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Committee for Medicinal Products for Human Use (CHMP)

ICH guideline Q3D on elemental impurities

Step 3

Adoption by CHMP for release for consultation	June 2013
End of consultation (deadline for comments)	31 December 2013

Comments should be provided using this [template](#). The completed comments form should be sent to ICH@ema.europa.eu

Scope:

The PDEs in this guideline have been established based on acceptable safety limits of potentially toxic elemental impurities. The guideline applies to new finished drug products (as defined in ICH Q6A and Q6B) and new drug products employing existing drug substances. The drug products containing: proteins and polypeptides (produced from recombinant or non-recombinant cell-culture expression systems), their derivatives, and products of which they are components (e.g., conjugates) are in the scope of this guideline. In addition, drug products containing synthetically produced polypeptides, polynucleotides, and oligosaccharides are within scope of this guideline.

This guideline does not apply to herbal products, radiopharmaceuticals, vaccines, cell metabolites, DNA products, allergenic extracts, cells, whole blood, cellular blood components, crude products of animal or plant origin, dialysate solutions not intended for systemic circulation or drug products containing elements that are intentionally included for therapeutic benefit.

This guideline does not apply to drug products used during clinical research stages of development. In the later stages of development, the principles contained in this guideline can be useful in evaluating elemental impurities that may be present in new drug product prepared by the proposed commercial process.

The application of this guideline to existing marketed drug products will be addressed by regional regulatory processes.

Link to: [Quality guidelines](#)

