|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| General information Customer | | | Product information | |
| Company name |  | Article name | |  |
| Preparation type | |  |
| Contact person |  | Batch number | |  |
| Email address |  | Reference to order  (PO number) | |  |
| Telephone number |  | Quotation number | | N/A |
| Add. Remarks CoA | | | | |

|  |  |
| --- | --- |
| **Sample and test information** | |
| Method of analysis  EP  USP  In-house  Other (please specify) | |
| Routine tests (Acc. to validation report:                          ) | |
| **Microbial quality of non-sterile product**  TAMC (<100 or 1000CFU/g/ml)  TYMC (<10 or 100CFU/g/ml)  *E.coli* (absence per 1 g/ml)  *S.aureus* (absence per 1 g/ml)  *P.aeruginosa* (absence per 1 g/ml)  *C.albicans* (absence per 1 g/ml)  Bile-tolerant gram-negative bacteria (absence per 1 g/ml)  *Salmonella* (absence per 10 g/ml)  Other | **Test for sterility**   * Batch size * Number of containers to be tested |
| Test for bacterial endotoxins (BET), Method C (Turbidimetric kinetic method)  **LIMIT** |
| Microbiological assay of antibiotics  **LIMIT** |
|  | |
| Non-Routine tests | |
| Suitability of the method**, Microbial quality of non-sterile product**  Please specify the required parameters above | Validation Test for bacterial endotoxins (BET), Method C (Turbidimetric kinetic method)  **LIMIT**       (3 batches required) |
| Suitability of the method**,Test for sterility**   * Batch size   Number of containers to be tested | Efficacy of antimicrobial preservation (challengetest) |
| Specifications Analysis (free text field): | |
|  | |
|  | |

|  |  |  |
| --- | --- | --- |
| **Sample Handling** | Normal (10 working days target) | Priority (Only on advance notice, confirmation by Synergy Health required) |

|  |  |  |
| --- | --- | --- |
| **Sample status** | **Sample size and/or container number** | |
| Final drug product; testing purpose: batch release  Final drug product; testing purpose: not for batch release (e.g., stability study, process validation)  Restricted substance **(OPIUM LAW)**  Final drug product, manufactured outside EU  Investigational medicinal product (IMP) |  | gram  ml  pieces |
| **Sample storage conditions** | |
| -20°C ± 5°C  2 - 8°C  Ambient temperature  Protected from light | |
| Customer is obliged to share a Safety Data Sheet /SDS when submitting **DANGEROUS** goods for the first time. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Signature Customer: |  | Date: |  |