

LGGS, Inc.

LGGS, Inc. is an independently owned contract laboratory specializing in U.S.P. and ANSI/AAMI/ISO microbiological testing. We are dedicated to providing safe and reliable product testing. We proudly produce accurate results with the utmost efficiency for every client. Our commitment is to developing ongoing business relationships with our customers.

Gamma Validations

LGGS, Inc. offers Gamma Validation and routine testing services as outlined in ANSI/AMMI/ISO 11137-2, *Sterilization of health care products—Radiation— Part 2: Establishing the sterilization dose*. The most common approaches are the Method 1 or VDmax methods. Both methods employ product bioburden enumeration followed by analysis with sub lethal radiation exposure to ensure sterility.

Action	Sponsor	LGGS, Inc.	Sample Requirements
Sample Submission	✓		N/A
Bioburden Enumeration		✓	10
Irradiation of Product		✓ Through contract sterilizer	10 (VDmax) 100 (Method 1)
Sterility Testing		✓	10 (VDmax) 100 (Method 1)

Validation Services

Protocol Development

Sample Item Portion(SIP)-if necessary

Bioburden Method Recovery/ Validation

Verification Dose Calculation

Verification Dose Experiment

Sterility Validation Test
(Bacteriostasis/Fungistasis)

Bioburden Enumeration/ Validation

Validation Summary Report

Routine Services

Bioburden Enumeration

Dose Auditing



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