3.2.S.4.2 Analytical Procedures

The analytical methods used for the release and stability testing of CX-024414 lots are described in the sections indexed in Table 1. Reference is made to 3.2.S.4.2 {CX-024414}, 3.2.P.5.2 and 3.2.S.4.2 {mRNA-1273 LNP} sections in those instances where the method used for CX-024414 testing is the same as the method performed for drug product or mRNA-1273 LNP.

Table 1: Index of Analytical Method Descriptions for CX-024414

Test	Method	Section
Appearance	Visual	Section 3.2.S.4.2 {CX-024414 -Appearance} Section 3.2.P.5.2 {Appearance}
Identity	RTSS	Section 3.2.S.4.2 {CX-024414 - Identity}
Total RNA content	UV	Section 3.2.S.4.2 {CX-024414 – Total RNA Content}
Purity	RP-IP-HPLC	Section 3.2.S.4.2 {CX-024414 – Purity and Product-Related Impurities} Section 3.2.P.5.2 {Purity and Product-Related Impurities}
Product-related impurities		Section 3.2.S.4.2 {CX-024414 – Purity and Product-Related Impurities – Direct Injection} Section 3.2.P.5.2 {Purity and Product-Related Impurities - Direct Injection}
% 5’ Capped	RP-IP-HPLC	Section 3.2.S.4.2{CX-024414 - % 5’ Capped}
% PolyA tailed RNA % Tailless RNA	RP-HPLC	Section 3.2.S.4.2 {CX-024414 -%PolyA Tailed RNA by RP-HPLC}
pH	USP <791>	Section 3.2.S.4.2 {CX-024414 - pH} Section 3.2.P.5.2 {pH}
Bacterial Endotoxins	USP <85>, EP 2.6.14	Section 3.2.S.4.2 {CX-024414 - Bacterial Endotoxin}
Bioburden	USP <61>, EP 2.6.12	Section 3.2.S.4.2 {CX-024414 -Bioburden} Section 3.2.S.4.2 {mRNA-1273 LNP - Bioburden}

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