**General Information**

|  |  |
| --- | --- |
| Company name |  |
| Company address |  |
| Contact person / Position |  |
| Contact details *(phone, email)* |  |

|  |  |  |
| --- | --- | --- |
| Product name |  | |
| Classification | IVD  Excipient  API  Other: Click here to enter text. | |
| Intended use of product *(Please describe)* |  | non-sterile  sterile |
| Project phase | R&D  preclinical  clinical phase I  clinical phase II  Other: Click here to enter text. | |
| Applicable regulations | ISO 9001  ISO 13485  EXCiPACT  EU GMP Guideline Part II and Annexes  Others:  Click here to enter text. | |
| Supplier qualification requirements |  | |
| Contractual requirements | Non-Disclosure Agreement (NDA)  Supply Agreement (SA)  Quality Assurance Agreement (QAA) | |

**Product Specifications**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of oligonucleotide | CpG ODN  ASO  siRNA  sgRNA  Aptamer  Other: Click here to enter text. | | | | |
| Backbone | Phosphodiester  Phosphothioate | | | | |
| Sequence and position of modifications  (5´-> 3´) | 1st strand | | | | |
| 2nd strand  N/A | | | | |
| Modifications /  Molecular weight (MW) | 5´ end: |  | | MW: |  |
| 3´ end: |  | | MW: |  |
| internal: |  | | MW: |  |
| internal: |  | | MW: |  |
| internal: |  | | MW: |  |
| Molecular weight (MW) Product (Da) |  | | | | |
| Chemical structure Product | *Please insert if needed* | | | | |
| Quantity delivered [unit] |  | | | | |
| Purification |  | | | | |
| Delivery form | lyophilzed  in solution/concentration adjusted  Solvent: Click here to enter text.  Final concentration [unit]: Click here to enter text. | | | | |
| Number of aliquots |  | | | | |
| Primary packaging |  | | no special requirements | | |
| Secondary packaging |  | | no special requirements | | |
| Additional comments |  | | | | |

**Quality control and Release criteria**

|  |  |  |
| --- | --- | --- |
| Identity [unit] | LC-MS: Click here to enter text. | |
| Analytical purity [unit] | RP-HPLC: Click here to enter text.  IEX-HPLC: Click here to enter text.  Other: Click here to enter text. | No requirements |
| Impurities |  | |
| Bact. Endotoxin [unit] / Reference |  | No requirements |
| Bioburden [unit] / Reference | TAMC: Click here to enter text.  TYMC: Click here to enter text. | No requirements |
| Residual solvents [unit] |  | No requirements |
| Heavy metals [unit] |  | No requirements |
| Na+ content [unit] |  | No requirements |
| Others |  | |

**Additional Requirements**

|  |  |  |
| --- | --- | --- |
| Manufacturing and Control | *Please provide CMC part of Investigational Medicinal Product Dossier (IMPD) or appropriate other regulatory documents (e.g. toxicity)*  Documents attached:  1.  2.  3.  4. | |
| Environment | ISO 7 cleanroom area  ISO 8 cleanroom area  Other: Click here to enter text. | No special requirements |
| Documentation | Manufacturing Protocol / Batch Record  Certificate of Analysis (CoA)  Certificate of Manufacturing Compliance (CoMC)  TSE/BSE Statement  Others: Click here to enter text. | |
| Transport | Temperature controlled [unit]:  Click here to enter text.  Ambient | No special requirements |
| Stability studies |  | No requirements |
| Others |  | No requirements |

|  |  |
| --- | --- |
| **Intended project start [mm/yyyy]** |  |
| **Budget [currency]** |  |
| **Requester name** |  |
| **Position** |  |
| **Date** | **Signature** |

**Please send back to sales@metabion.com**