ICH Quality Guidelines

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Q1A: 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 of New Drug 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 zone-III & IV
- Q1/Q5C EWG: Targeted revisions of ICH Stability guideline series

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

Q3: Impurities

- Q3A(R2): Impurities in New Drug substances
- Q3B(R2): Impurities in New Drug Products
- Q3C(R8): Guidelines for Residual solvents
- Q3C(R9): Maintenance EWG (Maintenance of Guideline for Residual solvents)

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- Q3D(R2): Guideline for Elemental Impurities
- Q3D(R3): Maintenance EWG (Maintenance of Guideline for Elemental Impurities)
- Q3D: Training implementation of Guideline for Elemental Impurities
- Q3E EWG: Impurity: Assessment and control of Extractables and leachables for Pharmaceuticals and Biologics

Q4: Pharmacopoeias

- Q4A: Pharmacopeial Harmonisation
- Q4B: Evaluation and recommendation of pharmacopeial test for use in the ICH regions
- Q4B Annexure 1(R1): Residue on ignition/sulphated ash general chapter
- Q4B Annexure 2(R1): Test for extractable volume of parenteral preparations General chapter
- Q4B Annexure 3(R1): Test for particulate contamination: sub-visible particles General chapter
- Q4B Annexure 4A(R1): Microbial examination of non-sterile products: Microbial enumeration test General chapter
- Q4B Annexure 4B(R1): Microbial examination of non-sterile products: Test for specified micro-organisms General chapter
- Q4B Annexure 4C(R1): Acceptance criteria for Pharmaceutical Preparations and substances for pharmaceutical use General chapter
- Q4B Annexure 5(R1): Disintegration test General chapter
- Q4B Annexure 6: Uniformity of dosage units General chapter
- Q4B Annexure 7(R2): Dissolution test General chapter

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- Q4B Annexure 8(R1): Sterility test General chapter
- Q4B Annexure 9(R1): Tablet friability test General chapter
- Q4B Annexure 10(R1): Polyacrylamide gel electrophoresis General chapter
- Q4B Annexure 11: Capillary electrophoresis General chapter
- Q4B Annexure 12: Analytical sieving General chapter
- Q4B Annexure 13: Bulk density and Tapped density of powders General chapter
- Q4B Annexure 14: Bacterial endotoxins test General chapter
- Q4B FAQs: Frequently asked question

Q5: 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 expression construct in cells used for production of r-DNA derived protein products
- Q5C: Quality of Biotechnology products (Stability testing of Biotechnology products/Biological products
- Q5D: Derivation and characterisation of cell substates used for production of Biotechnology products/Biological products
- Q5E: Comparability of Biotechnology products/Biological products subject to changes in their manufacturing process

Q6: Specifications

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- Q6A: Specifications: Test procedure and acceptance criteria for New drug substances and New drug products: Chemical substances

- Q6B: Specifications: Test procedure and acceptance criteria for Biotechnological/Biological products

Q7: Good Manufacturing practices

- Q7: Good Manufacturing practise guide for Active pharma Ingredients

- Q7 Q&As: Question and Answers: Good Manufacturing practise guide for Active pharma Ingredients

Q8: Pharmaceutical development

- Q8 (R2): Pharmaceutical development

- Q8/9/10 Q&As(R4): Q8/Q9/Q10 Implementation

Q9: Quality Risk management

- Q9 (R1) EWG: Quality Risk management

- Q8/9/10 Q&As(R4): Q8/Q9/Q10 Implementation

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: Question and Answers: Selection and justification of starting materials for Manufacturing of Drug substances

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Q12: Life cycle management

- Q12: Technical and regulatory considerations for pharmaceutical product Life cycle management

- Q12 IWG: Training on Technical and regulatory considerations for pharmaceutical product Life cycle management

Q13: Continuous manufacturing of Drug substances and Drug products

- Q13: Continuous manufacturing of Drug substances and Drug products

- Q13 IWG: Training on Continuous manufacturing of Drug substances and Drug products

Q14: Analytical procedure development

- Q2 (R2)/Q14 EWG: Analytical procedure development and revision of Q2 (R2) Analytical validation

Abbreviations: -

EWG: Experts working group

IWG: Implementation working group