



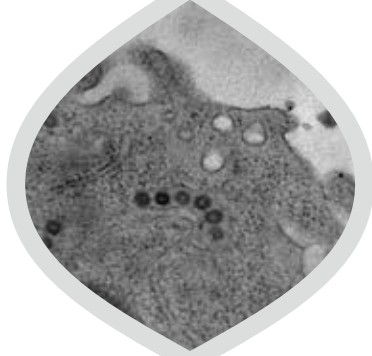
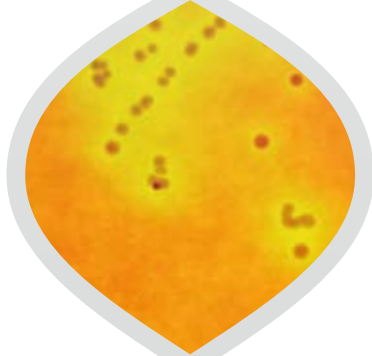
Testing Facility for Biological Safety (TFBS)

Bulk & Lot Release Tests

Every lot of product produced, requires a series of tests on both unprocessed and purified bulk material. All products entering domestic or global pharmaceutical markets require GLP testing to ensure safety and quality of the product.

TFBS offer a full range of biosafety testing services and assays required for all stage of the biopharmaceutical product development. All assays are fully validated and performed to comply with global regulatory requirements such as FDA , EMA and JP. Our experienced scientists can design a Lot Release Program, base on the characteristic of your biopharmaceutical products, or adapt an existing program to meet your requirement.

TFBS provides a full range of supports for our clients, from addressing biosafety concerns to potency analysis and determination of purity, identity and sterility of biopharmaceutical products. Our commitment is to provide one stop contract services for all our clients and helps to minimize the time between production and product release.





Assays Available for Service

1) Microbial Enumeration Test

2) Sterility

- > Direct Inoculation
- > Membrane Filtration

3) Endotoxin Detection (LAL assay)

4) Mycobacterium Detection

5) Mycoplasma Detection

- > Indicator Cell Culture
- > Direct Incubation
- > PCR & Q-PCR

6) In Vitro Adventitious Virus Detection

7) In Vivo Adventitious Virus Detection

8) Residual Contamination Assay

- > Host Residual Protein
- > Host Residual DNA

9) Specific Virus Detection

10) Transmission Electron Microscopy (TEM) Assay

Contact Us

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