

### 3.2.P.5.3 Validation of Analytical Procedures

The analytical procedures for testing of mRNA-1273 LS Injection have been confirmed as suitable for their intended use through executed method qualification experiments. The % purity by RP-HPLC method has been demonstrated to be stability indicating. The qualification parameters are provided in [Table 1](#).

(b) (4)

(b) (4)

Pharmacopoeial methods for pH (USP <791>), osmolality (USP <785>), container content (USP <697>) and particulate matter (USP <788>) used for testing are not described as testing complies with the appropriate compendial method.

Methods applicable for both mRNA-1273 LS LNP and mRNA-1273 LS Injection are noted with “a” and are described in [Section 3.2.S.4.3 {mRNA-1273 LNP}](#). Qualifications parameters specific for the mRNA-1273 sequence are noted with “b” in the following table.

**Table 1: Qualification Parameters for mRNA-1273 LS Injection Analytical Methods**

Method (Attribute)	Method Parameter
Reverse Transcription/ Sanger Sequencing <sup>(a)</sup> (Identity)	See <a href="#">Table 2</a> , <a href="#">Section 3.2.S.4.3 {mRNA-1273 LNP}</a>
AEX-HPLC <sup>(a)</sup> (RNA Content)	See <a href="#">Table 3</a> , <a href="#">Section 3.2.S.4.3 {mRNA-1273 LNP}</a>
RP-HPLC <sup>(a)</sup> (Purity)	See <a href="#">Table 4</a> , <a href="#">Section 3.2.S.4.3 {mRNA-1273 LNP}</a>
(b) (4) (% RNA Encapsulation)	See <a href="#">Table 5</a> , <a href="#">Section 3.2.S.4.3 {mRNA-1273 LNP}</a>
Dynamic Light Scattering <sup>(a)</sup> (Particle Size and Polydispersity)	See <a href="#">Table 6</a> , <a href="#">Section 3.2.S.4.3 {mRNA-1273 LNP}</a>
UPLC-CAD <sup>(a)</sup> (Lipid Content, Lipid Identification and Lipid Impurities)	See <a href="#">Table 7</a> , <a href="#">Section 3.2.S.4.3 {mRNA-1273 LNP}</a>
In vitro Translation/ Methionine Labelling (Potency) ( <a href="#">Table 2</a> )	(b) (4)

(a) Applicable for mRNA-1273 LS LNP and mRNA-1273 LS Injection

(b) Specific for the mRNA-1273 sequence

Analytical methods for the mRNA-1273 LS Injection are described in the following section.

(b) (4)

