Storage

Substances, dosage forms, and other materials must be stored under specified conditions in order to avoid contamination and deterioration.

(a) Containers

The container and its closure must not interact physically or chemically with the substance within in any way that would alter its quality. The following terms include general requirements for the permeability of containers:

Well-closed containers must protect the contents from extraneous matter or from loss of the substance under normal conditions of handling, shipment, or storage.

Tightly closed containers must protect the contents from extraneous matter, from loss of the substance, and from efflorescence, deliquescence, or evaporation under normal conditions of handling, shipment, or storage. If the container is intended to be opened on several occasions, it must be designed to be airtight after reclosure.

Hermetically closed containers must protect the contents from extraneous matter and from loss of the substance, and be impervious to air or any other gas under normal conditions of handling, shipment, or storage.

In addition, a *tamper-evident container* is one that is fitted with a device that reveals clearly whether it has ever been opened.

(b) Protection from light

Substances and dosage forms requiring protection from light should be maintained in a light-resistant container that - either by reason of the inherent properties of the material of which the container is composed, or because a special coating has been applied to the container - shields the contents from the effects of light. Alternatively, the container may be placed inside a suitable light-resistant (opaque) covering and/ or stored in a dark place.

(c) Temperature

Where storage at temperatures other than room temperature (15 to 25°C or, depending on the climatic conditions, up to 30°C) is recommended, this is stated in the monograph. Such substances and dosage forms should be labelled accordingly.