

S.6 CONTAINER CLOSURE SYSTEM [SMOLECULE, PHARMA USA]

1. DESCRIPTION OF CONTAINER CLOSURE SYSTEM

Bulk API is placed in a low density polyethylene plastic film bag and tied. The packaged API is placed in a high density polyethylene pail close with a HDPE screw cap with a gasket.

Ongoing stability studies have demonstrated that the container closure is compatible with the drug substance and the container closure system provides adequate protection.

Table S.6-1 Primary Packaging

Attribute	Description
Container Type	Bag made from tubular, monolayered film
Material Identification	Low-density polyethylene
Conformity	Food-contact plastic material - Complies with FDA 21 CFR 177.1520 (c) 2.2 (olefin polymers) - Complies with Commission Regulation (EU) No. 10/2011 including its amendments EU 321/2011, EU 1282/2011, EU 1183/2012, EU 202/2014 and EU 2015/174 Complies with Ph. Eur. 3.2.2

2. SPECIFICATION AND ANALYTICAL PROCEDURES

Packaging components are sampled, tested, and examined for conformance with written specifications

The specification for the primary packaging component are provided in Table S.6-2.

A representative IR spectrum of the primary packaging component is provided in Attachment 3.pdf

Table S.6-2 Specification - Low-Density Polyethylene Bag

Attribute	Analytical Procedure	Acceptance Criteria
Container Type	Visual inspection	Corresponds
Material Identification	Infrared spectroscopy	Corresponds with reference
Material-Conformity	Supplier Certificate of Analysis	Corresponds