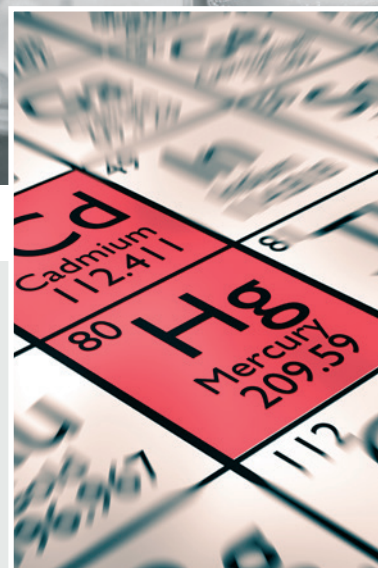


# Are your Elemental Impurity Methodologies ready for Winter 17/18?



Since the ICH Q3D was published in December 2014 the USP and EP have harmonised their approach to reflect these fundamental changes to the analysis of elemental impurities.

Winter 17/18 will see these chapters (EP 5.20 in December 17, and USP<232>/<233> in January 18) become effective.

ICH Q3D uses an elemental classification system and a risk based approach to determine which of the 24 elements detailed in the guidance to analyse for.

**Reading Scientific Services Ltd**

The Reading Science Centre, Whiteknights Campus, Pepper Lane, Reading, Berkshire RG6 6LA

Tel: +44 (0)118 918 4076 Email: [enquiries@rssl.com](mailto:enquiries@rssl.com) Web: [www.rssl.com](http://www.rssl.com)





RSSL has invested in a range of analytical technologies (ICP-QQQ, ICP-MS, ICP-OES, FAAS, GFAAS and MP-AES) and microwave digesters, to ensure that we can offer analysis to the new lower levels required by regulators.

We have been working with our clients to develop and validate methods specific and sensitive enough to determine levels of elemental impurities present in raw materials, APIs and finished products, including toxic metals which are required to be controlled down to ppb levels.

Our extensive method development program, managed by our Technical Specialists, combined with extensive analytical capabilities ensures the method is not only suitable for regulation submission, but also for routine testing as part of quality control procedures.

RSSL offers a range of other services for the testing of metals, including:

- Verification, validation and transfer of analytical methods to your specification
- Routine testing to EP, USP and JP monographs
- Semi-quantitative and quantitative screening
- Expert interpretation, support and advice
- Investigation and problem solving including a rapid response service

**Contact us to find out more about our expertise  
and how we can support you:**

Tel: **+44 (0)118 918 4076** Email: [enquiries@rssl.com](mailto:enquiries@rssl.com) Web: [www.rssl.com](http://www.rssl.com)

**Reading Scientific Services Ltd**

**The Reading Science Centre, Whiteknights Campus, Pepper Lane, Reading, Berkshire RG6 6LA**

