

Table 1: Freeze/ Thaw Cycling Data for Development mRNA-1273 Drug Product, Lot DHM-47522 (0.10 mg/mL) Stored Between -60°C to -90°C and Thawed to Room Temperature

Test	Target Criteria	Initial	1x Freeze/Thaw	3x Freeze/Thaw	5x Freeze/Thaw
Appearance	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
% RNA encapsulation	(b) (4)				
(b) (4)					
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by dynamic light scattering					
Polydispersity by dynamic light scattering					

Table 2: Freeze/ Thaw Cycling Data for Development mRNA-1273 Drug Product, Lot DHM-47522 (0.10 mg/mL) Stored Between -60°C to -90°C and Thawed to 2°C to 8°C

Test	Target Criteria	Initial	1x Freeze/Thaw	3x Freeze/Thaw	5x Freeze/Thaw
Appearance	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
% RNA encapsulation	(b) (4)				
(b) (4)					
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by dynamic light scattering					
Polydispersity by dynamic light scattering					

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Table 3: Freeze/ Thaw Cycling Data for Development mRNA-1273 Drug Product, Lot DHM-47518 (0.5 mg/mL) Stored Between -60°C to -90°C and Thawed to Room Temperature

Test	Target Criteria	Initial	1x Freeze/Thaw	3x Freeze/Thaw	5x Freeze/Thaw
Appearance	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
% RNA encapsulation (b) (4)	(b) (4)				
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by dynamic light scattering					
Polydispersity by dynamic light scattering					

Table 4: Freeze/ Thaw Cycling Data for Development mRNA-1273 Drug Product, Lot DHM-47518 (0.5 mg/mL) Stored Between -60°C to -90°C and Thawed to 2°C to 8°C

Test	Target Criteria	Initial	1x Freeze/Thaw	3x Freeze/Thaw	5x Freeze/Thaw
Appearance	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
% RNA encapsulation (b) (4)	(b) (4)				
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering					

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