

 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#:
For internal use only. This document contains confidential, proprietary information of Nucleus Biologics. It may not be reproduced or copied without prior written permission from Nucleus Biologics. Hardcopy versions of this document must be verified to the current revision level. ONCE PRINTED THIS DOCUMENT BECOMES UNCONTROLLED.		

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: 20%;">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:									



Nucleus
Biologics

Customer Description/ Part Name

Document #:	00-SPEC-XXX-XXX
Revision:	
Effective Date:	See iGMP
Page:	2 of 4

Owner Process: **19 - Custom FP Mfg.**

Doc Owner: **SVP of Operations**

CR#:

For internal use only. This document contains confidential, proprietary information of Nucleus Biologics. It may not be reproduced or copied without prior written permission from Nucleus Biologics. Hardcopy versions of this document must be verified to the current revision level. ONCE PRINTED THIS DOCUMENT BECOMES UNCONTROLLED.

Part Number	Part Name	CAS#	Grade/Purity	Concentration (g/L)
352	L-Arginine HCL	1119-34-2	EP, JP, USP	0.2110000000
761 765 840	L-Tyrosine Disodium Salt Dihy L-Tyrosine Disodium Salt Dihy L-Tyrosine Disodium Salt Dihydrate	122666-87-9	98% ACF 99%	0.0026100000
366	L-Proline	147-85-3	EP, JP, USP	0.0115000000
1153 365	Glycine-2 Glycine	56-40-6	98.5 to 101.0 % EP, JP, USP	0.0075100000
349	L-Alanine	56-41-7	EP, JP, USP	0.0089100000
367	L-Serine	56-45-1	EP, JP, USP	0.0105000000
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	0.0133000000
344	L-Glutamine Powder	56-85-9	DAB, JP, USP	0.1462000000
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	0.0147000000
361	L-Cysteine	52-90-4	DAB	0.0250000000
486 632	L-Asparagine Monohydrate L-Asparagine Monohydrate-2	5794-13-8	99.0% EP, NF	0.0150000000
355	L-Histidine HCL H2O	5934-29-2	EP, JP	0.0230000000
357	L-Leucine	61-90-5	EP, JP, USP	0.0131000000
360	L-Phenylalanine	63-91-2	EP, JP, USP	0.0049600000
359	L-Methionine	63-68-3	EP, JP, USP	0.0044800000
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	0.0293000000
371	L-Valine	72-18-4	EP, JP, USP	0.0035000000
368 825	L-Threonine L-Threonine-2	72-19-5	EP, JP, USP JP, USP	0.0035700000
369 501 826	L-Tryptophan L-Tryptophan-2 L-Tryptophan-3	73-22-3	EP, JP, USP USP BP, EP, JP, USP	0.0006000000
356	L-Isoleucine	73-32-5	EP, JP, USP	0.0026000000
477 729 829 857 858	Iron(II) Sulfate Heptahydrate Iron(II) Sulfate Heptahydrate-2 Iron(II) Sulfate Heptahydrate-3 Iron(II) sulfate heptahydrate-4 Iron(II) sulfate heptahydrate-5	7782-63-0	ACS ACS, NF, USP BP, EP, FCC, USP BP, EP, FCC, USP USP	0.0008300000
555 881 1331	Sodium Bicarbonate Sodium Bicarbonate-2 Sodium Bicarbonate-3	144-55-8	BP, EP, JP, USP BP, EP, JP, USP =99.5%	1.2000000000



Nucleus
Biologics

Customer Description/ Part Name

Document #: **00-SPEC-XXX-XXX**

Revision:

Effective
Date:

See iGMP

Page:

3 of 4

Owner Process: **19 - Custom FP Mfg.**

Doc Owner: **SVP of Operations**

CR#:

For internal use only. This document contains confidential, proprietary information of Nucleus Biologics. It may not be reproduced or copied without prior written permission from Nucleus Biologics. Hardcopy versions of this document must be verified to the current revision level. ONCE PRINTED THIS DOCUMENT BECOMES UNCONTROLLED.

550	Calcium Chloride Anhydrous	10043-52-4	FCC	0.0332900000
485 1268	Zinc Sulfate Heptahydrate Zinc Sulfate Heptahydrate-2	7446-20-0	USP USP	0.0000300000
554	Potassium Chloride	7477-40-7	BP, EP, JP, USP	0.2850000000
427 479 540	Magnesium Sulfate Anhy. Powder Magnesium Sulfate Anhydrous Magnesium Sulfate Anhydrous-2	7487-88-9	USP ACS USP	0.0746400000
340 556	Sodium Chloride Powder Sodium Chloride	7647-14-5	99.5% BP, EP, JP, USP	7.4000000000
750	Sodium Phosphate Dibasic Anhy	7558-79-4	USP	0.1535800000
747 757	Cupric Sulfate Pentahydrate Copper(II) Sulfate Pentah	7758-99-8	USP ACS	0.0000025000
749 902 903	Potassium Phosphate Monobasic Monobasic potassium phosphate Monobasic potassium phosphate-2	7778-77-0	NF ACS, EP 99.5-100.5%	0.0830000000
496 502 539	Thymidine-2 Thymidine-3	50-89-5	N/A 99% 99%	0.0007300000
495 794	DL-Thioctic Acid Lipoic acid	1077-28-7	99% 99%	0.0002000000
494 651 653	Pyruvic Acid Sodium Salt Pyruvic Acid Sodium Salt 2 Sodium Pyruvate	113-24-6	99% 99.0% 99%	0.1100000000
730 583	Phenol Red sodium salt-2 Phenol Red Sodium Salt	34487-61-1	ACS ACS	0.0013000000
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	1.1000000000
644 814	Biotin D-Biotin	58-85-5	99% USP	0.0000200000
				0.0054000000
461	Folic Acid	59-30-3	USP	0.0013200000
467 833 1501	Thiamine Hydrochloride Vitamin B1 Thiamine hydrochloride-2	67-03-8	FCC USP USP	0.0010100000
487 719	Choline Chloride Choline chloride-2 synthetic	67-48-1	USP 99.0%	0.0007000000
818 489	Vitamin B12-3 Vitamin B12	68-19-9	BP, EP, USP 98%	0.0013600000



Nucleus
Biologics

Customer Description/ Part Name

Document #: **00-SPEC-XXX-XXX**

Revision:

Effective
Date:

See iGMP

Page:

4 of 4

Owner Process: **19 - Custom FP Mfg.**

Doc Owner: **SVP of Operations**

CR#:

For internal use only. This document contains confidential, proprietary information of Nucleus Biologics. It may not be reproduced or copied without prior written permission from Nucleus Biologics. Hardcopy versions of this document must be verified to the current revision level. ONCE PRINTED THIS DOCUMENT BECOMES UNCONTROLLED.

	732	Vitamin B12-2		USP	
	466	Riboflavin	83-88-5	FCC	0.0003800000
	819	Vitamin B2		USP	
	830	Vitamin B2-2		USP	
	460	D-Calcium Pantothenate	137-08- 6	USP	0.0007100000
	462	myo-Inositol	87-89-8	FCC	0.0005400000
	884	myo-Inositol-2		EP, FCC, NF	
	463	Niacinamide	98-92-0	USP	0.0006100000
	465	Pyridoxine	58-56-0	FCC	0.0002000000
	608	Hydrochloride Pyridoxine Hydrochloride-2		USP	
	Total weight of dry components:				11.0061925000 g/L
	Liquid Components:				
	Part Number	Part Name	CAS#	Grade/Purity	Concentration (mL/L)
	Total volume of liquid components:				0.0000000000 mL/L
Preferred Filter Information (Pore Size and Material)					
Retain Information					



Nucleus
Biologics