 MedImmune Raw Material SPECIFICATION	Description: Custom Yeast Extract Powder - Ultrafiltered		
	Molecular Formula: N/A		
	Molecular Weight: N/A		
	CAS Number: N/A		
	Document Number: RWMT000620	ERP Number(s): 6000662 (10 kg) 6002238 (50 kg)	Batch Number: 278927
			Page: 1 of 4


Supplier Lot No.: 6203937	Date Received: 21 DEC 16
Expiration Date: 26 JUL 20	Quantity Received: 1500 KG
Received by: <input checked="" type="checkbox"/> N/A	Date: <input checked="" type="checkbox"/> N/A

- 1 **Material Used for:** Clinical ☒ Consistency/Commercial ☒
- 2 **Excipient:** Yes ☐ No ☒
- 3 **Material Grade:**
USP ☐ NF ☐ EP ☐ JP ☐ BP ☐ ACS ☐ FCC ☐
Custom ☒ N/A ☐ Other ☐ _____
- 4 **Animal Origin:** No ☒ Yes ☐
- 5 **Sterile:** No ☒ Yes ☐
- 6 **Storage and Handling Conditions:**
Ambient (15°C to 30°C) ☐ Refrigerated (2°C to 8°C) ☒ Frozen (-15°C to -25°C) ☐
Other ☐
- 7 **Approved Supplier(s)**
Supplier # 60006193
- 8 **Approved Package Configuration**

ERP Number	Package Size	Unit of Measure	Packaging Description
6000662	10	kg	Poly bag/pail
6002238	50	Kg	Poly pail

View

Status Dt: 03-Jun-2016 12:23 BST
Effective
Ver: 4.0 Status:
Doc Num: RWMT000620

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			Page: 3 of 4

11 Sampling Plan

Sampling will be performed per site SOP.

Sampling Type	QC	QC Micro	Retain
Full Sampling Amount	10 g	25 g	20 g
Abbreviated Sampling Amount	10 g		20 g
Individual Container Identity Sampling Amount	1 g		

Doc Num: RWMT000620
 Ver: 4.0 Status: Effective
 Status Dt: 03-Jun-2016 12:23 BST

View



Certificate of Analysis

Becton Dickinson and Company
BD Biosciences Miami AF
50 NW 176TH ST
Miami FL 33169-5043 US

Page: 1 of 2

Product Name : TC Yeastolate UFST 50 Kg
Catalog Number : 670055 **Manufacture Date** : 2016/08/02
Batch Number : 6203937
Expiration Date : 2020/07/26

01. Dehydrated Appearance: Beige, free-flowing, homogeneous fine powder.
02. Solubility: 2% solution, soluble in distilled or deionized water.
03. 2% Solution Appearance: Light to dark, yellow to tan; clear to slightly hazy with no significant precipitate.
04. There are no animal sourced ingredients or animal derived reagents used in the manufacture of this product.
05. Mycoplasma: None detected.

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		6.6	5.4	7.2
Loss on Drying	%	3	0	5
Beta Glucan	ug/gr	6	0	20
Endotoxin Beginnin	EU/g	5	0	500
Endotoxin Middle	EU/g	5	0	500
Endotoxin End	EU/g	5	0	500
Microbial Content	CFU/g	2	0	100
Microbial Content	CFU/g	15	0	100
Microbial Content	CFU/g	11	0	100
Microbial Content	CFU/g	7	0	100
Microbial Content	CFU/g	0	0	100
Microbial Content	CFU/g	3	0	100
Microbial Content	CFU/g	1	0	100
Microbial Content	CFU/g	2	0	100
Microbial Content	CFU/g	5	0	100

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Biosciences Advanced Bioprocessing is an ISO 9001:2008 Registered facility. This product met BD Biosciences Advanced Bioprocessing stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release. This material is not for human or animal consumption. BD Biosciences Advanced Bioprocessing Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be

Creation Date: 2016/09/28 15:26:26