SAFC®

Pharma & Biopharma Raw Material Solutions

MERCK

TRACE ELEMENTS

Data for Decisions

Cell Culture Media

There are many possible raw materials in a cell culture media formulation. Although the supply chain for these raw materials remains relatively unchanged over the last 40 years, the way we view the supply chain and the potential for variability on the bioprocesses has changed.

The role of trace elements and their impact on protein and product quality is well documented. As such, trace elements by formulation addition is critical. Variation in these same critical components has been linked to unintended impurities in the prevailing cell culture raw material supply chain. The first step in understanding and managing variability is acquiring reliable data on these critical trace elements.

As our organization is committed to developing industry leading products and capabilities, out of our Raw Material Characterization program we are able to offer on our cell culture products the following services.

Finished Product Testing

- Quantitative Testing by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) for these elements.
  - Copper, Manganese, Zinc, Molybdenum, Nickel, Vanadium, Aluminium, Selenium, Chromium, Cobalt
  - Results reported on the CofA are without specification limits. (data for informational purpose only)
- Testing performed on cell culture products from our Lenexa, KS, Irvine, Scotland, and St. Louis, MO (Broadway) facilities
- This testing is an additional charge, please consult with your sales representative regarding your product portfolio

Typical LOQ for a Chemically Defined Media

(LoQ's will vary based on media formulation)

Trace Element Symbol	Trace Element Name	LOQ for Liquids (mcg/L)	LOQ for Dry Powder (mcg/kg)
Cu	Copper	0.8	36
Mn	Manganese	0.8	36
Zn	Zinc*	80.0	3636
Mo	Molybdenum	0.8	36
Ni	Nickel	3.2	145
V	Vanadium	0.8	36
Al	Aluminium	4.0	182
Se	Selenium	6.4	291
Cr	Chromium	1.6	73
Co	Cobalt*	40.0	1818

* This formulation by design contains higher levels of Zinc and Cobalt. Lower LoQ's can be achieved. Note: Specification limits are not available

Customer Collaboration Projects

- Based on data generated from the finished product testing, customers can enter into collaboration projects with our R&D Team:
  - Our experienced team of scientists connected to our Raw Material Characterization Program
  - Data transparency for purpose of discovery
  - Strategy recommendations for managing trace element variability recognizing changes within the prevailing supply chain may not be possible
- Collaborations are defined and charged per a scope of work

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