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|---|--|------------------------------------|
|  Nucleus Biologics | <h2>Customer Description/ Part Name</h2> | Document #: 00-SPEC-XXX-XXX |
| | | Revision: |
| | | Effective Date: See iGMP |
| | | Page: 1 of 4 |
| Owner Process: 19 - Custom FP Mfg. | Doc Owner: SVP of Operations | CR#: |
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| Product Material Specification | | | | | | | | | | |
|---|---|-------------------------------------|----------------------------------|------------------------------|-------------|-------------|-----|---|------|---|
| Confidential Yes <input type="checkbox"/> No <input type="checkbox"/> | If yes, what is the customer code: | | | | | | | | | |
| Special Designation | Animal Source <input type="checkbox"/> | Antibiotic <input type="checkbox"/> | Steroid <input type="checkbox"/> | N/A <input type="checkbox"/> | | | | | | |
| 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 | 1.00000 ± 0.00500 L in 1.00000 <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Part Number</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>251</td> <td>PET Sterile Media Bottle with Tamper-Evident cap PTC1000S-A</td> </tr> <tr> <td>1022</td> <td>PET Corning Tamper Evident btl 1000mL, Fisher, 07-201-428</td> </tr> </tbody> </table> | | | | Part Number | Description | 251 | PET Sterile Media Bottle with Tamper-Evident cap PTC1000S-A | 1022 | PET Corning Tamper Evident btl 1000mL, Fisher, 07-201-428 |
| Part Number | Description | | | | | | | | | |
| 251 | PET Sterile Media Bottle with Tamper-Evident cap PTC1000S-A | | | | | | | | | |
| 1022 | PET Corning Tamper Evident btl 1000mL, Fisher, 07-201-428 | | | | | | | | | |
| Documentation | | | | | | | | | | |
| Quality Control Testing Requirements | | | | | | | | | | |
| 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: | | | | | | | | | |



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| Part Number | Part Name | CAS# | Grade/Purity | Concentration (g/L) |
|--|---|-----------------|--|---------------------|
| 369 501 826 | L-Tryptophan L-Tryptophan-2 L-Tryptophan-3 | 73-22-3 | EP, JP, USP USP BP, EP, JP, USP | 0.0160000000 |
| 349 | L-Alanine | 56-41-7 | EP, JP, USP | 0.0250000000 |
| 486 632 | L-Asparagine Monohydrate L-Asparagine Monohydrate-2 | 5794- 13-8 | 99.0% EP, NF | 0.0284000000 |
| 1153 365 | Glycine-2 Glycine | 56-40-6 | 98.5 to 101.0 % EP, JP, USP | 0.0300000000 |
| 364 724 824 | L-Aspartic Acid L-Aspartic Acid-2 non-animal source L-Aspartic Acid-3 | 56-84-8 | EP, JP, USP EP, JP, USP USP | 0.0300000000 |
| 359 | L-Methionine | 63-68-3 | EP, JP, USP | 0.0300000000 |
| 366 | L-Proline | 147-85- 3 | EP, JP, USP | 0.0400000000 |
| 367 | L-Serine | 56-45-1 | EP, JP, USP | 0.0420000000 |
| 355 | L-Histidine HCL H2O | 5934- 29-2 | EP, JP | 0.0420000000 |
| 360 | L-Phenylalanine | 63-91-2 | EP, JP, USP | 0.0660000000 |
| 581 353 472 535 545 728 | L-Glutamic Acid-5 L-Glutamic Acid L-Glutamic Acid-2 L-Glutamic Acid-3 L-Glutamic Acid-4 L-glutamic acid-6 non-animal source | 56-86-0 | EP, JP, USP EP 99.0% BP, EP, USP FCC EP | 0.0750000000 |
| 352 | L-Arginine HCL | 1119- 34-2 | EP, JP, USP | 0.0840000000 |
| 611 744 756 | L-Cystine Dihydrochloride-2 L-Cystine dihydrochloride-3 L-Cystine Dihydrochloride | 30925- 07-6 | 98.0-102.0% 97.0% 98.0% | 0.0912400000 |
| 371 | L-Valine | 72-18-4 | EP, JP, USP | 0.0940000000 |
| 368 825 | L-Threonine L-Threonine-2 | 72-19-5 | EP, JP, USP JP, USP | 0.0950000000 |
| 761 765 840 | L-Tyrosine Disodium Salt Dihy L-Tyrosine Disodium Salt Dihyd L-Tyrosine Disodium Salt Dihydrate | 122666- 87-9 | 98% ACF 99% | 0.1037900000 |
| 357 | L-Leucine | 61-90-5 | EP, JP, USP | 0.1050000000 |
| 356 | L-Isoleucine | 73-32-5 | EP, JP, USP | 0.1050000000 |
| 358 822 823 | L-Lysine HCL L-Lysine HCL-2 L-Lysine HCL-3 | 657-27- 2 | EP, JP, USP BP, EP, JP, USP BP, EP, FCC, JP, USP | 0.1460000000 |
| 483 752 | Sodium Phosphate Monobasic Sodium Phosphate Monobasic Anh | 7558- 80-7 | 98% USP | 0.1090000000 |
| 1256 551 | Calcium Chloride Dihydrate-2 Calcium Chloride Dihydrate | 10035- 04-8 | BP, EP, JP, USP BP, EP, FCC, JP, USP | 0.2190000000 |
| 554 | Potassium Chloride | 7477- 40-7 | BP, EP, JP, USP | 0.3300000000 |
| 555 | Sodium Bicarbonate | 144-55- | BP, EP, JP, USP | 3.0240000000 |



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| 881 1331 | Sodium Bicarbonate-2 Sodium Bicarbonate-3 | 8 | BP, EP, JP, USP =99.5% | |
|--|---|----------------|--|------------------------------|
| 340 556 | Sodium Chloride Powder Sodium Chloride | 7647- 14-5 | 99.5% BP, EP, JP, USP | 4.5050000000 |
| 644 814 | Biotin D-Biotin | 58-85-5 | 99% USP | 0.0000130000 |
| 417 664 | Sodium Selenite Sodium Selenite-2 | 10102- 18-8 | 99% 98% | 0.0000170000 |
| 537 | Potassium Nitrate | 7757- 79-1 | ACS | 0.0000760000 |
| 730 583 | Phenol Red sodium salt-2 Phenol Red Sodium Salt | 34487- 61-1 | ACS ACS | 0.0160000000 |
| 494 651 653 | Pyruvic Acid Sodium Salt Pyruvic Acid Sodium Salt 2 Sodium Pyruvate | 113-24- 6 | 99% 99.0% 99% | 0.1100000000 |
| 490 534 577 | D-Glucose D-Glucose-2 D-Glucose-3 | 50-99-7 | ACS, NF, USP BP, EP, JP, USP BP, EP, JP, USP | 4.5000000000 |
| 405 1327 | HEPES HEPES-2 | 7365- 45-9 | 99.5% N/A | 5.9580000000 |
| 818 489 732 | Vitamin B12-3 Vitamin B12 Vitamin B12-2 | 68-19-9 | BP, EP, USP 98% USP | 0.0000130000 |
| 466 819 830 | Riboflavin Vitamin B2 Vitamin B2-2 | 83-88-5 | FCC USP USP | 0.0004000000 |
| 461 | Folic Acid | 59-30-3 | USP | 0.0040000000 |
| 488 | Pyridoxal Hydrochloride | 65-22-5 | 98% | 0.0040000000 |
| 467 833 1501 | Thiamine Hydrochloride Vitamin B1 Thiamine hydrochloride-2 | 67-03-8 | FCC USP USP | 0.0040000000 |
| 487 719 | Choline Chloride Choline chloride-2 synthetic | 67-48-1 | USP 99.0% | 0.0040000000 |
| 463 | Niacinamide | 98-92-0 | USP | 0.0040000000 |
| 462 884 | myo-Inositol myo-Inositol-2 | 87-89-8 | FCC EP, FCC, NF | 0.0072000000 |
| 427 479 540 | Magnesium Sulfate Anhy. Powder Magnesium Sulfate Anhydrous Magnesium Sulfate Anhydrous-2 | 7487- 88-9 | USP ACS USP | 0.0976700000 |
| 460 | D-Calcium Pantothenate | 137-08- 6 | USP | 0.0040000000 |
| Total weight of dry components: | | | | 20.1488190000 g/L |
| Liquid Components: | | | | |
| Part | Part Name | CAS# | Grade/Purity | Concentration |



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| | Number | (mL/L) |
|---|---|-------------------------|
| | Total volume of liquid components: | 0.000000000 mL/L |
| Preferred Filter Information (Pore Size and Material) | | |
| Retain Information | | |



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