Be your Best

LIVOGEN

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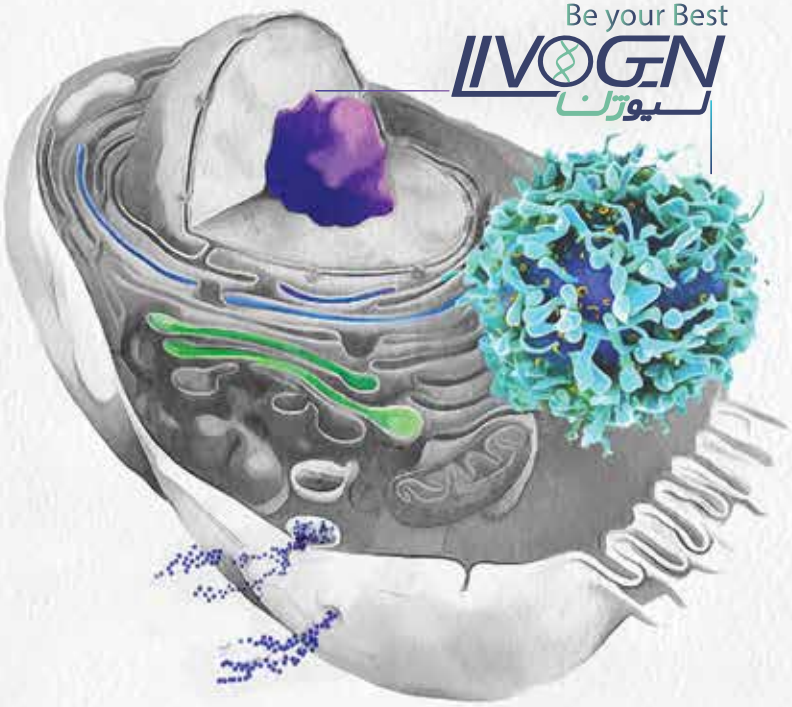

Products and Services Guide
Livogen Pharmed


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Be your Best

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Livogen Pharmed as a knowledge enterprise in the field of biotechnology was founded in **2004**. A team of motivated and highly skilled scientists along with the modern facilities and qualified infrastructure shape this company as the unique organization in Iran. Livogen Pharmed tries to deliver high quality products, offers a wide range of off-the-shell and customized assays and accelerates the novel ideas to enter the market. Some special features of Livogen Pharmed are summarized below:

- Providing GLP-approved standard BSL **2** infrastructure and clean room.
- The first and the only organization providing cell bank characterization services in Iran.
- The first and the only organization performing viral clearance /validation study in Iran.
- The first and the only that provides mass spectrometric services as well as consultancy.
- The only Iranian organization offering rapid detection services for viral, bacterial, and mycoplasma contamination.
- The only Iranian organization producing organism-specific host cell DNA kits for evaluating the residual host cell DNA in biopharmaceuticals.

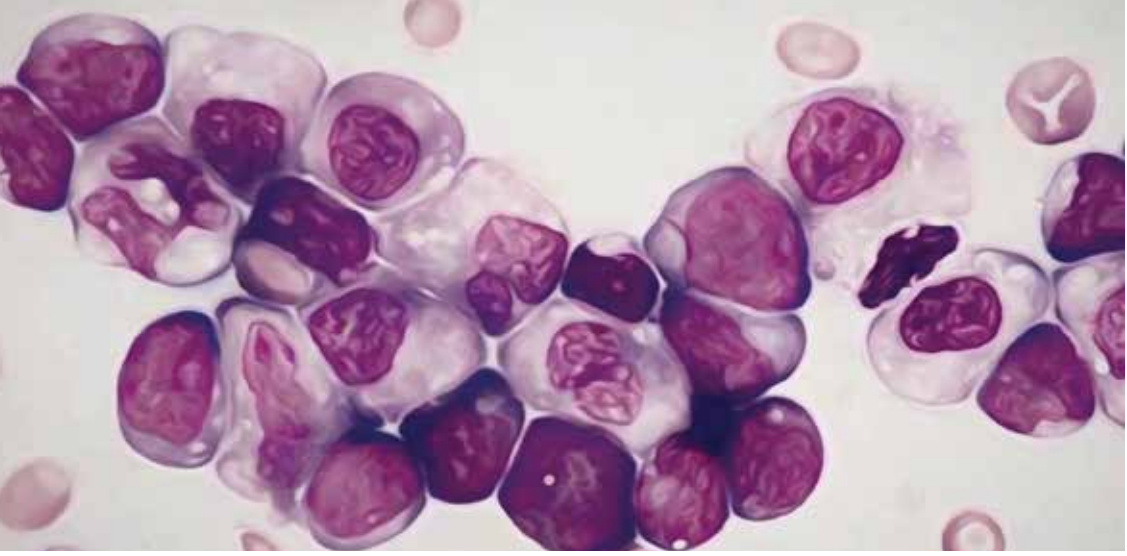
It is worth noting that all the services can be chosen and customized to address the client specific concerns and needs, ensuring that an appropriate testing plan is designed for the inquiry. Furthermore, the consulting team at Livogen Pharmed can provide the one-on-one support for choosing the assays/products and during the analysis process.

By providing the biotechnological services at high-level standards, Livogen Pharmed hopes to assist the customer in reaching the highest quality control and quality assurance of the products and the researches.

We will proudly stay by your side and accompany you to stand on the shoulders of giants and be your best.

Be your Best

LIVOGEN ليوژن



Cell Bank Characterization

Cell banks are the critical components in the biopharmaceutical industry. Hence, prior to evaluating the biosafety of cell-derived products, it is essential to perform a comprehensive characterization analysis in order to guarantee the purity and safety of the cell banks. A well-characterized cell bank provides a reliable source of contaminant-free production. As described in the FDA, ICH and EMEA guidelines, the recommended assays are partially different depending on the type of producing cell bank.

The biosafety package for any biopharmaceutical product must include an appropriate and specific plan for evaluation the cell line identity and its recombinant genome stability as well as detection of endogenous and adventitious agents such as bacteria, mycoplasma, fungi or viruses. These cell bank characterization services enable production of biologicals free of molecular, cellular, and viral contamination. Livogen Pharmed offers a portfolio of in vivo and in vitro safety assays for the mammalian, insect, and microbial cell lines at the level of the Master, Working, and End of Production Cell Banks. in the following page, the recommended tests will be listed according to the ICH guidelines and Pharmacopeia.

Identity
• DNA Barcoding Analysis
• DNA Fingerprinting
• Species-Specific Real-Time PCR
Purity
• Mycoplasma Contamination Detection (Culture method and Indicator cells)
• Mycoplasma Contamination Detection (Real Time PCR-based analysis)
Sterility
• Bacteria and Fungi Contamination
• Bacteriostasis and Fungiostasis
Genetic Stability Assessment
• Transgene insertion/Plasmid copy number by qPCR
• DNA Sequencing Analysis
• RNA Sequencing Analysis
• Restriction map analysis
• DNA stability
• RNA stability
• Gene Cloning
Bacteriophage Testing
• Detection of lytic and lysogenic phages by plaque assay
Retrovirus Test
• Transmission Electron Microscopy (TEM)
• Infectivity (Extended XC plaque assay/Extended S+L- focous assay)
• Reverse Transcriptase Assay using PERT Assay
In vivo Assay
• Testing the presence of adventitious viruses using Adult, Suckling mice, and Embryonated eggs
In vitro Assay
28/14- day in vitro assay for presence of viral contamination using three cell lines
Antibody Production Test
• Mouse Antibody Production Test (MAP), Hamster Antibody Production Test (HAP), Rat Antibody Production Test (RAP)
QPCR Test
• Bovine viruses, Porcine viruses, Human viruses

Virus Clearance Study

Pilar of the safety tripod contributes equally to the overall virus safety profile of a product, towards a view that virus inactivation and/or removal may play a more important role in assuring product safety.This shift in paradigm has plays an important role in the how virus clearance studies are perceived, and therefore the degree of regulatory scrutiny that such studies receive. Therefore, ensuring that such studies are performed in anticipation of such scrutiny, and that the design reflects current regulatory requirements, takes on great importance.The viral clearance studies involve deliberate spiking of virus agents into process intermediates and then demonstrating their inactivation or removal during the subsequent processing steps. This is usually done on a scaled-down version of the selected process steps.

The virus load of the spiked process intermediate and product-relevant process sample is determined and a reduction factor is calculated. For virus titer determination, virus-specific cell-based infectivity assay or quantitative PCR (QPCR) analysis are applied.

- Selection of Process Steps
- Verification of the Scaled-Down Process
- Selection of Viruses for Spike Study
- Determination of the Process Sample Interference to Virus Quantification System
- Performance of the Process Steps in the Presence of Virus Spike
- Evaluation of Virus Removal/Inactivation

Livogen Pharmed is the only Iranian company providing viral clearance services at BSL2 level. Our R&D team would be in touch with the responsible person from the client company for assay step planning, choosing the viruses, validation, and verification of downscaling aiming to perform the viral clearance study in a similar circumstance to the real condition and to obtain the most accurate and valid results.

Quantitative/Qualitative Determination of biological contamination

Eukaryotic cell cultures, blood and blood component samples, buffers, and all the biological materials are always susceptible to be contaminated with various agents such as mycoplasma, bacteria, and viruses. In biopharmaceutical industry, delayed detection or missing these contaminations could dramatically result in inconsistent results, wasting the products or fatal consequences.

Livogen Pharmed offers flexible contamination detection packages providing rapid and sensitive real-time PCR-based and culture based analysis for (bio)pharmaceutical companies, biotechnology research centers, and cellular and molecular institutes. The obtained results are carefully interpreted by our experts and presented as a full report along with certificate of analysis.

The current packages of contamination detection including:

- Detection of Mycoplasma contamination using real-time PCR and culturing method
- Rapid detection of Bacterial (*Escherichia coli and Treponema pallidum*) contamination using real-time PCR
- Rapid detection of Viral (HIV, HBV, HCV, and HTLV) contamination using real-time PCR

Livogen Pharmed is ready to provide you professional consults for choosing appropriate assays, sample preparation and shipment condition. Moreover, the R&D team is able to set up and validate the customized package of assays for determining potential contaminations.

Host Cell DNA Contamination Detection

The elimination of host cell impurities is a significant step in the purification of biopharmaceutical products. Consistent with the Regulatory guidelines, the DNA content in the final product lower than the defined limitations. In recent years, Livogen Pharmed has produced Host Cell DNA (HCD) determination kits that can specifically quantify the trace amount of residual DNA in biopharmaceuticals. These kits have been designed based on real-time PCR method and provide highly-sensitive analysis with a low detection limit.

The HCD kits currently produced by Livogen Pharmed are as following:

- CHO HCD Kit
- BHK HCD Kit
- SP0/2 HCD Kit
- *Escherichia coli HCD Kit*
- *Pichia pastoris HCD Kit*

In addition to HCD kit production, Livogen Pharmed provides specific HCD determination services for mentioned cell lines in validated analysis. With a sound knowledge of regulatory requirements and technical procedure, the R&D team of Livogen Pharmed is ready to fabricate customized kits/services regarding quantification of residual host cell DNA for biopharmaceutical companies and research institutes.

Furthermore, R&D team of Livogen Pharmed are working on design and fabrication of host cell protein and protein A determination kits via ELISA methodology.


نفرادی شده
سلول به سلول تَم
من در خود نرنداشت

Livogen Pharmed is a first company which provides mass spectrometry services under the brand of Mass Center in Iran. Mass Center serves a broad range of mass spectrometric services to the actors in the life sciences in Iran. Mass spectrometry is a powerful tool to accelerate, improve and reduce the costs associated with research and development and we hope to address the specific needs for the MS based high quality analysis. Having the expert service providers as our partners, enables us to consistently deliver MS services to our customers in the reasonable timeline with the highest quality. Our power is customizing the assays to address the customer's specific concerns and needs, ensuring that an appropriate testing plan is designed for the enquiry. The recommended services are listed for performing the comparability analysis between branded and biosimilar samples:

Mass Spectrometry Services:

- Protein/Lipid/Carbohydrate/Metabolite/Small molecules identification
- Label free Quantification/Labeling Quantification
- N/C-terminal sequencing
- Targeted quantification (SRM)
- Exact mass determination/Intact molecule analysis
- Glycosylation analysis
- PTMs analysis
- HDX-MS structural analysis
- Protein epitope mapping/Affinity-purification mass spectrometry
- Identification of organism(s)
- Clinical researches and Drug R&D
- Various Software Analysis

MASS CENTER
Let's Mass Spec On

Technology Transfer

Developing and validating appropriate biological/analytical assays is one of the key milestones on the road to success for the production of biologicals. Livogen Pharmed offers the complete development, optimization and validation of tests at GLP level that includes: definition of appropriate conditions and facility requirements, writing of validation plans, standard operating procedures (SOPs) and validation reports.

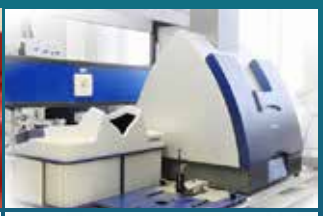
Consultancy

We can support you in choosing the appropriate method, analyzing your data and proceeding your study or project. You can also benefit from the courses or workshops in the various fields of biotechnology. **We are ready to share our knowledge with you.**

Project outsourcing

One of the key activities in Livogen Pharmed is simplifying the projects for the enterprises. You will save time and money by outsourcing your projects to our experts and we will customize the methods based on your needs. We have experiences in performing the drug R&D, cell bank characterization, viral safety, viral clearance, clinical researches, comparability studies, physicochemical analysis and etc.

We are available to discuss how we might create a program that suits your needs and let you stay ahead in your business.



Livogen Pharmed

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