3.2.P.8.2 POST-APPROVAL STABILITY PROTOCOL AND STABILITY COMMITMENT

Moderna TX, Inc commits to placing a minimum of one (1) drug product batch on stability annually and tested according to the protocol QC-STAB-PTL-0132 as summarized below.

Stability testing will be conducted to the shelf-life specifications provided in Section 3.2.P.5.1.

Table 1: mRNA-1273 Drug Product Annual Stability Protocol

Condition	Time Interval (months)					
	Release[(z)]	**T0[(z)]**	**3**	**6**	**9**	**12**
-20 °C	Full	abc	ab	a	a	abc

a = Purity and Product Related Impurities, Particle Size, Polydispersity
b = Appearance, pH, % RNA encapsulation, In vitro Translation, RNA content, Lipid Content and Lipid Impurities
c = Bacterial Endotoxins (BET), Particulate Matter, Container Closure Integrity test

[(z)] Release results will be utilized as the initial time point data for the stability study if the batch is initiated on stability ≤ 30 days from DOM; otherwise a new time point zero (T0) testing will be performed and will be the initial time point results for the study.

3.2.P.8.2.1 Stability Sampling

For post-approval commercial DP, stability samples are selected at random post packaging.