

## **B.2 Obtaining source material**

**B.2.1 Selection of candidate substance** When it is intended to establish a secondary reference substance for use as an assay standard for the determination of the content of the drug substance itself or in a drug formulation, a source(s) of pharmaceutical grade substance(s) is (are) identified. Availability of the required quantity is assured. The guidelines given in Section 2 of Part A also apply in this case. If a substance is intended to be used as an impurity standard, the candidate material may be obtained from commercial suppliers, provided that the percentage purity is more than 95% (or 90% if for use in TLC).

**B.2.2 Documentation to be supplied with the candidate reference substance** The supplier of the candidate reference substance is requested to supply the same documentation as required for a candidate primary reference substance (see Section 2, Part A).

**B.2.3 Initial testing for compliance with the requirements of the monograph** The coordinating laboratory is responsible for verifying that the candidate reference substance complies with the requirements of the monograph, where applicable. In such a case compliance is a prerequisite to proceeding to the interlaboratory study to assign the content of the secondary standard.