

3.2.P.7 Container Closure System

The drug product tablets are packed in white, high density polyethylene (HDPE) plastic bottles, or in blister packs with aluminum lidding.

Each bottle is capped with a white, child-resistant closure containing a pulp liner and aluminum foil induction seal

Tablets are also packaged as unit-dose in a base film consisting of rigid blister film laminated to a barrier film. A configuration scheme of the tablets is presented in Table 1.

Table 1: Configuration Scheme

Strength	Package Type	Supplier	Count
45 mg	white, high density polyethylene (HDPE) plastic bottles with child-resistant closure containing a pulp liner and aluminum foil induction seal	Container Co. of America (all components)	28 tablets
	Unit-dose blister strips consisting of a rigid blister film laminated to a barrier film; the package contains 2 blister strips of fourteen tablets	Foil – Reynolds Wrap USA	28 tablets
		Film - Plastics of America	
350 mg	white, high density polyethylene (HDPE) plastic bottles with child-resistant closure containing a pulp liner and aluminum foil induction seal	Container Co. of America (all components)	28 tablets
	Unit-dose blister strips consisting of a rigid blister film laminated to a barrier film; the package contains 2 blister strips of fourteen tablets	Foil – Reynolds Wrap USA	28 tablets
		Film - Plastics of America	

3.2.P.7.1 Primary Package

All strengths of the tablets are packaged as unit-dose in a white plastic bottle, or as a unit-dose in a base film consisting of PVC rigid film laminated in Aclar. The material complies with US FDA requirements for direct food contact, including applicable sections within 21 CFR SS174-186. The push-through blister lidding is made of aluminum which is heat-sealed to the base film. The blister lidding conforms to 21 CFR 175.300. The blister pack conforms to Commission Regulation (EU) No. 1183/2012, Ph. Eur. monographs, USP <661> (current edition).

A representative Certificate of Analysis for each component from the vendor is attached herein. (attachment.pdf)

Table 2: Dimensions of Primary Container Closure

White Bottle - Label Panel Dimensions 4.7124" W x 1.2000" H (100% wrap); Color White. Size 150 cc. Material HDPE. Diameter 2.09 in. Height 3.727 in. Label Dimensions 6.4375 x 2.375 in (width x height).- all strengths
Blister Pack – 4x5mm x 10.0 mm – all strengths

3.2.P.7.1 Secondary Package

The blister packs are as described below.

Attribute	Analytical Procedure	Acceptance Criteria
Material Type	Visual inspection	Transparent film for blisters (PVC/PVDC) Corresponds to material spectrum (Foil)
Color	Visual inspection	White (PVC/PVDC) Metallic, dull (Foil)
Material Identification	Infrared spectroscopy	Corresponds with reference spectrum
Thickness	Measurement	330 uM +/- 30 uM

The white bottles are packaged in a paperboard box. The specifications are outlined below.

Table 1: Secondary Package – Specifications

Appearance	Clean undamaged
Aspect (glue)	Clean, no surplus
Material ^a	Duplex board, carton
Grammage ^a	1315 mg/m2 ± 16
Dimensions ^a	1320 × 930 × 320 mm
^a Information is owned by the manufacturer/supplier of the packaging material and provided for reference purpose only; it is not considered as of regulatory relevance and will therefore not be subject to change control with regulatory involvement.	

A representative Certificate of Analysis for each component from the vendor is attached herein. (attachment2.pdf)