eurofins | BioPharma Product Testing

Genetic Stability Testing

Genetic stability testing is a key component of production cell bank characterization, and a regulatory requirement. Typical mammalian production cell lines are created by stable transfection of the expression vector into the host cell line. During subsequent cell culture, genomic events such as deletions, rearrangements and point mutations may occur and result in an altered cell phenotype and/or gene expression profile. The instability of the cell line is of great concern as it may negatively impact product integrity, posing a risk to patients. Even when product integrity is not immediately impacted, the possible reduction of productivity and the elevated risk of future events still raise concerns from an operational perspective.

Genetic stability testing includes an array of assays that are typically performed on a manufacturer's master cell banks (MCB), and representative lot(s) of end of production cells (EOPC). Genetic stability testing of the working cell banks (WCB) may also be performed at a manufacturer's discretion. Testing results from the EOPC and WCB are compared to those of the MCB to allow the detection of any changes that may be indicative of cell line instability.

Why Choose Eurofins BioPharma Product Testing?

We support all techniques currently used in the industry.

We have extensive experience with genetic stability testing for a wide variety of MCB, WCB and EOPC.

We can customize your Certificate of Analysis to suit your needs.

Techniques Available:

Eurofins BioPharma Product Testing offers all techniques available for evaluating the stability of cell lines throughout the cell line development process, including:

Measuring the integrity of the product transcript

- mRNA/cDNA sequencing
- Northern blot analysis

Identifying the genomic structure at the integration site

- Restriction digestion map via Southern Blot analysis

Measuring the ratio of insert gene copy number relative to host genome

- Copy number by qPCR

Determining transcript size

- Northern blot analysis

These generic methods for genetic stability testing can be quickly adapted to each client's unique cell line/cell bank. Product specific method validation can also be performed per client request to support CMC filings for later phase clinical trials and/or commercialization.

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)
PSS Insourcing Solutions®

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