes were not tested?

Create a scope statement listing reported tests and expressly identifying major conclusions the report does not support. Missing results should remain missing rather than being inferred from another method’s success. For example, identity and HPLC purity without content or microbial testing cannot substantiate an amount claim, sterility or endotoxin status. Where a method reports “not detected,” retain its detection capability rather than rewriting the result as absolute absence.

Glossary

Comparator
The reference group or intervention against which an outcome is compared, such as placebo or another treatment.

Endpoint
An outcome defined for a study. A biological measurement and a patient-important outcome are not necessarily the same thing.

Formulation
The composition and presentation of a product, including ingredients beyond the active substance.

Adverse event
An unwanted medical occurrence during observation; occurrence does not itself establish a causal connection to treatment.

Investigational
Under investigation. This describes research status, not proof of safety or benefit.

COA
Certificate of analysis: a report of specified tests and results for an identified material or sample. Its meaning depends on scope and provenance.

Identity
Whether a material matches the named substance within the methods and comparisons used.

Purity
A method-dependent assessment of detected components; chromatographic peak-area purity is not automatically total mass purity.

Assay / content
A measurement of the amount of a specified substance, stated with units and a defined basis.

Potency
Biological activity assessed by a specified assay; the term is sometimes used differently, so inspect the report’s definition.

Sterility
The absence of viable microorganisms; interpreting a sterility-test result requires its sampling and method context.

Endotoxin
A component of certain bacteria that can provoke inflammatory reactions. Endotoxin testing is distinct from sterility testing.

Traceability
A documented connection to an origin or reference. Measurement traceability and supply-chain provenance are related but different questions.

API
Active pharmaceutical ingredient: the substance intended to provide a medicine’s pharmacological activity. An API is not the same as a finished medicine.

503A / 503B
Different U.S. statutory pathways for qualifying compounded drugs. Neither makes a compounded drug FDA-approved.

CGMP
Current good manufacturing practice: requirements for manufacturing controls and quality. The applicable framework depends on the activity and product.

Gray market
An informal description of uncertain or unauthorized distribution channels, not a regulatory approval category.

Confidence interval
A range expressing statistical uncertainty under an analysis’s assumptions; it does not remove bias or establish applicability.

Learning worksheet

Certificate scope review

Use these prompts to record what you understand, what remains uncertain and which source could answer the question.

Learning prompt	Filled-in fictional example
Certificate scope review	Fictional example: Report for sample A lists identity only. Amount and sterility are unanswered. Next record: full methods, sample identifiers and documented connection to the claimed lot.

Record report issuer, date, sample identifier and claimed batch connection.

List methods, reported results, units and any stated acceptance criteria.

Mark untested attributes; do not infer sterility or clinical benefit from purity alone.

Record sampling and provenance gaps and the questions needed to interpret the report.

Educational information, not individualized medical or legal advice.

Explore another perspective in the Community Center