



SCHEME 8.7 Decision tree for the disposition of microbiological attributes. (Courtesy of Pharmquest Corporation, Mountain View, CA.)

specification. Information to support the safety of excipients, when appropriate, should be cross-referenced.

8.2.4 Stability Evaluation

The International Conference on Harmonization (ICH) guidelines regarding the quality of drug substances are specific and require frequent referral to keep the preformulation activities current with the regulatory requirements. The pertinent guidelines are listed in the following:

- Q1A(R2) Stability Testing of New Drug Substances and Products (issued 11/2003, posted 11/20/2003)
- Q1B Photostability Testing of New Drug Substances and Products (issued 11/1996, reposted 7/7/1998)
- Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (issued 1/2003, posted 1/15/2003)
- Q1E Evaluation of Stability Data (issued 6/2004, posted 6/7/2004)
- Q3A Impurities in New Drug Substances (issued 2/10/2003, posted 2/10/2003)