

### 3.2.P.5.2 Analytical Procedures {Bacterial Endotoxin}

Associates of Cape Cod, Inc. (ACC) SOP: M-CTS-CS-0929 (on file at ACC) is used for the detection and quantitation of bacterial endotoxin for mRNA-1273 Drug Product using a

(b) (4)

Testing is performed as outlined in the United States Pharmacopeia, (USP) <85>, Bacterial Endotoxin Test. These chapters are harmonized with the chapters of the same name in the European Pharmacopoeia (EP 2.6.14) and the Japanese Pharmacopeia (JP 4.01). The endotoxin level, measured as endotoxin units (EU), in the sample is divided by mRNA-1273 Drug Product volume and reported as EU/mL.