3.2.P.2.6 Compatibility

Compatibility testing that establishes the clinical in-use period for mRNA-1273 Injection, applicable for clinical doses under refrigerated and ambient conditions was performed. Materials of contact planned for clinical dosing (e.g., needles, syringes, vials etc.) was performed to determine material compatibility and clinical in-use stability. The study was designed using a bracketing approach to evaluate dose levels of 50 µg (0.1 mg/mL mRNA concentration) and 250 µg (0.5 mg/mL mRNA concentration) to enable clinical doses. Hold times in the syringe of 0 and 8 hours were assessed under ambient conditions (room temperature) and 5°C. Results showed that there was no notable change to attributes of mRNA-1273 Injection at either the 50 µg or the 250 µg as described in Section 3.2.P.8.3. Stability was demonstrated for clinical in-use with dose evaluated between 50 µg and 250 µg for up to 8 hours at either ambient temperature or at 5°C.