|  |  |  |  |
| --- | --- | --- | --- |
| Contact information Sender | | | |
| Company name    Contact person |  | Email address |  |
| Sender name |  | Phone number |  |
| Add remark CoA |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sample information | |  |  | |
| Article name |  | Batch number |  | |
| Sample Type | Excipient  Drug substance  Drug product  Medical device  Other: | Safety considerations / restricted compound  *(provide MSDS at first shipment to SHU)* | Antibiotic  Cytotoxic  Opioid  Precursor  Other: | |
| Sample size | ml  gram | Amount of containers | pieces | |
| Priority | Normal | Priority *Only on advance notice, confirmation by SHU required.* | | |
| Storage conditions | Ultralow (≤ -75 °C)  Frozen (≤ -20 °C)  Cooled (2 – 8 °C)  Ambient (15 – 25 °C)  Other: | Temperature logger enclosed:  Yes  No | | If yes, return address: |

|  |  |  |  |
| --- | --- | --- | --- |
| Commercial information | |  | |
| Purchase order number | N/A | Quote number | N/A |

|  |  |  |
| --- | --- | --- |
| **Sample and test information** | | |
| **Method of analysis:**  EP  USP  BP  Other: | | |
| **Tests:** | | **Tests:** |
| Microbial quality of non-sterile product  TAMC  < 100 CFU/g-ml  < 1000 CFU/g-ml  TYMC  < 10 CFU/g-ml  < 100 CFU/g-ml  Other: | | Endotoxines  Method A (Gel-clot method)  Limit:  Method C (kinetic turbidimetric method)  Limit:  Method D (Chromogenic turbidimetric method)  Limit:  Validation (3 batches required) |
| Absence of (per 1 g/ml)  *E. coli*  *S. aureus*  *P. aeruginosa*  *Bile-tolerant gram-*  *negative bacteria*  *C. albicans*  Other: | Absence of (per 10 g/ml)  *Salmonella*  *Burkholderia cepacia*  *Clostridium species*  *Burkholderia fungorum*  Other: | Sterility  Routine, direct inoculation  Routine, membrane filtration  Batch size:  Number containers to be tested: |
| Suitability of method (microbial quality)  Specify parameters: | | Suitability of method (sterility)  Specify parameters: |
| Preservative Efficacy Testing (challenge test) | | Antibiotic assay, limit: |
| Total Aerobic count Plates, please specify below | | Antibiotic assay disk diffusion |
| Total Aerobic count Waters, please specify below | | Identification of colony |
| Total Aerobic count Swabs, please specify below | | Growth Promotion Test |
| Specifications Analysis: | | |

Customer signature:       Date: