SteriTek

Expert Sterilization Services

Thank you for choosing Steri-Tek as your sterilization provider!

We are excited you have chosen us as your sterilization provider! It’s truly an honor to collaborate with you and fulfill all your sterilization requirements.

Within the document, you’ll discover comprehensive details on sample requirements, key contacts for your project, and answers to frequently asked questions.

Rest assured, we’re committed to delivering exceptional customer service and top-notch sterilization solutions.

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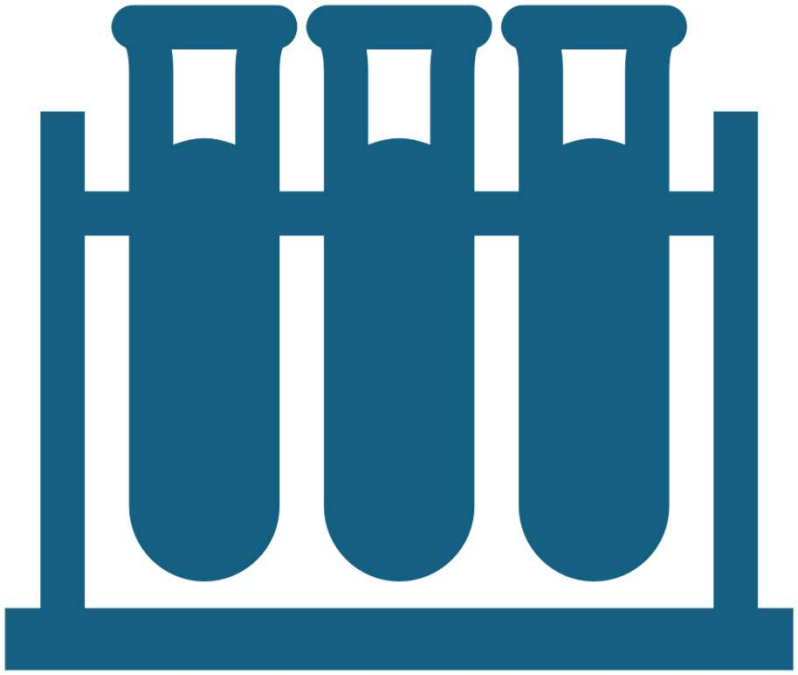
Sterilization Validation to claim Sterility

Sample Requirements

- 30 samples (10 from 3 separate batches) for bioburden analysis/enumeration
  - 10 samples for single batch release
- 3 samples for bioburden recovery (any batch)
- 3 samples for bacteriostasis/fungistasis
- 3 samples for additional method development (dependent on lab)
- 10 samples for sterility
- 10 samples for confirmatory
- 2 shippers + 3 samples of dunnage/simulated material for dose mapping activities



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Sterilization Validation Steps (16-24 weeks including dose map studies)

*turnaround time subject to change

- Protocol creation
- R&D (research and development)
- Microbiology testing
- Dose map studies
- Verification dose
- Final report

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Microbiology Tests

- Bioburden recovery
- Bioburden enumeration/analysis
- Bacteriostasis/Fungistasis
- Sterility

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Dose Audit Requirements

4 quarterly for at least one year

Semi annual for two years

Annual

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Dose Audit Process

- Protocol creation
- Bioburden enumeration/analysis (10 unprocessed samples)
- Verification dose/DVS (10 samples to be processed)
- Sterility using the verification dose samples
- Dose audit report

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Frequently Asked Questions

- Why do I need to validate my sterilization process? To claim sterility.
- I'm doing a clinical trial with human patients, does my product need to be validated? Yes, for product going into human patients, clinical trials included, products needs to be sterile, meaning validated.
- When does my turnaround time start? Once we have all required paperwork and product for the first activity on site.
- What paperwork is needed for my sterilization validation? Dose study questionnaire for the single layer dose map and full dose map, sterilization validation questionnaire, and SOF for all services

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Frequently Asked Questions

- Can I choose the lab? Yes. Steri-Tek has many partner labs that we have worked with and can always provide the best option for your specific product/needs.
- What documentation do I receive showing my product is sterile? After your first routine production run post sterilization validation, you will receive a Certificate of Irradiation (COI).
- I have made changes to my packaging, materials, configuration, manufacturing, etc. Contact your study director, customer success, and dose map department.
- I do not need to claim sterility, I just want my product processed at a specific external dose. This is considered an R&D run and can be performed at any time. You will receive an external dosimetry report post irradiation.

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Contacts

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THANK YOU