|  |
| --- |
| 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 |

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| **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: