3.2.S.4.3 Validation of Analytical Procedures

The analytical procedures for used for release and stability testing of CX-024414 lots were confirmed as suitable for their intended use through method validation and/or qualification studies. Summaries of these studies are indexed in Table 1. Reference is made to 3.2.S.4.3 {CX-024414} and 3.2.P.5.3 and 3.2.S.4.3 {mRNA-1273 LNP} sections in those instances where the validation performed for CX-024414 testing is included in the same summary as for drug product or mRNA-1273 LNP.

Table 1: Index of Method Validation Summaries for CX-024414

Test	Method	Section
Appearance	Visual	Section 3.2.P.5.3 {Appearance}
Identity	RTSS	Section 3.2.S.4.3 {CX-024414 - Identity}
Total RNA content	UV	Section 3.2.S.4.3 {CX-024414 - Total RNA Content}
Purity	RP-IP-HPLC	Section 3.2.P.5.3 {Purity and Product-Related Impurities}
Product-related impurities		Section 3.2.P.5.3 {Purity and Product-Related Impurities – Direct Injection}
% 5’ Capped	RP-IP-HPLC	Section 3.2.S.4.3 {CX-024414 - % 5’ Capped}
% PolyA tailed RNA % Tailless RNA	RP-HPLC	Section 3.2.S.4.3 {CX-024414 - %PolyA Tailed RNA by RP-HPLC}
pH	USP <791>	Section 3.2.P.5.3 {pH}
Bacterial Endotoxins	USP <85>, EP 2.6.14	Section 3.2.S.4.3 {CX-024414 - Bacterial Endotoxin}
Bioburden	USP <61>, EP 2.6.12	Section 3.2.S.4.3 {CX-024414 - Bioburden} Section 3.2.S.4.3 {mRNA-1273 LNP - Bioburden}

Abbreviations: qPCR = quantitative polymerase chain reaction; RP-HPLC = reverse-phase high-performance liquid chromatography; RP-IP-HPLC = reverse-phase ion-pair high-performance liquid chromatography; RTSS = reverse transcription Sanger sequencing; UV = ultraviolet