|  |  |
| --- | --- |
|  | 705 Front Street  Toledo, OH 43605  Phone: 419-693-5307  Fax: 419-691-0418  **SAMPLE SUBMISSION FORM**  www.lexamed.net |

# (Use one form per sample)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Client #: | |  | | | | Purchase Order #: | | | | | | | |  | | | | | | | | | LexaMed Lab #: | | | | | | | |  | | | | | |
| Company: | |  | | | | | | | | | | | | | |  | | Results: | | | **STAT (extra fee)** | | | | | | | | Phone | | | | Fax | | | Email |
| Address: | |  | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | |  | | Samples Received on: | | | | | | | | Cold Packs | | | | | | Ice | | | Room Temp | |
| Contact Person: | | |  | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
| Phone: |  | | | | Fax: | | |  | | | | | | | |  | | Storage Conditions: | | | | | | Room Temp | | | | | | | Refrigeration | | | | | Freezer |
| Email: |  | | | | | | | | | | | | | | **(Product will be discarded after testing unless requested otherwise)** | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | # Samples Supplied: | | | | | |  | | | | | Sterile | | | | | Non-Sterile | |
| **TEST ARTICLE DESCRIPTION** (appears on Final Report): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Part #: |  | | | | | | | | | Lot #: | | |  | | | | | | | | | | | | | | Batch #: | | |  | | | | | | |
| Test Article is a: | | | | **Medical Device** | | | | | **Pharmaceutical** | | | | | | | | | | | **Combination Device** | | | | | | | | **Other:** | | | |  | | | | |
| Is the test article FDA regulated? | | | | | | | Yes | | | | No | |  | | | | Is testing for: | | | | | **R&D** | | | **FDA Submission** | | | | | | | | | (Type: | | | | ) |
| List any acceptance specifications if applicable: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |

*Please perform the following tests:*

|  |  |  |  |
| --- | --- | --- | --- |
| **GENERAL MICROBIOLOGY TESTS** | | **BIOBURDEN TESTING** | **CHEMISTRY TESTS** |
| Environmental Monitoring Plates | | Bioburden Method Validation – Spore  Inoculation | pH |
| Total Plate Count – Direct Plating | |  | Conductivity |
| Total Plate Count – Membrane Filtration | | Bioburden Method Validation – Exhaustive | Hydrogen Peroxide Assay |
| Organism ID – Gram Stain | | Total Aerobic | Total Organic Carbon |
| Organism ID – Genus & Species | | Total Aerobic Spore | UV analysis |
| USP <51> Antimicrobial Effectiveness | | Total Anaerobic | HPLC analysis |
| USP <61> TAMC/TYMC – Suitability | | Total Fungi (Yeast and Mold) | GC analysis |
| USP <61> TAMC/TYMC – Routine | | **BIOLOGICAL INDICATOR TESTS** | Bradford Protein Assay |
| USP <62> Test for Specific Org - Suitability | | USP BI Population Verification – 4 BIs | Hemoglobin Assay |
| USP <62> Test for Specific Org – Routine | | ISO BI Population Verification – 4 BIs | Carbohydrate Assay |
| Particulate Analysis – Light Obscuration | | D-value Steam Stumbo-Murphy | USP Heavy Metals |
| Choose one: USP <788>  USP <789 | | D-value Steam Spearman-Karber | Osmolality |
| Particulate Analysis – Microscopic Count | | D-value Steam Limited Spearman-Karber | **ACCELERATED AGING TESTS** |
| Choose one:  USP <788>  USP <789 | | D-value Survivor Curve | Real Time Accelerated Aging |
| **STERILITY TESTS** | | z-value Steam Stumbo-Murphy | Temperature: |
| Aseptic SIP Preparation | | z-value Steam Spearman-Karber | **CONTAINER CLOSURE INTEGRITY** |
| Method Suitability SCD  FTM | | z-value Moist Heat | Microbial Aerosol Challenge |
| Membrane Filtration – Qty: | | **CYTOTOXICITY TESTS** | Microbial Ingress Challenge |
| Product Immersion – Qty: | | MEM Elution – ISO Method | Dye Ingress Challenge |
| Biological Indicators – Qty: | | MEM Elution – USP Method | **PACKAGE INTEGRITY TESTS** |
| **ENDOTOXIN TESTS** | | Agar Overlay – ISO Method | Burst Test |
| Device - Kinetic Method | | Agar Overlay – USP Method | Dye Penetration |
| Liquid Sample – Kinetic Method | | **EO RESIDUAL TESTS** | Seal Peel |
| Inhibition / Enhancement – 1 lot – Kinetic | | Ethylene Oxide (EO) | **MATERIAL BARRIER TESTS** |
| Inhibition / Enhancement – 3 lot – Kinetic | | Ethylene Chlorohydrin (EC) | BFE Test |
| Device – Gel Clot | | Ethylene Glycol (EG) | Synthetic Blood Penetration |
| Liquid Sample – Gel Clot | | *Extraction Method:* | Hydrostatic Pressure Test |
| Inhibition / Enhancement – 1 lot – Gel Clot | | Simulated Use Temp     Time | Spray Impact Test |
| Inhibition / Enhancement – 3 lot – Gel Clot | | Exhaustive (24 hour intervals) | **EO CYCLE DEVELOPMENT** |
|  | | TCL required; Surface Area | Sterilizer Run |
| **OTHER (test not listed):** |  | | |
|  |  | | |
| **Special Instructions:** | | | |

**Client Signature: Date:**

|  |
| --- |
| **For LexaMed Use only:**  Date Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received Via:  UPS  FedEx  Other: \_\_\_\_\_\_\_\_\_\_\_\_ Logged in by: \_\_\_\_\_\_\_\_\_ |