

3.2.P.7 Container Closure System [{Drug Product Name}, {Dosage Form}]

A description of the container closure systems should be provided, including the identity of materials of construction of each primary packaging component and its specification. The specifications should include description and identification (and critical dimensions, with drawings, where appropriate). Noncompendial methods (with validation) should be included, where appropriate.

For nonfunctional secondary packaging components (eg, those that neither provide additional protection nor serve to deliver the product), only a brief description should be provided. For functional secondary packaging components, additional information should be provided.

For example, name and code, description (type, size, shape, color), manufacturer and DMF reference, materials of construction, specifications and drawings, and any methods performed by the manufacturer should be included here. If there are associated components (dropper, spoon, cup, syringe) information about this item should be included as well.

Suitability information should be located in 3.2.P.2.