

**TABLE 3.1**

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

<b>Category</b>	<b>Title</b>	<b>Type</b>	<b>Date</b>
International Council on Harmonisation—Quality	Q1A(R2) Stability Testing of New Drug Substances and Products (PDF—58 KB)	Final guidance	11/01/03
International Council on Harmonisation—Quality	Q1B Photostability Testing of New Drug Substances and Products (PDF—339 KB)	Final guidance	11/01/96
International Council on Harmonisation—Quality	Q1C Stability Testing for New Dosage Forms (PDF—101 KB)	Final guidance	05/09/97
International Council on Harmonisation—Quality	Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (PDF—31 KB)	Final guidance	01/01/03
International Council on Harmonisation—Quality	Q1E Evaluation of Stability Data (PDF—221 KB)	Final guidance	06/01/04
International Council on Harmonisation—Quality	Q2(R1) Validation of Analytical Procedures: Text and Methodology (PDF—190 KB)	Final guidance	03/01/95
International Council on Harmonisation—Quality	Q2A Text on Validation of Analytical Procedures (PDF—25 KB)	Final guidance	05/19/97
International Council on Harmonisation—Quality	Q2B Validation of Analytical Procedures: Methodology (PDF—132 KB)	Final guidance	06/06/08
International Council on Harmonisation—Quality	Q3A(R) Impurities in New Drug Substances (PDF—55 KB)	Final guidance	08/04/06
International Council on Harmonisation—Quality	Q3B(R) Impurities in New Drug Products (Revision 2) (PDF—171 KB)	Final guidance	12/24/97
International Council on Harmonisation—Quality	Q3C Impurities: Residual Solvents (PDF—41 KB)	Final guidance	07/24/17
International Council on Harmonisation—Quality	Q3C Tables and List (PDF—185 KB)	Final guidance	07/24/17
International Council on Harmonisation—Quality	Q3C Impurities: Residual Solvents; Maintenance Procedures for the Guidance for Industry Q3C (PDF—531 KB)	Procedures/ recommendations	07/24/17
International Council on Harmonisation—Quality	Q3C Appendix 4 (PDF—120 KB)	Draft guidance	03/18/98
International Council on Harmonisation—Quality	Q3C Appendix 5 (PDF—216 KB)	Draft guidance	03/18/98
International Council on Harmonisation—Quality	Q3C Appendix 6 (PDF—128 KB)	Draft guidance	03/18/98
International Council on Harmonisation—Quality	Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions (PDF—55 KB)	Final guidance	02/20/07
International Council on Harmonisation—Quality	Q4B: Annex 1: Residue on Ignition/Sulphated Ash General Chapter (PDF—58 KB)	Final guidance	09/18/17

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