eurofins | BioPharma Product Testing



Rapid Bioburden and Sterility

Eurofins BioPharma Product Testing helps bio/pharmaceutical companies manage the transition from traditional methods to rapid methods for raw materials, intermediates and finished products. We utilize the Celsis rapid microbial detection method for GMP testing in Europe and the US.

Rapid methods can have a significant impact on pharmaceutical supply chains:

- The rapid release results in shorter production cycle times and overall improved production efficiency.
- Inventories and hold times are reduced by multiple days with screening performed using this method.

We support transitional validation activity to move our clients onto rapid methods and can support the implementation of in-house testing activity or test samples on an outsourced basis. Our three-tiered service models will ensure the most cost-effective solution is implemented for your specific needs.

Why Choose Eurofins BioPharma Product Testing?

- Experienced in the development, validation and testing using rapid methods, we have validated methods for over 200 products/materials.
- With faster detection of contamination events, we are able to help clients reduce the financial and operational impact of a contamination event by initiating investigations and corrective action early in the process.
- Our range of service models allows us to provide the most appropriate variable cost solution to achieve your rapid method establishment and testing goals. We will evaluate various approaches based on the project's scope, timeline, cost and client capabilities to determine the best approach to the project.

Method Development and Validation

We use a multi-phase approach to method development and validation consistent with industry guidance, including those of the EP, USP and PDA.

- Initial method development, including sample preparation procedures to overcome inhibitory properties of the materials, is performed following current compendial approaches.
- Method validation includes sample effects testing to confirm lack of sample matrix interference with the rapid assay, time to detect studies to validate reduced incubation times and equivalency studies to statistically demonstrate equivalence between the rapid assay and the compendial method.

While there are industry and pharmacopeial guidances to assist companies on how to validate rapid microbial methods, some companies find that they may lack the available resources or the expertise to do so. Outsourcing the validation project reduces the interruption of day-to-day operations and allows companies to utilize the expert resources of their contract partner.
The challenge of this transition is often managing the increased workload associated with method development and validation activities. Once established, methods can be transferred to the client site or executed on an outsourced basis. If our clients already have the facilities, instrumentation and quality systems in place ,we can deploy analysts under our award-winning Professional Scientific Services^{SM} model to undertake medium-term method establishment projects.

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About Amplified Bioluminescence Technology

Celsis has developed a proprietary enzyme-amplified ATP Bioluminescence technology to determine the presence or absence of viable micro-organisms (bacteria, moulds and yeasts) in products. ATP amplification used in the AMPiScreen assay increases sensitivity and reduces time-to-results when compared with traditional bioluminescence methods. In the presence of micro-organisms, the assay produces a light signal that is measured and recorded in Relative Light Units. Elevated RLUs indicate the presence of micro-organisms.

The assay is suitable for bioburden testing of a wide range of non-sterile products such as raw materials, in-process materials and finished products, including those that are non-filterable, heavily pigmented or preserved. The assay can also be used as a rapid method for testing of sterile products. Time to results is reduced by five to seven days for bioburden testing and seven days or more for sterility testing.

The flexible protocol for this method accommodates varying sample types, sample sizes, enrichment broths and volumes. With faster micro screening and shorter production cycle times, this method delivers significant cost savings and efficiencies.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
Professional Scientific Services® (PSS)

Global Facilities

Australia	Denmark	India	Japan	Spain	UK
Belgium	France	Ireland	Netherlands	Sweden	US
Canada	Germany	Italy	New Zealand	Switzerland	

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