TABLE 3.1 (*Continued*)

International Conference on Harmonization (ICH) Guidelines for the Characterization of the Drug Substance

Category	Title	Type	Date
International Council on Harmonisation—Quality	Q3D Elemental Impurities (PDF—685 KB)	Final guidance	09/09/15
International Council on Harmonisation—Quality	Q11 Development and Manufacture of Drug Substances—Questions and Answers (Chemical Entities and Biotechnological/Biological Entities) (PDF—843 KB)	Final guidance	02/23/18
International Council on Harmonisation—Quality	Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Questions and Answers Guidance for Industry (PDF—218 KB)	Final guidance	04/19/18
International Council for Harmonisation—Quality	Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Core Guideline Guidance for Industry (PDF—451 KB)	Draft guidance	05/30/18
International Council for Harmonisation—Quality	Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Annex (PDF—223 KB)	Draft guidance	05/30/18
International Council on Harmonisation—Quality	Q3D(R1) Elemental Impurities (PDF—177 KB)	Draft guidance	07/13/18