

# AstraZeneca

**Owner**

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**Approvals****Approval Reason**

Management Approval  
Quality Approval

**Approver**

Bowman, Allison  
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**Date**

2018/04/25 18:18:39  
2018/04/27 15:56:12

Uncontrolled Print

#### 4 Approved Package Configuration

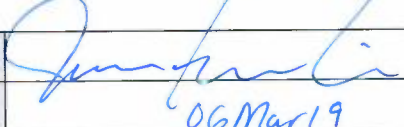
| ERP No. | Package Size | Unit of Measure | Packaging Description |
|---------|--------------|-----------------|-----------------------|
| 6002963 | 10           | kg              | Plastic container     |
| 6002965 | 50           | kg              | Plastic container     |

#### 5 Material Inspection

Inspect the number of containers as per site SOP.

|                              |         |
|------------------------------|---------|
| No. of Containers Inspected: | 5 of 15 |
|------------------------------|---------|

| Parameter                          | Specification   | Reference               | Result<br>(Pass/Fail) |
|------------------------------------|---|-------------------------|-----------------------|
| Supplier Number and Catalog Number | Supplier # 60006193<br>6002963: 670081<br>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<br>6002965: 50 kg plastic container            | Meets Specification     | pass                  |

|               |   |
|---------------|---|
| Inspected by: |  |
| Date:         | 06 Mar 19   |

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

\* Abbreviated test program requirements  
◇ Every container identity testing

# Microbiological test  
△ Identity test

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

|                    |                   |      |                   |
|--------------------|-------------------|------|-------------------|
| Results Entered by | N/A MSN 22 Apr 19 | Date | N/A MSN 22 Apr 19 |
|--------------------|-------------------|------|-------------------|

|                    |   |                                 |                                      |
|--------------------|---|---------------------------------|--------------------------------------|
| QA Disposition:    | <input checked="" type="checkbox"/> Release | <input type="checkbox"/> Reject | <input type="checkbox"/> Other _____ |
| QA Disposition by: | Mary Sue Respolito                          |                                 |                                      |
| Date:              | 22 Apr 19                                   |                                 |                                      |
| Comments:          | <input checked="" type="checkbox"/> N/A     |                                 |                                      |

#### 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**: 2019/01/07  
**Batch Number** : 9002684  
**Expiration Date** : 2023/01/06

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     | %     | 2.4   | 0.0         | 5.0         |
| Beta Glucan        | ug/gr | 2     | 0           | 100         |
| 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 | 14    | 0           | 100         |
| Microbial Content  | CFU/g | 10    | 0           | 100         |
| Microbial Content  | CFU/g | 6     | 0           | 100         |
| Microbial Content  | CFU/g | 4     | 0           | 100         |
| Microbial Content  | CFU/g | 5     | 0           | 100         |
| Microbial Content  | CFU/g | 6     | 0           | 100         |
| Microbial Content  | CFU/g | 6     | 0           | 100         |
| Microbial Content  | CFU/g | 44    | 0           | 100         |
| Microbial Content  | CFU/g | 8     | 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: 2019/02/26 23:07:05