

Document Type

Raw Material Specification

Doc ID

RWMT000620

Status

Effective

Version

6.0

Page/Pages

1 of 6

Title: Custom Yeast Extract Powder - Ultrafiltered

AstraZeneca



RWMT000620 ver 6.0 Batch 1

Owner

Bowman, Allison

Authors

Marnell, Sara

Approvals**Approval Reason**Management Approval
Quality Approval**Approver**Bowman, Allison
Macafity, Rochelle**Date**2018/04/17 16:05:34
2018/04/18 13:18:25

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1 Raw Material Specification

Custom Yeast Extract Powder – Ultrafiltered, RWMT000620

2 Material Receipt

Supplier Lot No.: 7013626	Date Received: 12 JUL 2018
ERP Number: 6002238	Batch Number: 301302
① Expiration Date: 7013626	Quantity Received: 2,400 KG
Received by: Shannon Shaeffer <input type="checkbox"/> N/A	Date: <input checked="" type="checkbox"/> N/A

3 Material Details

- 3.1 Material Used for: Clinical/Consistency/Commercial
- 3.2 Excipient: No
- 3.3 Material Grade: Custom
- 3.4 Animal Origin: No
- 3.5 Sterile: No
- 3.6 Material State: Solid
- 3.7 Molecular Formula: N/A
- 3.8 Molecular Weight: N/A
- 3.9 CAS Number: N/A
- 3.10 Storage and Handling Conditions: Refrigerated (2 to 8°C)
- 3.11 Expiration Date: Assign the expiration date found on the supplier's certificate.
- 3.12 Approved Supplier(s): 60006193

4 Approved Package Configuration

ERP No.	Package Size	Unit of Measure	Packaging Description
6000662	10	kg	Plastic bag/pail
6002238	50	kg	Plastic pail

① Expiration date is 17 JAN 2021. SS 12 JUL 18

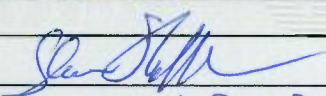


5 Material Inspection

Inspect the number of containers as per site SOP.

No. of Containers Inspected:	5
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Parameter	Specification	Reference	Result (Pass/Fail)
Supplier Number and Catalog Number	Supplier # 60006193 6000662: 215321 6002238: 670055	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
	6000662: 10 kg plastic bag/pail 6002238: 50 kg plastic pail	Meets Specification	PASS

Inspected by:	
Date:	12 JUL 2018

6 Sampling Plan

Sampling will be performed per site SOP. Part number, 6002238, requires top, middle, bottom sampling.

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		

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7 Test Results

Tests Required:	<input checked="" type="checkbox"/> Full <input type="checkbox"/> Abbreviated	QC LIMS ID:	645756	<input type="checkbox"/> N/A
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Testing Requirements

Parameter	Test Method		Specification	Test Result (Pass/Fail)
	FMC	BMC		
* 1 Appearance		QC-6302	Beige, free-flowing, homogeneous fine powder	pass
* 1 Identification - Infrared Spectrum	QC-6254	1-P-QM-WI-9040345	Conforms to reference	pass
1 pH of a 2% Solution		QC-9522	5.4 - 7.2	pass <input type="checkbox"/> N/A
# Bioburden (@1g/100 ml)	QC-9535	AZDoc0041065	≤ 100 CFU/g	pass <input type="checkbox"/> N/A
# Endotoxin (@1g/100 ml)	QC-6310	AZDoc0041134	≤ 500 EU/g	pass <input type="checkbox"/> N/A
# Glucan		QC-9516	≤ 20 µg/g of yeast extract	pass <input type="checkbox"/> N/A
Mycoplasma	Confirm from Certificate		Negative	pass

* Abbreviated test program requirements

◇ Every container identity testing

† Apply test parameter to top, middle and bottom samples for part number 6002238.

Microbiological test

◇ Identity test

Results Entered by

Lacey Mathews

Date

10 Aug 2018

Print Reason: Controlled print for personal use

Printed By: Shaeffer, Shannon

Recipient: Shaeffer, Shannon

Print Date: 12 Jul 2018

Controlled Copy Number: 1

Effective Date: 2018/05/02 14:52:24

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QA Disposition:	<input checked="" type="checkbox"/> Release	<input type="checkbox"/> Reject	<input type="checkbox"/> Other
QA Disposition by:	<i>Ch Long</i>		
Date:	13 Aug 2018		
Comments:	The GLIMS characteristic valuation did not have a value passed to SAP from LIMS. All LIMS information was reviewed during the disposition process. The batch is acceptable for release. DL 13 Aug 2018 <input type="checkbox"/> N/A		

Print Reason: Controlled print for personal use
Printed By: Shaeffer, ShannonRecipient: Shaeffer, Shannon
Print Date: 12 Jul 2018Controlled Copy Number: 1
Effective Date: 2018/05/02 14:52:24

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Title: Custom Yeast Extract Powder - Ultrafiltered

Version History

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

<u>Version</u>	<u>Description</u>
6.0	(1) Change: Added top, middle, bottom sampling instructions to the sampling plan and testing table. Reason: Change Control Rec 180977 Action Item: 181107.

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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** : 2017/01/24
Batch Number : 7013626
Expiration Date : 2021/01/17

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 :		7.0	5.4	7.2
Loss on Drying	%	2	0	5
Beta Glucan	ug/gr	11	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	0	0	100
Microbial Content	CFU/g	0	0	100
Microbial Content	CFU/g	0	0	100
Microbial Content	CFU/g	2	0	100
Microbial Content	CFU/g	0	0	100
Microbial Content	CFU/g	2	0	100
Microbial Content	CFU/g	0	0	100
Microbial Content	CFU/g	0	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 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

Creation Date: 2017/03/17 18:50:33



Certificate of Analysis

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

Page: 2 of 2

Product Name : TC Yeastolate UFST 50 Kg
Catalog Number : 670055 **Manufacture Date** : 2017/01/24
Batch Number : 7013626
Expiration Date : 2021/01/17

materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Biosciences Advanced Bioprocessing of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD Biosciences Advanced Bioprocessing. See "COA Animal origin Information Position Statement" located at <http://www.bd.com/regdocs> under "position Statements" for the impact that retrospective information has on BD Biosciences Advanced Bioprocessing COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostics-Diagnostic Systems, COA Animal Origin Information Position Statement", at <http://www.bd.com/readocs/> under "Position Statements".

DIANA NOGUERA
Quality Manager, BD Biosciences



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PACK LIST

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Doe and Ingalls of MD, LLC
8220 Patuxent Range Road
Suite A
Jessup, MD 20794
919-598-1986

Ship To: AstraZeneca Pharmaceuticals LP
4000 Nelson Road
Dock #1-#6
Longmont CO 80503

Order 06/08/18
Request 07/03/18

Co/Cust	P.O. No.	Order No	Ship Via	WH
04/0000400079	4500097409	34173/00	MFRT - PPA	04

Item No / Description	Order	Ship	B/O	U/M	Loc	Seq
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Carrier: Motor Freight

Material must ship on refrigerated truck with temperature
range 2-8°C with set point 5°C.

Customer Item Number: 6002238

B670055MED	48.000	48.000	.000	EA		13
TC YEASTOLATE, UF, PWD						
50-KG, BIOBURDEN TESTED, REF						
Lot/Lot-Qty: 7013626		48.000				

Material must ship on refrigerated truck with temperature
range 2-8°C with set point 5°C.

Please include AstraZeneca's part number on all paperwork.

Deliveries must be scheduled. Please call 303-882-4297 to
schedule.

/1

Shipping and Handling

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Dock date 07/12/18