Impurities

In certain tests, the concentration of impurity is given in parentheses either as a percentage or in parts per million by weight (ppm). In chromatographic tests such concentrations are stated as a percentage irrespective of the limit.

In chromatographic tests in which a comparison is made between spots or peaks in chromatograms obtained with solutions of different concentrations of the test substance, the percentage given in parentheses indicates an impurity limit expressed in terms of a nominal concentration of the medicinal substance itself.

In all cases where an impurity limit is given in parentheses, the figures given are approximations for information only; conformity with the requirements is determined on the basis of compliance or otherwise with the stated test.

A list of all known and potential impurities that have been shown to be controlled by the tests in a monograph may be given for information at the end of the monograph.