

SAFC®

Pharma & Biopharma Raw
Material Solutions

Millipore SIGMA



Media Stability & Testing Services

Project resources matter in today's rapid paced biopharmaceutical market. Having a choice to outsource provides companies the ability to direct their valuable internal resources to other core goals. Our Media Stability and Testing Services are two ways we can help you achieve your project timelines by letting us share your workload.

Media Stability Service

Custom products require individualized studies to establish and support an expiration date assignment. As the owner of a formulation, this work can burden the biomanufacturer to complete the study. Our Media Stability Service is a flexible and easy program aimed to reduce your project workload. We can initiate the stability study with the coordination of your cell culture product manufacture. The data we generate allows you to make the right decision for your product shelf life assignment.

Tailored Approach

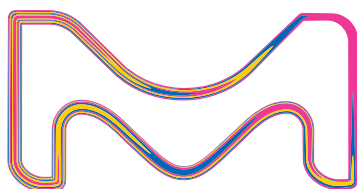
- One to one consultative approach to define the study protocol.
- Protocol selections for time points of testing, storage temperatures and tests beyond product specifications.
- Study service available for liquid and dry powder cell culture media, feeds, supplements and buffer solutions.

Reliable Data

- Data is reviewed and compared to starting point values, major changes communicated upon discovery.
- Report with testing results delivered after each time point, and at the conclusion of the study.
- Testing aligned with the same standards as product release testing.

Media Testing Service

We offer nutritional analysis on unused or spent liquid cell culture media, supplements and feeds. Our testing service provides you the nutritional component data needed to optimize your bioprocess. Testing can be performed on our GMP and/or ImMEDIATE ADVANTAGE® products.



The life science business of Merck KGaA,
Darmstadt, Germany operates as
MilliporeSigma in the U.S. and Canada.

Media Stability and Testing Services are performed as a global service. Lead times are variable depending on project scope. Please consult with your sales representative for a quote.

Standard Product Release Specification Tests

Test Name	Technique	Compendial (Y/N)	Stability Testing	Media Analysis
Appearance	Visual Test/Sigma Color Chart	Y	✓	✓
pH	pH Meter	Y	✓	✓
Osmolality	Osmometer	Y	✓	✓
Endotoxin	LAL Chromogenic	Y	✓	✓
Bioburden	Bioburden Membrane Filtration	Y	✓	✓
Solubility	Hydration Instructions	Y	✓	✓

Optional Tests

Test Name	Technique	Compendial (Y/N)	Stability Testing	Media Analysis
Growth Promotion	Cell Culture	N	✓	
Density	Density Calculation (g/L)	N	✓	
Amino Acids (not Cysteine)	Liquid Chromatography	N	✓	✓
B12 Vitamin w/ Folic Acid	Liquid Chromatography	N	✓	✓
Particle Size	Horiba Particle Analyzer	N	✓	✓
Linoleic	Gas Chromatography	N	✓	✓
Lipoic	Reversed-Phase HPLC	N	✓	✓
Pluronic	Size Exclusion HPLC	N	✓	✓
Fatty Acids	Gas Chromatography	N	✓	✓
Cholesterol	Gas Chromatography	N	✓	✓
Cysteine	Liquid Chromatography	N	✓	✓
Moisture (KF)	Karl Fischer Method	Y	✓	✓
Glucose	BIURET	N	✓	✓
Turbidity	Turbidity Meter (NTU)	N	✓	✓
Trace Elements (Cu, Mn, Zn, Mo, Ni, V, Al, Se, Cr, Co only)	ICP MS	N		✓
Mycoplasma	Cell Culture	Y		✓
Standard Elements (Ca, Mg, Na, P, K, S only)	ICP	N		✓

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