

### **3.2.P.5.4 Batch Analyses**

Batch analysis data for GMP mRNA-1273 Drug Product Lot 6007520001, Lot 6007520002, Lot 6007520003, Lot 6007520004, Lot 6007520005, Lot 6007520006 and Lot 6007520007 was generated in accordance with the specifications listed in [Table 1](#) (valid at the time of release). Batch analysis data for GMP mRNA-1273 Drug Product Lot 6007320001, Lot 6007320002 and Lot 6007320003 was generated in accordance with the specification as provided in [Section 3.2.P.5.1](#). The certificates of analysis for GMP mRNA-1273 Drug Product lots in [Table 1](#) are provided as an attachment ([CofAs mRNA-1273 Drug Product Lots](#)).

Table 1: Batch Analysis Data for mRNA-1273 Drug Product

GMP mRNA-1273 Drug Product Lot Number		6007520001	6007520002	6007520003	6007520004	6007520005	6007520006	6007520007	6007320001	6007320002	6007320003
Manufacturer Lot Number									057G20	062G20	001H20
Date of Manufacture		28May2020	02Jun2020	04Jun2020	25Jun2020	30Jun2020	08Jul2020	09Jul2020	30Jul2020	06Aug2020	11Aug2020
Test	Acceptance Criteria	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	PPQ lot	PPQ lot	PPQ lot
Appearance (SOP-0278)	White to off-white dispersion. May contain visible, white or translucent product-related particulates	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.
RNA content by AEX-HPLC (SOP-0235)	(b) (4)	(b) (4)							N/A	N/A	N/A
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	(b) (4)		
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(b) (4)							N/A	N/A	N/A		
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a) The stability Acceptance Criteria for %purity is (b) (4) as presented in [Section 3.2.P.8.3](#)  
N/A = specification is not applicable for product; kDa = kilodalton; RT = retention time; (b) (4) ; EUA = Emergency Use Authorization