Microbiological Evidence: Separate Three Different Claims

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Abstract. Bioburden, bacterial endotoxins and sterility describe different aspects of microbiological control. This guide helps mineral-powder buyers read supplier evidence without treating a low microbial count, an endotoxin result or a raw-material report as interchangeable proof.

Keywords: bioburden; bacterial endotoxins; sterility; raw powder; method suitability

1. Name the measurement

Bioburden concerns recoverable viable microorganisms under the defined sampling, extraction and culture conditions. ISO 11737-1 includes health-care products, components, raw materials and packages in its scope [1]. A result must retain its test conditions and reporting basis.

Bacterial endotoxin testing measures a different target from viable counts. Low bioburden does not establish low endotoxin; a bacterial endotoxin result does not address every possible pyrogen.

Sterility assurance requires an appropriate controlled process and supporting evidence. A negative result from a limited sample cannot by itself establish that every unit is sterile [3].

2. Keep raw powder and final product distinct

Identify whether the report covers incoming powder, a processed intermediate, a final packaged product or an extract. Record the lot, sampling date and whether testing was before or after a specified treatment.

Do not transfer a result across later handling, formulation or packaging without evaluating the added contamination pathways. A customer's final product assessment is separate from incoming-powder screening.

3. Check method suitability

For a powder extract, retain sample mass, extract volume, preparation, hold time and dilution. Establish that the test can detect its target in that matrix rather than assuming a low reading means absence.

FDA's March 2026 endotoxin guidance discusses interference and limits to dilution [2]. A diluted sample needs sensitivity appropriate to the decision limit. Dilution alone must not create an apparently acceptable result by making the test unable to detect the relevant amount.

For viable recovery, ask for a justified recovery method and any correction or method limitation. Distinguish "below the reporting limit" from a numerical zero.

4. Avoid ambiguous shorthand

Spell out **bacterial endotoxins test** in microbiological documents. "BET" also denotes Brunauer–Emmett–Teller surface-area analysis in the mineral-powder series. The two measurements have different units, methods and purposes.

Record CFU/g, EU/g, EU/mL or other stated units exactly as reported. A raw-powder limit must be justified for the intended use; a finished-device limit must not simply be copied into an EU/g specification.

5. Read the result with its evidence package

Illustrative unit conversion, not a specification: an extract result of 0.10 EU/mL from 1.00 g powder in 20.0 mL corresponds to 2.0 EU/g on that extraction basis. If 0.10 EU/mL is the measured concentration of a tenfold diluted extract, the dilution-corrected value is 20 EU/g. This arithmetic does not establish extraction recovery or method suitability.

Claim / record	Evidence to retain	Do not infer
Bioburden result	Method, recovery basis, sample quantity, reporting limit and organism characterization as relevant.	Low endotoxin or sterility.
Endotoxin result	Method, extraction, dilution, sensitivity and interference controls.	Absence of every pyrogen.
Sterile supply claim	Defined product/package and relevant process-validation and routine-control evidence.	Universal sterility from one negative test.
Below reporting limit	Actual limit and sample/dilution basis.	Zero contamination.
Raw-material specification	Intended use, reporting units and agreed decision rule.	Automatic compliance of the finished device.

6. A precise purchasing conclusion

State which measurement was provided and which evidence remains missing. If a report only shows a microbial count, record that as a bioburden result. Do not describe the material as sterile or endotoxin-free. Agree any additional testing with a qualified laboratory against the actual material and intended use.

Scope

This is a document-review aid, not a sterilization procedure, universal acceptance limit or release authorization. It makes no claim that a Kannrybio grade is supplied sterile, pyrogen-free or tested by a particular microbiological method.

References and evidence boundaries

[1] ISO. ISO 11737-1:2018, Sterilization of health care products — Microbiological methods — Part 1. January 2018; Amendment 1, 2021. Official ISO catalog. Public scope checked; no claim of access to the complete standard.

[2] FDA. Pyrogen and Endotoxins Testing: Questions and Answers, Edition 2. March 2026. Official guidance PDF. Method and interference principles; product-specific limits are not reproduced as powder specifications.

[3] WHO. Sterility testing. Official resource. Publication date not stated. Scope is biological medicinal products; sampling limitations are used here as a general evidence boundary.

Sources checked 30 October 2026. Research planning guidance only; no Kannrybio lot-performance, clinical or regulatory-approval claim.

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