General requirements

A substance or a dosage form stated to be of pharmacopoeial quality must comply with all the requirements set out in *The international pharmacopoeia*. A monograph is to be interpreted in accordance with any general notice or monograph or with any general method text that is contained in this edition and that is applicable to that monograph. The requirements in monographs have been designed to provide appropriate control of potential impurities rather than to provide against all possible contaminants or adulterants. Material found to contain a contaminant or adulterant not detectable by means of the prescribed tests is not of pharmacopoeial quality if the nature or amount of the foreign substance found is incompatible with good manufacturing or good pharmaceutical practice.

General methods of analysis that are commonly used in carrying out the tests and assays included in the monographs of the International Pharmacopoeia are described in the section on "Methods of Analysis". In some cases a specific cross-reference to the method required is provided within the monograph text. Examples include references to Spectrometry in the infrared region, *1.14.1 Chromatography*, High-performance liquid chromatography and 2.2.3 Limit test for heavy metals. In other cases, where the relevant method can be inferred from the title of the test, no explicit cross-reference is given. Examples include tests for Specific optical rotation, Sulfated ash, Loss on drying and pH value. Whether or not a specific cross-reference is included, the requirements of the monographs of the International Pharmacopoeia are to be interpreted in relation to the relevant method of analysis.

Limits are evaluated on the basis of normal analytical practice. Variations in manufacture and/or compounding, any possible deterioration, and normal analytical errors are taken into consideration. However, further tolerances beyond the limits stated are not permitted.

Limits are generally expressed in terms of the equivalent content in per cent (%) of the chemical formula for a given substance, as determined in the assay.

The requirements for biological substances and preparations such as certain antibiotics, if determined biologically, are given in International Units (IU) per milligram (mg). The material is not of pharmacopoeial quality if the upper fiducial limit of error is less than the stated potency, with fiducial limits of error based on a probability of 95% (P = 0.95).

Where it is specified that the results are to be calculated with reference to the dried or anhydrous substance, the determination of loss on drying or water is to be carried out using the test conditions indicated in the monograph.