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3.2.P.8.3 STABILITY DATA

The data for the Clinical and Registration stability studies are referenced in [Table 1](#), [Table 2](#), [Table 3](#), and [Table 4](#). The stability data used for modeling is presented in the [Modeling Stability Report](#). The freeze/thaw study stability data is presented in the [Freeze/Thaw Stability Report](#).

Certain Acceptance Criteria ranges were revised based on increased process knowledge, as described in [Section 3.2.P.2.3 {Comparability}](#), after initiation of some stability studies. The acceptance criteria ranges presented in this section represent the updated specifications. All stability study results were evaluated against the specification effective at the time of testing.

Two additional Clinical lots (6007520005 and 6007520006) were tested only at the -60°C to -90°C condition, with timepoints available only to 3 months. These results were included in the stability modeling but are not provided in data tables since during the initial 3 months at this condition very little change in attributes is observed.

Table 1: Drug Product Clinical Stability Data

Lot	Purpose	Manufacturing Location	Lot Size	Fill Volume (mL)	Container Closure	Conditions		Data Available	Stability Report
						Temperature	Duration		
6007520001	Clinical	ModernaTX, Inc.	(b) (4) vials	5.0	Ompi® 10R clear Type 1 borosilicate glass vial	-60°C to -90°C	12 months	12 months	6007520001
						-20 ± 5°C	12 months	12 months	
						5 ± 3°C	6 months	4 months	
						25 ± 2°C	72 hours	72 hours	
6007520002	Clinical	ModernaTX, Inc.	(b) (4) vials	5.0	Ompi® 10R clear Type 1 borosilicate glass vial	-60°C to -90°C	12 months	12 months	6007520002
						-20 ± 5°C	12 months	12 months	
						5 ± 3°C	6 months	6 months	
						25 ± 2°C	72 hours	72 hours	
6007520003	Clinical	ModernaTX, Inc.	(b) (4) vials	5.0	Ompi® 10R clear Type 1 borosilicate glass vial	-60°C to -90°C	12 months	12 months	6007520003
						-20 ± 5°C	12 months	12 months	
						5 ± 3°C	6 months	6 months	
						25 ± 2°C	72 hours	72 hours	
6007520004	Clinical	ModernaTX, Inc.	(b) (4) vials	5.0	Ompi® 10R clear Type 1 borosilicate glass vial	-60°C to -90°C	12 months	3 months	6007520004
						-20 ± 5°C	12 months	4.5 months	
						5 ± 3°C	6 months	4 months	
						25 ± 2°C	72 hours	72 hours	

Table 2: Drug Product Registration Stability Data in Type 1 Borosilicate Glass Vials

Lot	Purpose	Manufacturing Location (Vial Line)	Lot Size	Fill Volume (mL)	Container Closure	Conditions		Available Data	Stability Report
						Temperature	Duration		
6007320005	Scale B	Catalent Biologics, LLC (Flexible Fill Line)	(b) (4)	6.3	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	9 months	6007320005
						5 ± 3°C	6 months	6 months	
6007320008	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		6.3	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6007320008
						5 ± 3°C	4 months	4 months	
6007320009	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		6.3	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6007320009
						5 ± 3°C	4 months	4 months	
6007320010	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		6.3	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6007320010
6007320012	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		6.3	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6007320012
						5 ± 3°C	4 months	4 months	
6008520001	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))		6.3	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6008520001
						5 ± 3°C	3 months	3 months	
6009921006	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))		8.0	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6009921006
6003921002	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))		8.0	Corning Velocity™ 10R clear Type 1 borosilicate glass vials	-20 ± 5°C	12 months	Pending	N/A
6009821002	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		8.0	Ompi® 10R clear Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6009821002
6008921001	Scale B	Baxter (Vial Line (b) (4))		8.0	Corning Velocity Vial Type 1 borosilicate glass vial	-20 ± 5°C	12 months	3 months	6008921001
						5 ± 3°C	3 months	3 months	

Abbreviations: COP = cyclic olefin polymer; I = inverted; N/A = not applicable; PPQ = process performance qualification

Table 3: Drug Product Registration Stability Data in Aluminosilicate Glass Vials

Lot	Purpose	Manufacturing Location	Lot Size	Fill Volume (mL)	Container Closure	Conditions		Available Data	Stability Report
						Temperature	Duration		
6008620001	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))	(b) (4)	6.3	Corning Valor 10R clear aluminosilicate glass vial	-20 ± 5°C	12 months	6 months	6008620001
6008620002	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))		6.3	Corning Valor 10R clear aluminosilicate glass vial	-20 ± 5°C	12 months	6 months	6008620002
6008620007	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))		6.3	Corning Valor 10R clear aluminosilicate glass vial	-20 ± 5°C	12 months	6 months	6008620007
6010121002	Scale B	Catalent Biologics, LLC (Vial Line (b) (4))		8.0	Corning Valor 10R clear aluminosilicate glass vials	-20 ± 5°C	12 months	3 months	6010121002
						5 ± 3°C	3 months	3 months	
6008221002	Scale B	Baxter (Vial Line (b) (4))		8.0	Corning Valor 10R clear aluminosilicate glass vials	-20 ± 5°C	12 months	3 months	6008221002
						5 ± 3°C	3 months	3 months	
6008221003	Scale B	Baxter (Vial Line (b) (4))		8.0	Corning Valor 10R clear aluminosilicate glass vials	-20 ± 5°C	12 months	3 months	6008221003
			5 ± 3°C			3 months	3 months		

Table 4: Drug Product Registration Stability Data in Cyclic Olefin Polymer Vials

Lot	Purpose	Manufacturing Location	Lot Size	Fill Volume (mL)	Container Closure	Conditions		Available Data	Stability Report
						Temperature	Duration		
6007920001	Scale B	Catalent Biologics, LLC (Flexible Fill Line)	(b) (4)	6.3	10R cyclic olefin polymer vials with SiO2 coating	-20 ± 5°C	12 months	6 months	6007920001
						25°C ± 2°C	72 hours	72 hours	
6007920002	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		6.3	10R cyclic olefin polymer vials with SiO2 coating	-20 ± 5°C	12 months	6 months	6007920002
						25°C ± 2°C	72 hours	72 hours	
6007920003	Scale B	Catalent Biologics, LLC (Flexible Fill Line)		6.3	10R cyclic olefin polymer vials with SiO2 coating	-20 ± 5°C	12 months	3 months	6007920003
						5 ± 3°C	4 months	4 months	