tablets. For API and solid dosage forms, this is usually a drum double-lined with polyethylene.

Some components of a bulk package fall within the definition of a 'primary package' since they are in direct contact with the product.

3.7 Primary Package

Any material employed in the packaging of a pharmaceutical product or active pharmaceutical ingredient. Primary packaging material(s) form the container/closure system for the product and therefore may be in direct contact with the product. Examples include HDPE bottles/caps, blister strip packs, tubes/caps for ointments, syringes, Turbuhaler or plastic bag.

For the purposes of commercial stability studies, the primary package, i.e. the container closure system, shall be considered to be independent of any differences in labeling and/or printing attached to, or on, the primary package, providing that appropriate product/container/label interactions have been conducted on all such variants.

3.8 Secondary Packaging

Secondary packages are not in direct contact with the product or active pharmaceutical ingredient. Examples include, cartons used to contain blister packs, fibreboard drums for plastic bags, cartons for tubes.

Secondary packaging components essential to the function or stability of the product, although not in direct contact with the product, should be regarded as primary materials or components. Examples include blister packages of single dose pipettes (needed for stability), ampoules stated to be sterile on the outside, needle covers of syringes, inks for printing on primary plastic containers, capping for stoppers, desiccant sachets, etc.

4 Responsibilities

Quality Assurance Agreement Co-ordination (QAAC) Team/Site/ Lead Team/Site

4.1 It is the responsibility of the assigned Lead team/Site (or Quality Assurance Agreement Co-ordination (QAAC) Site if one is assigned) to have a written QA Agreement with the contractor that clearly identifies the need, if any, for the contractor to perform stability studies.

4.2 It is the responsibility of the Lead team/site to agree with the contractor a Stability Master Plan and stability study protocol (or Integrated Stability Protocol) that have been approved through company business processes.

4.3 It is the responsibility of the Lead team/site to transfer to the contractor the test methodology identified in the stability protocol.

4.4 Where necessary, e.g. when stability studies are assigned to contract laboratories, it is the responsibility of the Lead team/site (or another Site if agreed by the Lead Site) to provide to the contractor appropriate quantities of stability study batches.

