The European Medicines Agency's scientific guidelines on the stability of drug substances and drug products help medicine developers prepare marketing authorisation applications for human medicines.

For a complete list of scientific guidelines currently open for consultation, see Public consultations

Guidelines

- ICH Q1A (R2) Stability testing of new drug substances and drug products
- ICH Q1B Photostability testing of new active substances and medicinal products
- ICH Q1C Stability testing: requirements for new dosage forms
- ICH Q1D Bracketing and matrixing designs for stability testing of drug substances and drug products - Scientific guideline
- ICH Q1E Evaluation of stability data
- ICH Q1F Stability data package for registration in climatic zones III and IV
- Declaration of storage conditions for medicinal products particulars and active substances (Annex)
- In-use stability testing of human medicinal products
- Maximum shelf-life for sterile products for human use after first opening or following reconstitution - Scientific guideline
- Start of shelf-life of the finished dosage form (Annex to the note for guidance on the manufacture of the finished dosage form) - Scientific guideline
- Stability testing for applications for variations to marketing authorisation
- Stability testing of existing active ingredients and related finished products