

## **FACT SHEET/ TERMS AND CONDITIONS: Bioburden Test (as per ISO 11737-1:2018, USP <61>)**

(24 April 2024)

### **FEATURES**

- Bioburden test
  - Either the entire product or a portion of the product may be used for determination of bioburden.
  - If a portions are to be separated from product, this should be done under clean conditions in a controlled environment (e.g. inside a laminar flow cabinet) in order to avoid adding contamination.
  - Entire product or sample item portion to be transported for testing to the laboratory under clean conditions in a controlled environment in order to avoid adding contamination.
  - Every effort should be made to transfer items for testing to the laboratory as quickly as possible. If delay in transfer is unavoidable, the conditions under which the items are stored should be selected to minimize changes in the microbial population
  - Bioburden testing is carried out in aseptic conditions
  - Removal of microorganisms from the test material is conducted by elution in sterile eluent through vigorous shaking or ultrasonication.
  - Culturing of microorganisms is done on Soybean Casein Digest Agar for aerobic bacteria and on Sabouraud Dextrose Agar for yeasts and moulds
  - The enumeration is done with Total Aerobic Bacterial Count (TABC) and Total Yeast and Mold Count (TYMC)
  - The bioburden level is reported in colony forming unit (CFU)
- Venture Center offers Bioburden Test using Spread Plate method or Membrane Filtration method as per ISO 11737-1:2018 and USP<61>. This service is being offered specifically with the larger purpose of promoting technology development and entrepreneurship.
- Venture Center only supports researchers with scientific data. Venture Center is not an accredited testing lab. Venture Center does not provide certificates. This data cannot be used for any certifications/ approvals. Venture Center does not offer to certify or confirm data in front of any agency or any court of law.

### **ELIGIBILITY**

- The Bioburden testing service is open to all researchers and technology developers. However, priority shall be given to:
  - Proof-of-concept studies aiming to create start-ups
  - Requests from incubatee companies (resident and AIP)
- At this time, Venture Center can only offer this service to a limited number of applicants. In this context, Venture Center retains the right to refuse applications without providing a reason.

### **TERMS & PRICING**

#### **GENERAL CONDITIONS:**

- This service sheet only offers standardized experimental protocol. The terms and conditions are specifically for these standardized studies. All publications, posters and presentations by researchers using Bio Burden studies data from Venture Center are expected to acknowledge use of Venture Center facilities as follows in the acknowledgement section: "Bioburden studies were performed by\_\_\_at the DBT-BIRAC supported Venture Center BioIncubator at CSIR-NCL, Pune, India"
- Any studies involving intellectual inputs relating to design of experiments or new method development etc are treated different from the above mentioned standardized studies. Such collaborative efforts involving Venture Center staff have to be approved by the Venture Center management on a case-to-case basis. The terms of engagement shall be different in these cases. Typically, in these cases, Venture Center requires that all publications, posters and presentations by researchers using Bioburden studies data generated with intellectual contributions from Venture Center staff be acknowledged through co-authorship.
- Experiments can fail for various reasons. Venture Center shall not be liable for the loss of samples and time in this case.

#### HOW TO APPLY?

- Request a discussion meeting with the Venture Center Lab Manager OR write to [lab@venturecenter.co.in](mailto:lab@venturecenter.co.in)
- Fill and submit application form. Venture Center raises an invoice against this application form. Payments are expected in full in advance prior to start of Bio-burden studies.

#### PAYMENT TERMS:

- All services are offered against advance payment in full. Service tax and other taxes applicable at the prevailing rate shall in addition to the above.
- Payment via a) Demand Draft, b) Cheque payable in Pune or at par or c) bank transfer is possible. All payments have to be made in the name of “**Entrepreneurship Development Center**”
- Booking once made shall not be transferrable or payment made thereof shall be non-refundable. On the occasional case where Venture Center is unable to carry out the experiment due to equipment failure or contamination or absence of staff, Venture Center shall inform the applicant immediately and refund the payments made to it.

#### USAGE TERMS:

- Service users shall not (intentionally or otherwise) do or say anything to suggest that Venture Center or CSIR-NCL has any connection to the samples being studied.
- Venture Center shall maintain records of BB studies for each applicant. These will be made available to the applicant prior to billing. User agrees that in case of any dispute, Venture Center’s assessment of the number of samples / number of hours and fees applicable will be considered final and the same shall be used for billing purposes.
- Venture Center reserves the right to deny use of its services at its sole discretion, without providing any reason whatsoever. In case of scheduling conflicts, Venture Center will be the sole and final authority on the schedule and availability of the BB studies.

#### PRICING:

Service Type		Price
BBT-01	Bioburden Test	Rs. 1500 for one unit and Rs. 500 per unit for additional units
BBT-02	Bioburden with Growth Promotion Test	Rs. 3000 for one unit and Rs 500 per unit for additional units

#### DISCOUNTS:

Venture Center’s standard discounts shall apply. See latest discounts at:  
<http://www.venturecenter.co.in/discounts.php>

It is hereby declared that the undersigned has read and understood the terms and conditions of Venture Center’s Bioburden Test services and accepts the same.

For and on Behalf of  
(Name of the Company)

Name of the authorized signatory

Designation