

I. Analytical and Bioanalytical Studies

- 1 Guideline on bio-analytical method validation
https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-bioanalytical-method-validation_en.pdf
- 2 Bioanalytical Method Validation Guidance for Industry
<https://www.fda.gov/files/drugs/published/Bioanalytical-Method-Validation-Guidance-for-Industry.pdf>
- 3 Quality control methods for medicinal plant materials
<https://apps.who.int/iris/handle/10665/41986>
- 4 Quality control methods for herbal materials
(<https://apps.who.int/iris/handle/10665/44479>)
- 5 1A (R2) – Stability Testing of New Drug Substances and Product
<https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf>
- 6 Q1 B – Stability Testing: Photo Stability Testing of New Drug Substances and Products
<https://database.ich.org/sites/default/files/Q1B%20Guideline.pdf>
- 7 Q1C – Stability Testing for New Dosage Forms
<https://database.ich.org/sites/default/files/Q1C%20Guideline.pdf>
- 8 Q1D – Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q1d-bracketing-and-matrixing-designs-stability-testing-new-drug-substances-and-products>
- 9 Q1E – Evaluation of Stability Data
<https://database.ich.org/sites/default/files/Q1E%20Presentation.pdf>
- 10 Q1F – Stability Data Package for Registration Application in Climatic Zones III and IV
https://database.ich.org/sites/default/files/Q1F_Stability_Guideline_WHO_2018.pdf
- 11 Q2 (R1) – Validation of Analytical Procedures : Text and Methodology
<https://www.fda.gov/files/drugs/published/Analytical-Procedures-and-Methods-Validation-for-Drugs-and-Biologics.pdf>
- 12 Q3A (R2) – Impurities in New Drug Substances
<https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf>
- 13 Q3B (R2) – Impurities in New Drug Products
<https://database.ich.org/sites/default/files/Q3B%28R2%29%20Guideline.pdf>
- 14 Q3C (R5) – Impurities : Guideline for Residual Solvents
https://database.ich.org/sites/default/files/Q3C-R6_Guideline_ErrorCorrection_2019_0410_0.pdf
- 15 Q3D – Impurities : Guideline for Elemental Impurities
https://database.ich.org/sites/default/files/Q3D-R1EWG_Document_Step4_Guideline_2019_0322.pdf

- 16 Q5B – Quality of Biotechnology Products:
<https://www.fda.gov/media/71417/download>
- 17 Q5C – Quality of Biotechnology Products: Stability Testing of Biotechnological/Biological Products
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q5c-quality-biotechnological-products-stability-testing-biotechnologicalbiological-products>
- 18 Q5D – Derivation and Characterisation of Cell Substrates used for Production of Biotechnological/Biological Products
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q5d-quality-biotechnologicalbiological-products-derivation-and-characterization-cell-substrates-used>
- 19 Q5E – Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q5e-comparability-biotechnologicalbiological-products-subject-changes-their-manufacturing-process>
- 20 Q6A – Specifications: Test Procedure and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
<https://www.ema.europa.eu/en/ich-q6a-specifications-test-procedures-acceptance-criteria-new-drug-substances-new-drug-products>
- 21 Q6B–Specifications: Test Procedure and Acceptance Criteria for Biotechnological/Biological
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q6b-specifications-test-procedures-and-acceptance-criteria-biotechnologicalbiological-products>
- 22 HPTLC
- 23 HPTLC online training course <https://www.hptlc-association.org/home.cfm>
- 24 HPTLC Association
https://www.hptlcassociation.org/projects/identification_of_herbal_drugs.cfm
- 23 Mass Database
- 24 mzCloud <https://www.mzcloud.org/>
- 25 MassBank <https://massbank.eu/MassBank/>
- 26 Global Natural Products Social Molecular Networking
<https://gnps.ucsd.edu/ProteoSAFe/static/gnps-splash.jsp>