| **Product Material Specification** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Confidential**  **Yes** **☐ No** **☐** | If yes, what is the customer code: | | |  | |
| Special Designation | **Animal Source ☐** | **Antibiotic ☐** | **Steroid ☐** | | **N/A** **☐** |
| Nucleus Biologics Description |  | | | | |
| Final Product Part Number |  | | | | |
| Manufacturer |  | | | | |
| Unit of Measure (UOM) |  | | | | |
| Expiration Date |  | | | | |
| Storage Requirements  Prior to QC Testing |  | | | | |
| Storage Requirements |  | | | | |
| Shipping Requirements |  | | | | |
| Packaging | ${packaging\_option}  ${fill\_volume} ± ${fill\_tolerance} L in ${max\_fill\_volume}  ${packaging\_table}  ${/packaging\_option} | | | | |
| Documentation |  | | | | |
| Quality Control Testing Requirements | ${testing\_options}  ${testing\_options\_table}  Sampling Plan: TBD  ${/testing\_options} | | | | |
| Ingredients per Liter | **Abbreviations:**  ACF=Animal Component Free  BP= British Pharmacopeia  ChP= China Pharmacopeia  EP= European Union Pharmacopeia  FCC=Food Chemical Codex  JP= Japan Pharmacopeia  NA= not available  NF-National Formulary  QS = Quantity Sufficient  USP = United States Pharmacopeia  **Powder Components:**  ${powder\_components} | | | | |
| **Liquid Components:**  ${liquid\_components} | | | | |
| ${custom\_components}  **Custom Components:**  ${custom\_components\_table}  ${/custom\_components} | | | | |
| Preferred Filter Information  (Pore Size and Material) |  | | | | |
| Retain Information |  | | | | |

**Revision History**

| Rev | CR # | Author | Change Description | Effective Date |
| --- | --- | --- | --- | --- |
| 01 | 2020-001 | A. Master | Origination of document | 01/06/2020 |
| 02 | 2020-041 | L. Sheehan | Changed to Template from 28-4104 to 28-6015 | 03/08/2020 |
| 03 | 2020-072 | L. Sheehan | Added iGMP # to header | 04/28/2020 |
| All revisions that follow were executed and released with InstantGMP revision numbers | | | | |
| 03 | 2020-114 | K. Muela | WHAT: Convert to iGMP numbering system  WHY: Consistency | See iGMP |
| 04 | 2021-026 | J. Morrison | WHAT:   1. Updated the Header with new document numbering. 2. Formatted the Cells.   WHY:   1. New numbering format. 2. Consistency | See iGMP |
| 05 | 2021-064 | J. Morrison | Updating document | See iGMP |
| 06 | 2021-163 | L. Brown | WHAT: Updating template  WHY: Consistency | See iGMP |
| 07 | 2021-278 | A. Master | WHAT:   1. Added Filter Information 2. Updated wording on storage ‘prior to’ QC testing   WHY:   1. Clarity of communication between customer and manufacturing 2. Accuracy | See iGMP |
| 08 | 2021-355 | A. Master | WHAT:   1. Updated to add Final Product 2. Updated to Animal Source   WHY: Clarity | See iGMP |