

Without measurement there is no control®

# BioCapt® Single-Use

Microbial Impactor with TSA, Neutralizers,  
and Lactamator



## BSCU with TSA, Neutralizers, and Lactamator Technical Data

Tryptone Soy Agar (TSA) is a general purpose medium used for cultivation of a wide variety of microorganisms and for environmental monitoring in pharmaceutical processes.

TSA is a widely used medium, which supports the growth of a wide variety of organisms, even that of fastidious ones such as *Neisseria*, *Listeria*, *Brucella*, etc.

The pharmacopoeias recommend TSA as a general purpose microbiological medium<sup>1,2,3</sup>. The formulation of the basic medium TSA is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia and supplemented with neutralizers and Lactamator™. Lactamator is an innovative enzyme-based product designed for the inactivation of a wide range of beta-lactam antibiotics. It efficiently inactivates penicillins, cephalosporins of first, second, third, fourth, and fifth generation and penems, and is an optimal choice for antibiotic manufacturers to inactivate their active ingredients and prevent cross contaminations in their facilities.

This medium is used in Biocapt® Single-Use (BCSU) units, enabling the detection and enumeration of viable airborne microorganisms in sanitary or aseptic processes. The BSCU units are particularly useful for monitoring air in cleanrooms, biosafety cabinets, isolator systems and other environmentally-controlled areas.

The BioCapt® Single-Use Impactor is a sterile, ready-to-use device for viable active air sampling in critical and controlled environments. Designed for integration with portable and continuous monitoring systems, it combines the culture medium and impactor head in a single disposable unit and supports continuous active air

### PRODUCT PROFILE

#### PMS Product Code

79001210

#### Media Description

Tryptone Soy Agar + Neutralizers + Lactamator (TSA+IN+LCT)

#### Model

BioCapt Single-Use Microbial Impactor

#### Packaging

Units packed in a double bag (3 units/double bag). All units (24x3) wrapped in an additional two protective bags, and are gamma irradiated.

monitoring for up to 4 hours (validation needed).

It is a sterile, ready-to-use unit already filled with medium, eliminating agar plate preparation and minimizing operator handling. The units are supplied in a gamma-irradiated, H<sub>2</sub>O<sub>2</sub>-impermeable packaging configuration, with three units per double bag. Each triplet is enclosed within two additional protective bags, providing a total of four packaging layers. This multi-layer packaging configuration facilitates the controlled transfer of the BCSU from uncontrolled or lower-grade areas into Grade A environments, allowing successive removal of the outer bags as the product progresses through areas of increasing cleanliness. This approach supports the facility's Contamination Control Strategy (CCS) and the contamination control principles outlined in EU GMP Annex 1.

The combination of pancreatic digest of casein and papaic digest of soybean meal makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance. TSA does not contain X and V growth factors.

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## QUALITY CONTROL TEST

| Incubation                                          |                                                      |
|-----------------------------------------------------|------------------------------------------------------|
| At 32.5 ± 2.5 °C for 24 - 72 hours                  | Fertility (Growth Promotion) Test on Bacteria        |
| At 32.5 ± 2.5 °C for 72 - 120 hours                 | Fertility (Growth Promotion) Test for Yeast and Mold |
| At 32.5 ± 2.5 °C and at 22.5 ± 2.5°C for seven days | Sterility control for absence of contamination       |

## QUALITY CONTROL MICROORGANISMS

| Organism (ATCC)                | Inoculum (viable organisms) | Conditions                      | Recovery                      |
|--------------------------------|-----------------------------|---------------------------------|-------------------------------|
| <i>E. coli</i> (8739)          | 10-100                      | 24 - 72 hours at 32.5 ± 2.5 °C  | 70% ≤ P <sub>R</sub> % ≤ 200% |
| <i>P. paraeruginosa</i> (9027) | 10-100                      | 24 - 72 hours at 32.5 ± 2.5 °C  | 70% ≤ P <sub>R</sub> % ≤ 200% |
| <i>S. aureus</i> (6538)        | 10-100                      | 24 - 72 hours at 32.5 ± 2.5 °C  | 70% ≤ P <sub>R</sub> % ≤ 200% |
| <i>B. spizizenii</i> (6633)    | 10-100                      | 24 - 72 hours at 32.5 ± 2.5 °C  | 70% ≤ P <sub>R</sub> % ≤ 200% |
| <i>C. albicans</i> (10231)     | 10-100                      | 72 - 120 hours at 32.5 ± 2.5 °C | 70% ≤ P <sub>R</sub> % ≤ 200% |
| <i>A. brasiliensis</i> (16404) | 10-100                      | 72 - 120 hours at 32.5 ± 2.5 °C | 70% ≤ P <sub>R</sub> % ≤ 200% |
| Environmental strain #1        | 10-100                      | 24 - 72 hours at 32.5 ± 2.5 °C  | 70% ≤ P <sub>R</sub> % ≤ 200% |
| Environmental strain #2        | 10-100                      | 24 - 72 hours at 32.5 ± 2.5 °C  | 70% ≤ P <sub>R</sub> % ≤ 200% |

## GENERAL INSTRUCTIONS

Only qualified laboratory personnel must handle the device according to aseptic precautions.

The culture media must be used only for the specific microbiological analysis following norms and procedures for the application.

It is good practice to let the device reach room temperature before using.

After incubation, follow standard procedures to enumerate colonies on the unit's media; results must be interpreted by qualified personnel in context of use.

## PRECAUTIONS

Do not utilize the device if:

- It is broken
- Media show signs of accidental contamination
- Media is past expiration date

## DISPOSAL

On completion of work, all used or unusable preparations of this product and derivatives thereof are to be disposed of by autoclaving and/or by incineration.

Sterilize all biohazard waste before disposal. Dispose of waste in accordance with all applicable Federal, State and local laws.

## DESIGN

The Single-Use Impactor uses a radial slit design, validated at the Centre for Applied Microbiology & Research (CAMR), a Health Protection Agency (HPA) at Porton Down. It achieves isokinetic sampling for minimal air turbulence in compliance with ISO 14698-1 and ISO 17141, and is ideal for sampling with a flow rate between 25 and 50 L/min.

The BCSU is designed to virtually eliminate operator-induced false positives associated with direct agar manipulation because the agar surface remains protected throughout handling, sampling, and transfer.

Its ergonomic design enables one-handed operation and minimizes operator intervention. The workflow requires only removal of the packaging, cap, and lid; installation into the monitoring system; replacement of the lid and cap after sampling; and transfer directly to incubation. With protection and minimal handling, the BCSU reduces accidental contamination, false-positive results, unnecessary investigations, and related costs. Reduced handling and simplified operation also decrease interventions within the filling line, supporting improved process efficiency, reduced disruption, and increased production capacity.



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| PARAMETER           | SPECIFICATION                                                                                                                                                                                                                |                                                                                                              |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Materials           | Polystyrene                                                                                                                                                                                                                  |                                                                                                              |
| Air inlets          | 20 slits, 0.1 mm nominal width                                                                                                                                                                                               |                                                                                                              |
| Flow rates          | 25 - 50 LPM recommended                                                                                                                                                                                                      |                                                                                                              |
| Dimensions          | 120 mm exterior diameter<br>38.5 mm exterior height (with lid)<br>90 mm diameter agar surface                                                                                                                                |                                                                                                              |
| Filling volume      | 30 ml                                                                                                                                                                                                                        |                                                                                                              |
| Vacuum connectors   | Hose Barb 11 mm OD and 31.5 mm long (includes removable cap)                                                                                                                                                                 |                                                                                                              |
| Composition Medium* | <b>TSA</b><br>Pancreatic digest of casein (Tryptone)<br>Papaic digest of soybean meal (Soya Peptone)<br>Sodium chloride<br>Lecithin<br>Polysorbate 80 (Tween 80)<br>L-histidin<br>Sodium thiosulphate<br>Agar<br>Lactamator™ | <b>g/L of deionized water</b><br>15.00<br>5.00<br>5.00<br>0.70<br>5.00<br>1.00<br>0.50<br>15.00<br>1000 IU/L |
| Color of medium     | Light yellow colored, clear to slightly opalescent                                                                                                                                                                           |                                                                                                              |
| pH at 25 °C storage | 7.3 ± 0.2                                                                                                                                                                                                                    |                                                                                                              |
| Storage Temperature | 2 - 25 °C until expiration date. Protect from light, excessive heat, moisture and freezing.<br>Avoid fast change of temperature within the range                                                                             |                                                                                                              |

\* The medium can be adjusted and/or supplemented according to the performance criteria required

## REFERENCES

<sup>1</sup>The United States Pharmacopoeia / National Formulary, USP last edition, The United States Pharmacopoeial Convention Inc., Rockville, MD.

<sup>2</sup>European Pharmacopoeia, EP last edition.

<sup>3</sup>Indian Pharmacopoeia, last edition, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India

<sup>4</sup>Gunn B. A., Ohashi D K., Gaydos C. A., Holt E. S., 1977, J. Clin. Microbiol., 5(6) : 650.



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