|  |  |
| --- | --- |
|  | 705 Front StreetToledo, OH 43605 Phone: 419-693-5307Fax: 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: \_\_\_\_\_\_\_\_\_ |