PURE7 Knowledge Center

PURE7 Knowledge Center - Phase 3 Quality & Testing

Educational framework for understanding quality controls, Certificates of Analysis, lot traceability, independent laboratory testing, contaminant screening, and GMP-style manufacturing documentation.

Category: Botanical Science **Phase:** Introductory **Topic:** Mitragyna Speciosa

Purpose of this section

This knowledge-center section is designed to help consumers, retailers, and internal teams understand how product quality is documented and reviewed. It does not make medical claims or guarantee any specific product outcome. Instead, it explains the basic quality concepts that are commonly used in botanical, supplement, and consumer packaged goods supply chains.

A strong quality program is built around documentation, repeatable procedures, supplier accountability, and independent testing. The goal is to make sure each batch can be identified, reviewed, and connected back to supporting records.

Educational note: Quality testing is not just one lab result. It is a system of checks that may include raw material review, in-process controls, finished-good testing, packaging verification, recordkeeping, and retention of batch documents.

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01 How To Read a COA

A Certificate of Analysis, often called a COA, is a laboratory document that summarizes test results for a specific sample, batch, or lot. A COA is usually used to show whether the tested material matches expected quality specifications. For botanical products, a COA may include potency results, contaminant screening, sample details, test methods, laboratory information, and the date the analysis was performed.
The most important part of reading a COA is confirming that the document connects to the product in question. A COA is only useful when the product name, batch number, lot number, sample description, and date line up with the item being reviewed.

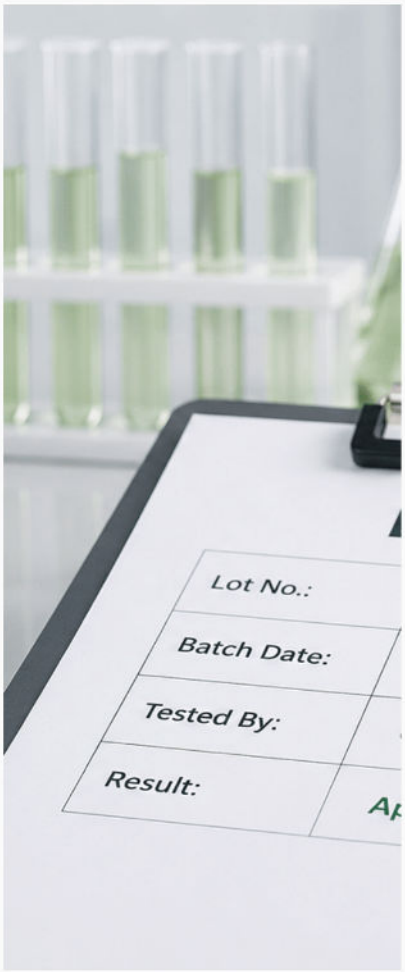
Key areas to review on a COA

- Product or sample name: Identifies what was tested. The name should be clear enough to match the product or raw material.
- Lot or batch number: Connects the test result to a specific production run or ingredient batch.
- Laboratory information: Shows who performed the testing. Many companies prefer independent third-party laboratories.
- Test date and report date: Helps show when the sample was analyzed and when the report was issued.
- Analytes: The specific compounds or contaminants being measured.
- Results and units: Results may be shown in percent, milligrams per gram, parts per million, colony forming units, or other units depending on the test.
- Methods: Shows the testing approach used, such as chromatography for potency or microbiological methods for microbial screening.
- Pass/fail criteria: Some COAs show whether the result meets an internal or regulatory specification.

02 Understanding LOT Codes

A lot code is a tracking identifier assigned to a batch of product, raw material, packaging component, or finished good. Lot codes help a company trace where materials came from, when a product was made, and which records support that batch. This is one of the most important tools in quality control because it turns a product into a traceable record rather than an anonymous item.

A lot code can be printed on a bottle, pouch, carton, blister card, case, master case, or shipping label. The exact format depends on the company, but a well-designed lot code should be easy to record, easy to read, and consistent across production records.



What a lot code may represent

- Production date: The day or period when the product was manufactured or packaged.
- Batch sequence: A number or letter showing which production run it came from.
- Facility or line identifier: Useful when more than one facility or packaging line is used.
- Raw material connection: Links the finished product back to ingredient lots and supplier documents.
- Recall support: Allows a company to identify affected product quickly if a quality issue is discovered.

Example: A company might use a code such as P7-240518-A01, where P7 identifies the brand or product family, 240518 represents the production date, and A01 identifies the batch sequence. This is only an example; each company should use a format that matches its documentation system.

03 Third-Party Laboratory Testing

Third-party laboratory testing means the sample is analyzed by a laboratory that is separate from the company selling or manufacturing the product. Independent testing can help create an additional layer of review because the testing is performed by a specialized lab rather than only by the internal team.

Third-party testing is commonly used to verify potency, check for contaminants, compare a finished product against specifications, and support quality documentation. It is important to understand that testing is only as good as the sample submitted, the method used, the lab procedures, and the way the company reviews the final report.

What consumers and retailers can look for

- Does the COA match the product lot? The lot number on the report should correspond to the item being reviewed.
- Is the laboratory identified? The report should name the lab and provide enough information to understand who performed the testing.
- Are the test methods listed? Method names help show how the results were generated.
- Are the units clear? Potency and contaminant results should be expressed in understandable units.
- Is the report current enough? Date matters, especially when a product has changed formulation, supplier, packaging, or batch number.
- Are both potency and safety-related screens included? A complete quality review often looks beyond active compounds and includes contaminant testing.

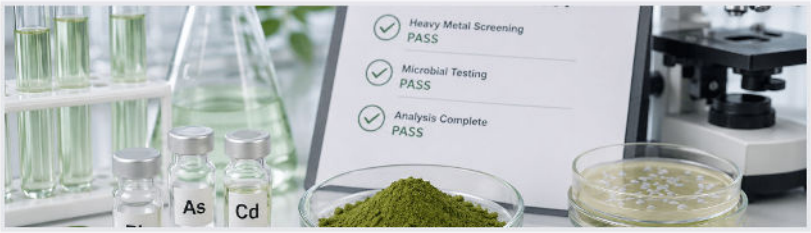
Important distinction: A third-party lab report documents the tested sample. It should not be treated as a blanket guarantee for unrelated batches, old inventory, or products with different lot codes.

04 Heavy Metal & Microbial Testing

Botanical materials can be exposed to environmental and handling risks before they become finished products. Quality programs often use contaminant testing to screen for heavy metals and microorganisms. These tests are part of a broader safety and quality review process.
Heavy metals are elements that may be present in soil, water, or processing environments. Common heavy metal screens include lead, arsenic, cadmium, and mercury. Microbial testing checks for unwanted microorganisms or indicators of poor handling, such as yeast, mold, E. coli, and salmonella.

CATEGORY	EXAMPLES	WHY IT MATTERS
Heavy metals	Lead, arsenic, cadmium, mercury	Can come from soil, water, or environmental exposure and are usually monitored against strict limits.
Microbial indicators	Total yeast and mold, aerobic plate count	Can indicate sanitation, handling, storage, or moisture-control issues.
Pathogens	E. coli, salmonella	Specific organisms that are commonly screened because their presence may indicate serious contamination risk.

Educational note: Passing contaminant testing depends on the applicable specification used by the company, lab, market, or regulator. The COA should make the result and unit clear enough for the quality team to evaluate.



05 GMP Manufacturing Standards

GMP stands for Good Manufacturing Practice. GMP-style systems focus on making products in a controlled, documented, and repeatable way. The purpose is to reduce avoidable errors, improve consistency, and create records that explain how a batch was made, reviewed, packaged, and released.

GMP is not just a clean room or a label on a facility. It is a system of procedures, training, sanitation, equipment controls, supplier review, batch records, deviation handling, and quality checks. A facility can look impressive, but the documentation is what shows whether the process is controlled.

Core GMP-style quality elements

- Written procedures: Standard operating procedures explain how tasks should be performed.
- Training records: Employees should be trained on the procedures they are responsible for following.
- Sanitation controls: Cleaning schedules and logs help reduce contamination risk.
- Equipment checks: Scales, mixers, packaging machines, and measuring tools should be maintained and verified as appropriate.
- Batch records: Production records document what was made, when it was made, what materials were used, and who performed or reviewed each step.
- Label and packaging checks: Helps confirm that the correct labels, lot codes, and packaging components are used.
- Quality review: A designated quality process should review records before product release.
- Deviation documentation: Unexpected issues should be recorded, investigated, and resolved before release when needed.

How the quality system works together

A practical quality system connects each step. Raw material lots connect to supplier records and incoming testing. Production records connect to finished goods and packaging records. Finished goods connect to COAs and lot codes. Distribution records connect products to customers or retailers. When these pieces are organized, the company can answer basic quality questions faster and more accurately.

Simple quality workflow: Supplier review -> incoming material lot -> production batch record -> finished product lot code -> third-party COA -> quality release -> distribution traceability.

Quality & Testing Summary

Quality and testing are best understood as a connected documentation system. A COA helps explain what was tested. A lot code connects the report to a specific batch. Third-party lab testing adds

an independent review point. Heavy metal and microbial panels help screen for common contamination risks. GMP-style manufacturing controls help make the process repeatable and reviewable.

For consumers and retailers, the strongest question is not simply, "Does a COA exist?" The stronger question is, "Does this COA clearly match this product, this lot, this date, and this quality specification?"