EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

January 2015
EMA/CHMP/ICH/353369/2013

ICH guideline Q3D on elemental impurities

Step 4

Adoption by CHMP for release for consultation	June 2013
End of consultation (deadline for comments)	31 December 2013
Final adoption by CHMP	December 2014
Date for coming into effect	**For new marketing authorisation applications:** June 2016 **For authorised medicinal products:** December 2017

Scope:

The guideline applies to new finished drug products (as defined in ICH Q6A and Q6B) and new drug products containing existing drug substances. The drug products containing purified proteins and polypeptides (including proteins and polypeptides produced from recombinant or non-recombinant origins), their derivatives, and products of which they are components (e.g., conjugates) are within the scope of this guideline, as are drug products containing synthetically produced polypeptides, polynucleotides, and oligosaccharides.

This guideline does not apply to herbal products, radiopharmaceuticals, vaccines, cell metabolites, DNA products, allergenic extracts, cells, whole blood, cellular blood components or blood derivatives including plasma and plasma derivatives, dialysate solutions not intended for systemic circulation, and elements that are intentionally included in the drug product for therapeutic benefit. This guideline does not apply to products based on genes (gene therapy), cells (cell therapy) and tissue (tissue engineering). In some regions, these products are known as advanced therapy medicinal products.

This guideline does not apply to drug products used during clinical research stages of development. As the commercial process is developed, the principles contained in this guideline can be useful in evaluating elemental impurities that may be present in a new drug product.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Application of Q3D to existing products is not expected prior to 36 months after publication of the guideline by ICH.

Link to: Quality guidelines