

4. CONTAINER CLOSURE SYSTEM [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

The suitability of the container closure system (described in 3.2.P.7) for the storage, transportation (shipping), and use of the drug product should be discussed. This discussion should consider, for example, choice of materials, protection from moisture and light, compatibility of the materials of construction with the dosage form (including sorption to container and leaching), safety of materials of construction, and performance (such as reproducibility of the dose delivery from the device when presented as part of the drug product).

See FDA Container Closure Guidance May 1999 (table 1 page 6 and table 2 page 12)