

2.3.P.6. REFERENCE STANDARDS OR MATERIALS

2.3.P.6.1. Clinical Reference Material

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, (b) (4) and used for the release and stability testing of drug product are presented in Table 2.3.P.6-1.

Table 2.3.P.6-1. Summary of Lipid Reference Materials

Reference Material Designation	Supplier	Types of Material Released/Evaluated	
ALC-0315 Reference Material	(b) (4)	Clinical Supplies, Process Validation, EUA Supplies	DP
ALC-0159 Reference Material	(b) (4)	Clinical Supplies, Process Validation, EUA Supplies	DP
DSPC Reference Material	(b) (4)	Clinical Supplies, Process Validation, EUA Supplies	DP
Cholesterol Reference Material	(b) (4)	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.

Future lots of ALC-0315 and ALC-0159 reference materials will be sourced from an appropriately qualified vendor and qualified to ensure the same level quality of materials. [Reference Section 3.2.P.6 Qualification of Future Reference Standards](#) for further information on qualification of the lipid reference materials.

Cholesterol for use as a reference material will be sourced from an appropriately qualified vendor. Future lots of cholesterol reference material will meet the USP or Ph. Eur. requirements for cholesterol.

Future lots of DSPC for use as a reference material will be sourced from an appropriately qualified vendor and will meet the acceptance criteria for current vendors outlined in [Section 3.2.P.4.1. Specifications \(Non-Compendial\)](#).

The (b) (4) period of use applied to new lipid materials will be assigned based (b) (4)
(b) (4)

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