

 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: 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:									



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)
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%	0.0312000000
352	L-Arginine HCL	1119- 34-2	EP, JP, USP	0.1264000000
761 765 840	L-Tyrosine Disodium Salt Dihy L-Tyrosine Disodium Salt Dihyd L-Tyrosine Disodium Salt Dihydrate	122666- 87-9	98% ACF 99%	0.0519000000
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	0.0075000000
349	L-Alanine	56-41-7	EP, JP, USP	0.0089000000
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	0.2920000000
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
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	0.0419000000
357	L-Leucine	61-90-5	EP, JP, USP	0.0525000000
360	L-Phenylalanine	63-91-2	EP, JP, USP	0.0325000000
359	L-Methionine	63-68-3	EP, JP, USP	0.0150000000
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	0.0725000000
371	L-Valine	72-18-4	EP, JP, USP	0.0468000000
368 825	L-Threonine L-Threonine-2	72-19-5	EP, JP, USP JP, USP	0.0476000000
369 501 826	L-Tryptophan L-Tryptophan-2 L-Tryptophan-3	73-22-3	EP, JP, USP USP BP, EP, JP, USP	0.0100000000
356	L-Isoleucine	73-32-5	EP, JP, USP	0.0525000000
753	Sodium Phosphate Monobasic Mo	10049- 21-5	USP	0.1400000000
555 881 1331	Sodium Bicarbonate Sodium Bicarbonate-2 Sodium Bicarbonate-3	144-55- 8	BP, EP, JP, USP BP, EP, JP, USP =99.5%	1.5000000000
550	Calcium Chloride Anhydrous	10043- 52-4	FCC	0.2000000000
554	Potassium Chloride	7477-	BP, EP, JP, USP	0.4000000000



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.

	427 479 540	Magnesium Sulfate Anhy. Powder Magnesium Sulfate Anhydrous Magnesium Sulfate Anhydrous-2	40-7 7487- 88-9	USP ACS USP	0.0977000000
	340 556	Sodium Chloride Powder Sodium Chloride	7647- 14-5	99.5% BP, EP, JP, USP	6.8000000000
	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	0.0100000000
	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	1.0000000000
	465 608	Pyridoxine Hydrochloride Pyridoxine Hydrochloride-2	58-56-0	FCC USP	0.0010000000
	461	Folic Acid	59-30-3	USP	0.0010000000
	467 833 1501	Thiamine Hydrochloride Vitamin B1 Thiamine hydrochloride-2	67-03-8	FCC USP USP	0.0010000000
	487 719	Choline Chloride Choline chloride-2 synthetic	67-48-1	USP 99.0%	0.0010000000
	466 819 830	Riboflavin Vitamin B2 Vitamin B2-2	83-88-5	FCC USP USP	0.0001000000
	460	D-Calcium Pantothenate	137-08- 6	USP	0.0010000000
	462 884	myo-Inositol myo-Inositol-2	87-89-8	FCC EP, FCC, NF	0.0020000000
	463	Niacinamide	98-92-0	USP	0.0010000000
	Total weight of dry components:				11.2200000000 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

Customer Description/ Part Name

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

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.



Nucleus
Biologics

DRAFT