References

Note: The references below are those quoted in the revised guidelines published as Annex 3 to the Forty-first Report of the Expert Committee on Specifications for Pharmaceutical Preparations, Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 943). For current WHO guidelines on, for example, GMP, consult the WHO Medicines website (http://www.who.int/medicines/).

1. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Twenty-fifth report.* Geneva, World Health Organization, 1975, Annex 3 (WHO Technical Report Series, No. 567).

2. *The International Pharmacopoeia*, fourth edition, Vols 1 and 2. Geneva, World Health Organization, 2006.

3. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Twenty-eighth report.* Geneva, World Health Organization, 1982, Annex 1 (WHO Technical Report Series, No. 681).

4. General guidelines for the establishment, maintenance and distribution of chemical reference substances. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fifth report.* Geneva, World Health Organization, 1999, Annex 3 (WHO Technical Report Series, No. 885).

5. Good practices for national pharmaceutical control laboratories. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report.* Geneva, World Health Organization, 2002, Annex 3 (WHO Technical Report Series, No. 902).

6. Good manufacturing practices for pharmaceutical products. In: *Quality assurance of pharmaceuticals. A compendium of guidelines and related materials*, Vol. 2, second updated edition. *Good manufacturing practices and inspection.* Geneva, World Health Organization, 2007.

7. Good manufacturing practices for biological products. In: *Quality assurance of pharmaceuticals. A compendium of guidelines and related materials*, Vol. 2, second updated edition. *Good manufacturing practices and inspection.* Geneva, World Health Organization, 2007.

8. General recommendations for the preparation and use of infrared spectra in pharmaceutical analysis. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth report.* Geneva, World Health Organization, 1996, Annex 4 (WHO Technical Report Series, No. 863).

9. International Organization for Standardization. *General requirements for the competence of reference material producers.* 2000, ISO Guide 34.

10. International Organization for Standardization. *Certification of reference materials – general and statistical principles.* 2006, ISO Guide 35.

11. International Organization for Standardization. *Reference materials – content of certificate and labels.* 2000, ISO Guide 31.

12. International Organization for Standardization. *General requirements for the competence of testing and calibration laboratories.* 2006, ISO/ IEC Guide 17025.