

### 3.2.P.6. PREPARATION AND CHARACTERIZATION OF REFERENCE MATERIALS

The drug substance reference material detailed in [Section 3.2.S.5.1 Reference Standards or Materials](#) is used for DP release and stability testing in the Fluorescence assay. Lipid reference materials, currently purchased from Avanti and used for the release and stability testing of drug product are presented in Table 3.2.P.6-1.

**Table 3.2.P.6-1. Summary of Current Lipid Reference Materials**

Reference Material Designation	Supplier	Types of Material Released/Evaluated	
ALC-0315 Reference Material	Purchased from Avanti	Clinical Supplies, Process Validation, EUA Supplies	DP
ALC-0159 Reference Material	Purchased from Avanti	Clinical Supplies, Process Validation, EUA Supplies	DP
DSPC Reference Material	Purchased from Avanti	Clinical Supplies, Process Validation, EUA Supplies	DP
Cholesterol Reference Material	Purchased from Avanti	Clinical Supplies, Process Validation, EUA Supplies	DP

[Section 3.2.A.3.5 Reference Standards or Materials \[ALC-0315\]](#) describes qualification information of ALC-0315 reference material. [Section 3.2.A.3.5 Reference Standards or Materials \[ALC-0159\]](#) describes qualification information of ALC-0159 reference material.