



Beyond Elemental Impurity Testing: Understanding the Impact of Trace Elements on Biological Drug Production

While the importance of trace elements for cellular metabolism is widely known, it is rarely considered as a defined parameter for biological drug production. Yet, for some elements, **variations as small as a few parts-per-billion (ppb) can lead to dramatic differences in production yield**, potentially creating an out of specification (OOS) result and, thereby, limiting supply.



To mitigate risk and help ensure the success of every manufacturing batch, all material inputs, particularly growth media, needs to be studied to characterize the effects of minute changes in trace elemental concentrations and what impact they have on the drug manufacturing process. **These studies and integration of our services into your process stream can lead to millions of dollars in savings** by maximizing the production yield and preventing catastrophic OOS failures.



While many labs have just recently begun to offer methods for low-level metals determination, Brooks Applied Labs (BAL) has been offering low-level elemental and elemental speciation analyses analytical services for over 20 years! Low detection limits, outstanding data quality, and unparalleled customer service have established BAL as the premier specialty metals analytical laboratory services provider. As experts in the determination and characterization of trace metals in complex matrices, BAL has the capabilities to meet even the most challenging project requirements.

BAL holds ISO 17025 accreditation and has been audited by the FDA with no findings.

