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SESSION 5

ICH-Q

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Q1A - Q1F Stability

- > Q1A(R2) Stability Testing of New Drug Substances and Products
- > Q1B Stability Testing : Photostability Testing of New Drug Substances and Products
- > Q1C Stability Testing for New Dosage Forms
- > Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- > Q1E Evaluation of Stability Data
- > Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV

Q2 Analytical Validation

- > Q2(R1) Validation of Analytical Procedures: Text and Methodology
- > Q2(R2)/Q14 EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation



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Q3A - Q3E Impurities

- > Q3A(R2) Impurities in New Drug Substances
- > Q3B(R2) Impurities in New Drug Products
- > Q3C(R6) Maintenance of the Guideline for Residual Solvents
- > Q3C(R8) Maintenance EWG Maintenance of the Guideline for Residual Solvents
- > Q3D(R1) Guideline for Elemental Impurities
- > Q3D(R2) Maintenance EWG Revision of Q3D(R1) for cutaneous and transdermal products
- > Q3D training Implementation of Guideline for Elemental Impurities
- > Q3E EWG Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics



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Q4A - Q4B Pharmacopoeias

- > [Q4A Pharmacopoeial Harmonisation](#)
- > [Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions](#)
- > [Q4B Annex 1\(R1\) Residue on Ignition/Sulphated Ash General Chapter](#)
- > [Q4B Annex 2\(R1\) Test for Extractable Volume of Parenteral Preparations General Chapter](#)
- > [Q4B Annex 3\(R1\) Test for Particulate Contamination: Sub-Visible Particles General Chapter](#)
- > [Q4B Annex 4A\(R1\) Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter](#)
- > [Q4B Annex 4B\(R1\) Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-Organisms General Chapter](#)
- > [Q4B Annex 4C\(R1\) Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparation and Substances for Pharmaceutical Use General Chapter](#)
- > [Q4B Annex 5\(R1\) Disintegration Test General Chapter](#)
- > [Q4B Annex 6 Uniformity of Dosage Units General Chapter](#)
- > [Q4B Annex 7\(R2\) Dissolution Test General Chapter](#)
- > [Q4B Annex 8\(R1\) Sterility Test General Chapter](#)
- > [Q4B Annex 9\(R1\) Tablet Friability General Chapter](#)
- > [Q4B Annex 10\(R1\) Polyacrylamide Gel Electrophoresis General Chapter](#)
- > [Q4B Annex 11 Capillary Electrophoresis General Chapter](#)
- > [Q4B Annex 12 Analytical Sieving General Chapter](#)
- > [Q4B Annex 13 Bulk Density and Tapped Density of Powders General Chapter](#)
- > [Q4B Annex 14 Bacterial Endotoxins Test General Chapter](#)
- > [Q4B FAQs Frequently Asked Question](#)



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Q5A - Q5E Quality of Biotechnological Products ^

- > [Q5A\(R1\) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin](#)
- > [Q5A\(R2\) EWG Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin](#)
- > [Q5B Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products](#)
- > [Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products](#)
- > [Q5D Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products](#)
- > [Q5E Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process](#)

Q6A- Q6B Specifications

- > [Q6A Specifications : Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances](#)
- > [Q6B Specifications : Test Procedures and Acceptance Criteria for Biotechnological/Biological Products](#)

Q7 Good Manufacturing Practice

- > [Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients](#)
- > [Q7 Q&As Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients](#)

Q8 Pharmaceutical Development

- > [Q8\(R2\) Pharmaceutical Development](#)
- > [Q8/9/10 Q&As \(R4\) Q8/Q9/Q10 - Implementation](#)

Q9 Quality Risk Management

- > [Q9 Quality Risk Management](#)
- > [Q9\(R1\) EWG Quality Risk Management](#)
- > [Q8/9/10 Q&As \(R4\) Q8/Q9/Q10 - Implementation](#)



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Q10 Pharmaceutical Quality System ✓

- > Q10 Pharmaceutical Quality System
- > Q8/9/10 Q&As (R4) Q8/Q9/Q10 - Implementation

Q11 Development and Manufacture of Drug Substances ✓

- > Q11 Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)
- > Q11 Q&As Questions & Answers: Selection and Justification of Starting Materials for the Manufacture of Drug Substances

Q12 Lifecycle Management ✓

- > Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- > Q12 IWG Training on Regulatory and Technical Considerations for Pharmaceutical Product Lifecycle Management

Q13 Continuous Manufacturing of Drug Substances and Drug Products ✓

- > Q13 EWG Continuous Manufacturing of Drug Substances and Drug Products

Q14 Analytical Procedure Development ✓

- > Q2(R2)/Q14 EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation



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THANK YOU