

Document Type

Raw Material Specification

Doc ID

RWMT001864

Status

Effective

Version

2.0

Page/Pages

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Title: Yeast Extract Powder, UF, Custom-II

AstraZeneca

Owner

Bowman, Allison

Authors

Marnell, Sara

Approvals**Approval Reason**Management Approval
Quality Approval**Approver**Bowman, Allison
Moore, Melissa**Date**2018/04/25 18:18:39
2018/04/27 15:56:12

Uncontrolled Print

4 Approved Package Configuration


ERP No.	Package Size	Unit of Measure	Packaging Description
6002963	10	kg	Plastic container
6002965	50	kg	Plastic container

5 Material Inspection

Inspect the number of containers as per site SOP.

No. of Containers Inspected:	50/11
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Parameter	Specification	Reference	Result (Pass/Fail)
Supplier Number and Catalog Number	Supplier # 60006193 6002963: 670081 6002965: 670082	SAP	PASS
Labeling	Each package labeled to indicate catalog number and lot number	Label Visual Inspection	PASS
Supplier's Certificate	Required with supplier name, catalog number, lot number, and approval signature	Certificate	PASS
Visual Inspection	Container must be clean, intact and free of visible defects	Meets Specification	PASS
	6002963: 10 kg plastic container 6002965: 50 kg plastic container	Meets Specification	PASS

Inspected by:	
Date:	29 JAN 19

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	Parameter	Test Method	Specification	Test Result (Pass/Fail)
#	Bioburden (@ 1g/100mL)	QC-9535	≤ 100 CFU/g	<input type="checkbox"/> N/A
#	Endotoxin (@ 1g/100mL)	QC-6310	≤ 500 EU/g	<input type="checkbox"/> N/A

* Abbreviated test program requirements

◇ Every container identity testing

Microbiological test

△ Identity test

¹ Apply test parameter to top, middle and bottom samples for part number 6002965.

Results Entered by	N/A MSN 08 Feb 19	Date	N/A MSN 08 Feb 19
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QA Disposition:	<input checked="" type="checkbox"/> Release	<input type="checkbox"/> Reject	<input type="checkbox"/> Other _____
QA Disposition by:	MS Mary Sue Neapolitan		
Date:	08 Feb 19		
Comments:	<input type="checkbox"/> N/A Entry Error QA MSN 08 Feb 19		

Version History

The following is included for reference only and is not part of the executable record.

Version	Description
2.0	(1) Change: Added top, middle, bottom sampling instructions to the sampling plan and testing table. Reason: Change Control Rec 180977 Action Item: 181107. (2) Change: Update of material specification template per QC-040685. Reason: For clarity and consistency; administrative change. (3) Change: Removed previous records of version history. Reason: Required per QA-041038; administrative change. (4) Change: Revised packaging configuration from "poly" to "plastic." Reason: Per QC-040685; generic identifiers for packaging configuration should be used when possible. (5) Change: Revised the sampling plan for glucans to QC micro and clarified need for separate container. Removed statement "individual sample for glucan is not required when abbreviated testing is being performed." Reason: Glucan testing is performed by the microbiology group and the footnote is redundant to the testing table; administrative change.



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 100 50 KG
Catalog Number : 670082 Manufacture Date: 2018/12/05
Batch Number : 8330558
Expiration Date : 2022/12/04

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 :		6.8	5.4	7.2
Loss on Drying	%	2.6	0.0	5.0
Beta Glucan	ug/gr	12	0	100
Endotoxin Beginnin	EU/g	6	0	500
Endotoxin Middle	EU/g	6	0	500
Endotoxin End	EU/g	6	0	500
Microbial Content	CFU/g	7	0	100
Microbial Content	CFU/g	11	0	100
Microbial Content	CFU/g	3	0	100
Microbial Content	CFU/g	8	0	100
Microbial Content	CFU/g	15	0	100
Microbial Content	CFU/g	13	0	100
Microbial Content	CFU/g	16	0	100
Microbial Content	CFU/g	13	0	100
Microbial Content	CFU/g	21	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 9001:2015 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 contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at <http://www.bd.com/regdocs>. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw

Creation Date: 2019/01/28 21:15:41