

Increased demand for detection of heavy metals & other metal residues in pharmaceuticals

A USP working group recommends modification of the analytical methods for detection of heavy metals. New default procedures (ICP-OES and ICP-MS) will be introduced. The present limit tests described in <231> will be phased out over a not yet defined period.

Initial focus will be on the 'Big Four' (Arsenic, Cadmium, Lead, and Mercury). However, focus will change as the present view where metal impurities are considered to be random contamination will be replaced by the assumption that metal impurities are part of the product composition profile. Thus future analysis of metals impurities are expected to involve analysis of a high number of metals far exceeding the Big Four.

Furthermore, as these new requirements get implemented producers of excipients must expect an increased demand from the pharmaceutical companies regarding a well-characterized metal profile of the excipient in question.

EMA has issued a guideline that came into effect September 2008. This guideline recommends maximum acceptable concentration limits for the residues of metal catalysts or metal reagents that may be present in pharmaceutical substances (API and excipients) or in drug products. Importantly, EMA consider both existing products as well as new products to be included by such investigations.

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Conclusion

- All new activities regarding detection of heavy metals should be developed on an ICP-OES or an ICP-MS platform.
- All pharmaceutical companies must consider how to comply with pharmacopoeias when the present limit tests are phased out.
- All producers of excipients and APIs must prepare for the expected higher demands from pharmaceutical companies regarding the metal composition profile of the excipients.

Qualified equipment for metal analysis at Eurofins Pharma:
ICP-MS, ICP-OES, AAS, GFAAS, FIMS and relevant sample preparation techniques.

We offer method development and full validation on these platforms.

Please contact Eurofins Pharma if you are interested to receive more information about the planned changes.

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