Name of the component	Test Item	Specification	Method of analysis
			the mixture of 3.0 ml of standard zinc solution (44.0 mg of zinc sulfate heptahydrate dissolved in cool boiled water, and further diluted to 1000.0 ml), 8 ml of blank control and 1 ml of 2 mol/L hydrochloric acid as well as 3 drops of potassium ferrocyanide.
	Conductivity	It shall not exceed 40.0 μS/cm.	The following test shall be performed within 5 hours after the preparation of sample infusion with a conductivity determinator. Rinse the probes several times with water and at least twice with blank control. The conductivity of blank control shall not exceed 3.0 μS/cm at 20°C±1°C. And rinse the probes with sample infusion at least twice, and test the conductivity, with a result of not exceeding 40.0 μS/cm. If the above determination is not performed at 20℃±1℃, calibration on temperature should be done. It shall not exceed 40.0 μS/cm.

A list of secondary packaging is presented in *Table 3.2.P.7-5*.

Table 3.2.P.7-5 List of secondary packaging materials

Name of the component	Manufacturer	Reference
Aluminum-plastics combination Cap	Hebei Jinhuan	YBB00372003
Label	Beijing Oriental Jinxiu	In-house
Package Insert	Beijing Baodao	In-house
Inner Box	Beijing Baodao	In-house

3.2.P.8 Stability

3.2.P.8.1 Summary and conclusion

The objective of stability test is to evaluate the storage conditions for long-term and under accelerated conditions to provide evidence for the establishment of expiry date and provide accordance for the comparability studies for the later process & analytical method optimization and enables quality consistency for the scale-up from pilot scale to commercial scale.

3.2.P.8.1.1 Summary

The stability studies for COVID-19 Vaccine (Vero Cell), Inactivated, were initiated in February, 2020 upon completion of manufacturing of three batches of pilot-scale vaccine continuously and followed by three continuously manufactured pilot scale batches filled in pre-filled syringes and three continuously manufactured pilot scale batches filled in vials later in March and April. This study is further extended to include three batches of final bulk and three batches of finished product from commercial scale. The packaging material of the vaccine is prefilled syringe and vials as per specification for IND/NDA products.

Design of the stability studies

Pilot scale

Accelerated stability test: 6 batches of COVID-19 Vaccine are applied in the accelerated stability study, sufficient vials of sample are stored respectively at two conditions, sufficient vials of sample are stored respectively at two conditions, 25℃ for 56 days (testing interval: 0, T7D, T14D, T28D, T42D and T56D) and 37℃ for 42 days (testing interval: 0, T3D, T5D, T7D, T14D, T21D, T28D and T42D) the accelerated stability study is performed until the post-dissociation antigen content in the drug product fails to comply with the specifications.

Long-term stability test: 9 batches of COVID-19 Vaccine are applied in the long-term stability study, sufficient vials of sample are protected from light and stored in pharmaceutical refrigerator at 2-8℃, the designed duration for stability test is 48 months and the sampling interval is 0, T1M, T2M, T3M, T6M, T9M, T12M, T18M, T24M, T36M and T48M.

Commercial scale

Final bulk

Accelerated stability test: 3 batches of COVID-19 Vaccine final bulk are applied in the accelerated stability study, sample are stored respectively at two conditions, 25℃ for 56 days (testing interval: 0, T7D, T14D and T56D) and 37℃ for 28 days (testing interval: 0, T3D, T5D, T7D, T14D, T21D and T28D) the accelerated stability study is performed until the post-dissociation antigen content in the drug product fails to comply with the specifications.

Long-term stability test: 3 batches of COVID-19 Vaccine final bulk are applied in the long-term stability study, sample are protected from light and stored in pharmaceutical refrigerator at 2-8℃, the designed duration for stability test is 15 months and the sampling interval is 0, T1M, T2M, T3M, T6M, T9M, T12M and T15M.

COVID-19 Vaccine

Accelerated stability test: 3 batches of COVID-19 Vaccine are applied in the accelerated stability study, sufficient vials and syringes of sample are stored respectively at two conditions, 25℃ for 56 days (testing interval: 0, T7D, T14D, T28D, T42D and T56D) and 37℃ for 42 days (testing interval: 0, T3D, T5D, T7D, T14D, T21D, T28D and T42D).

Long-term stability test: 3 batches of COVID-19 Vaccine are applied in the long-term stability study, sufficient vials and syringes of sample are protected from light and stored in pharmaceutical refrigerator at 2-8℃, the designed duration for stability test is 48 months and the sampling interval is 0, T1M, T2M, T3M, T6M, T9M, T12M, T18M, T24M, T36M, T42M and T48M.

Batch information of sample used in the stability study

Information of the batches that are evaluated in the described stability tests are presented in *Table 3.2.P.8.1-1*

Table 3.2.P.8.1-1 Information for Stability Batches

Scale***	Packaging materials	Batch number	Date of Manufacture	Date of entering the stability sample chamber**
Pilot scale	Prefilled syringe	20200203**	2020.03.02	2020.03.02
		20200304**	2020.03.04	2020.03.04
		20200305**	2020.03.04	2020.03.04
		20200308	2020.03.22	2020.03.22

Scale***	Packaging materials	Batch number	Date of Manufacture	Date of entering the stability sample chamber**
		20200412	2020.04.10	2020.04.10
		20200419	2020.04.19	2020.04.19
	Vial	20200414	2020.04.17	2020.04.17
		20200415	2020.04.17	2020.04.17
		20200416	2020.04.17	2020.04.17
Commercial scale	Final bulk	202009003-2	2020.09.26	2020.09.26
		202009004-2	2020.09.27	2020.09.27
		202009009-1	2020.10.17	2020.10.17
	Prefilled- syringe	202009004	2020.09.19	2020.10.01
		202009006	2020.09.19	2020.10.01
		202009008	2020.09.22	2020.10.01
	Vial	202009005	2020.09.22	2020.10.01
		202009007	2020.09.24	2020.10.01
		202009009	2020.09.24	2020.10.01

** The stability time point is calculated as per the following strategy: T0 takes the releasing test result, the T1M is calculated starting from the date that the samples entering the stability chamber. Considering the duration of the testing, collection of the data and analysis of the results, the data is available 30-40 days after each due date, for example, for batch 202009003-2, the T1M date is 2020.10.26 while the T1M data is available in late November to early December, 2020.*

*** Due to the shortage of sample, we could not finish the full long-term stability study for these three batches as per the plan shown in Table 3.2.P.8.2-5. In order to give indicative data for the establishment of shelf-life, we changed stability strategy for these three batches to test the post-dissociation antigen content starting T6M instead of full testing. Therefore, in the following section, only post-dissociation antigen content is presented for these three batches starting from T6M.*

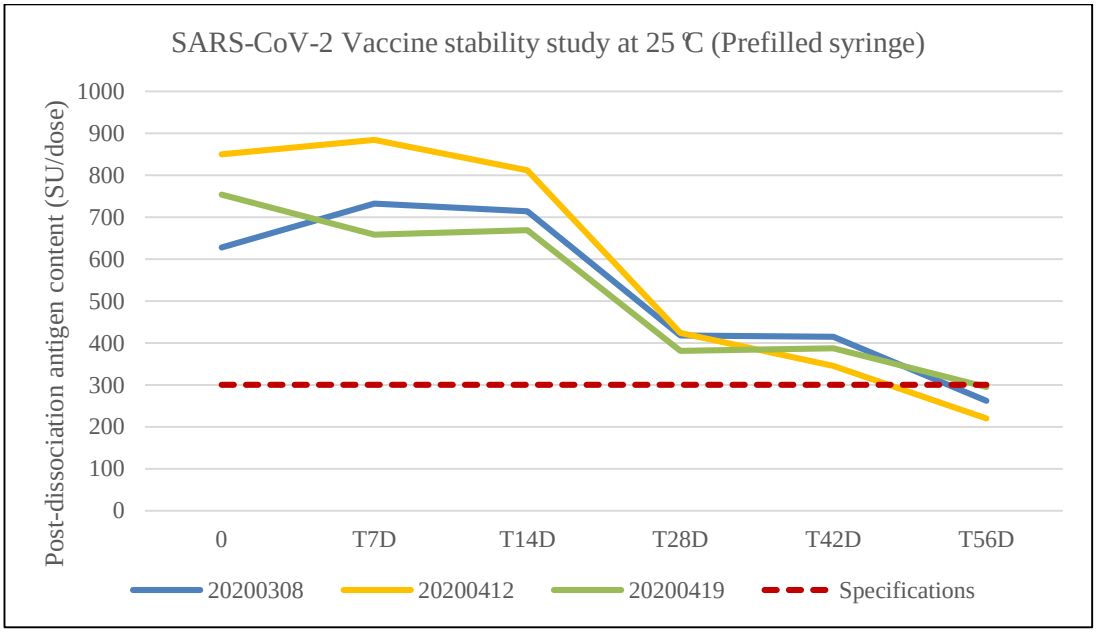
**** As described in 3.2.P.5.1, there was a change of specifications between the IND stage and NDA stage, the pilot scale batches follow IND specifications while the commercial batches follow NDA specifications.*

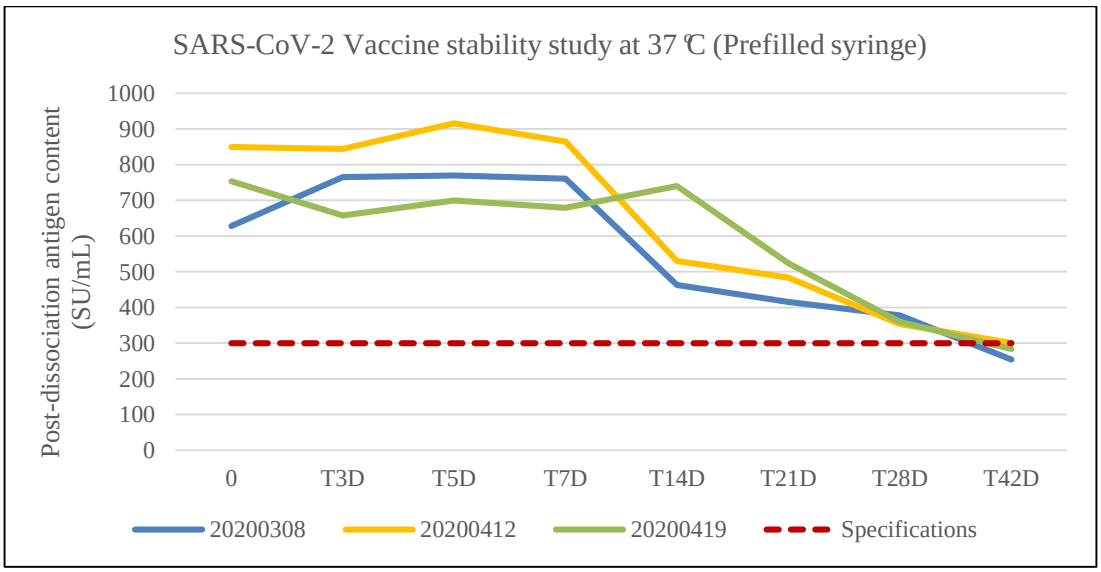
Analytical methods

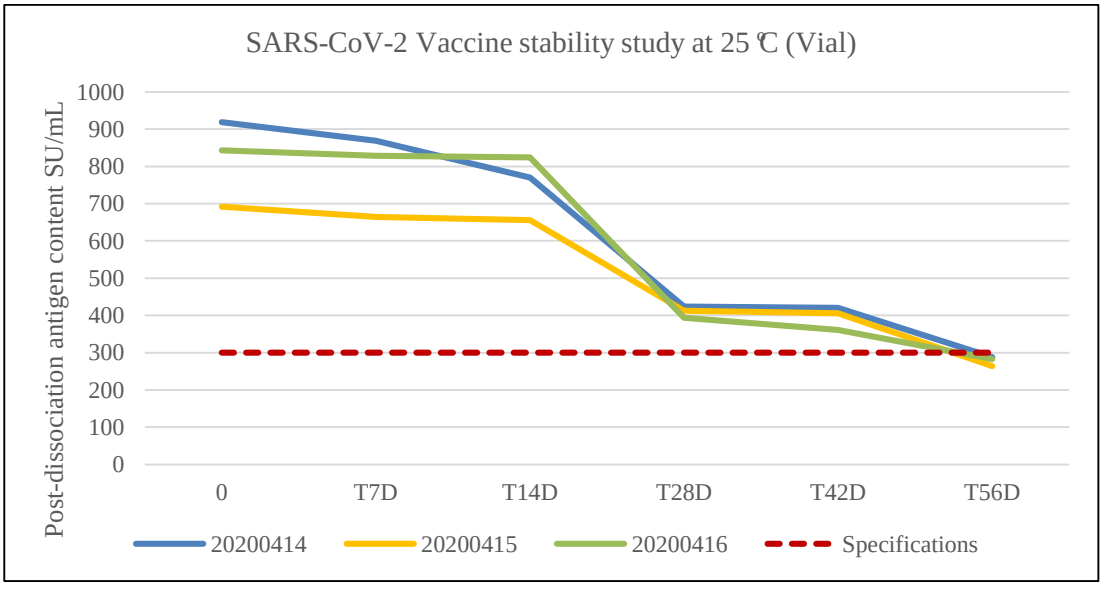
The items tested in the stability test are the same as in release tests. Therefore, the analytical methods are the ones used for routine control of COVID-19 Vaccine as presented in *3.2.P.5.2*.

3.2.P.8.1.2 Conclusion

For the pilot scale products, the post-dissociation antigen content is presented in *Figure 3.2.P.8.1-1*. While for the commercial scale products, the post-dissociation antigen content is presented in *Figure 3.2.P.8.1-2*.


SARS-CoV-2 Vaccine stability study at 25 ℃ (Prefilled syringe)
Post-dissociation antigen content (SU/dose)
1000
900
800
700
600
500
400
300
200
100
0
0
T7D
T14D
T28D
T42D
T56D
20200308
20200412
20200419
Specifications


SARS-CoV-2 Vaccine stability study at 37 ℃ (Prefilled syringe)
Post-dissociation antigen content (SU/mL)
1000
900
800
700
600
500
400
300
200
100
0
0
T3D
T5D
T7D
T14D
T21D
T28D
T42D
20200308
20200412
20200419
Specifications


SARS-CoV-2 Vaccine stability study at 25 ℃ (Vial)
Post-dissociation antigen content SU/mL
1000
900
800
700
600
500
400
300
200
100
0
0
T7D
T14D
T28D
T42D
T56D
20200414
20200415
20200416
Specifications

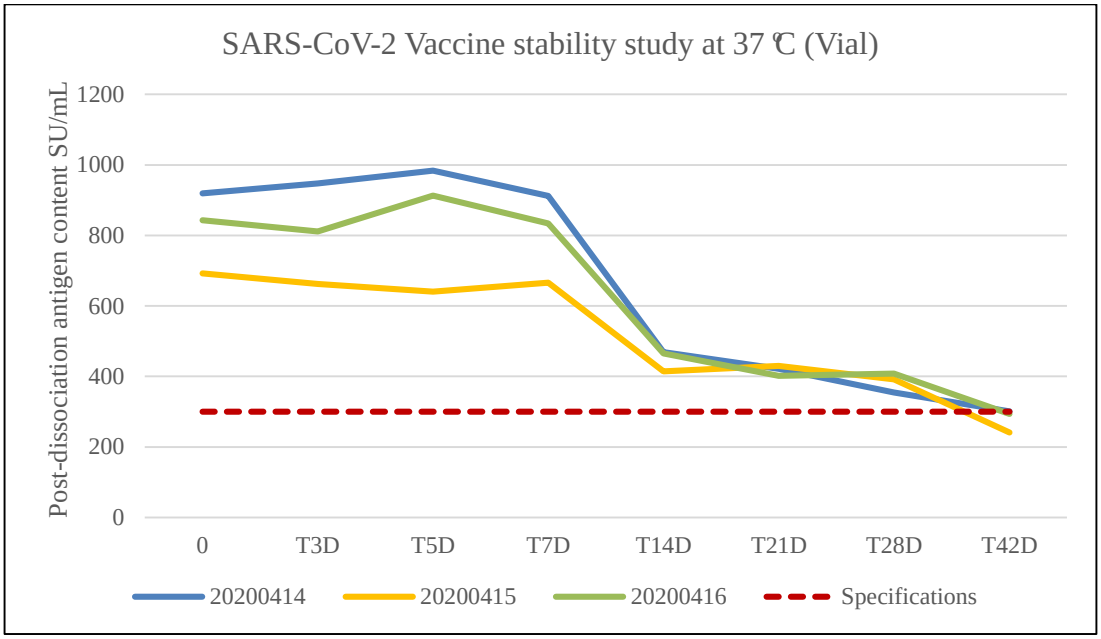
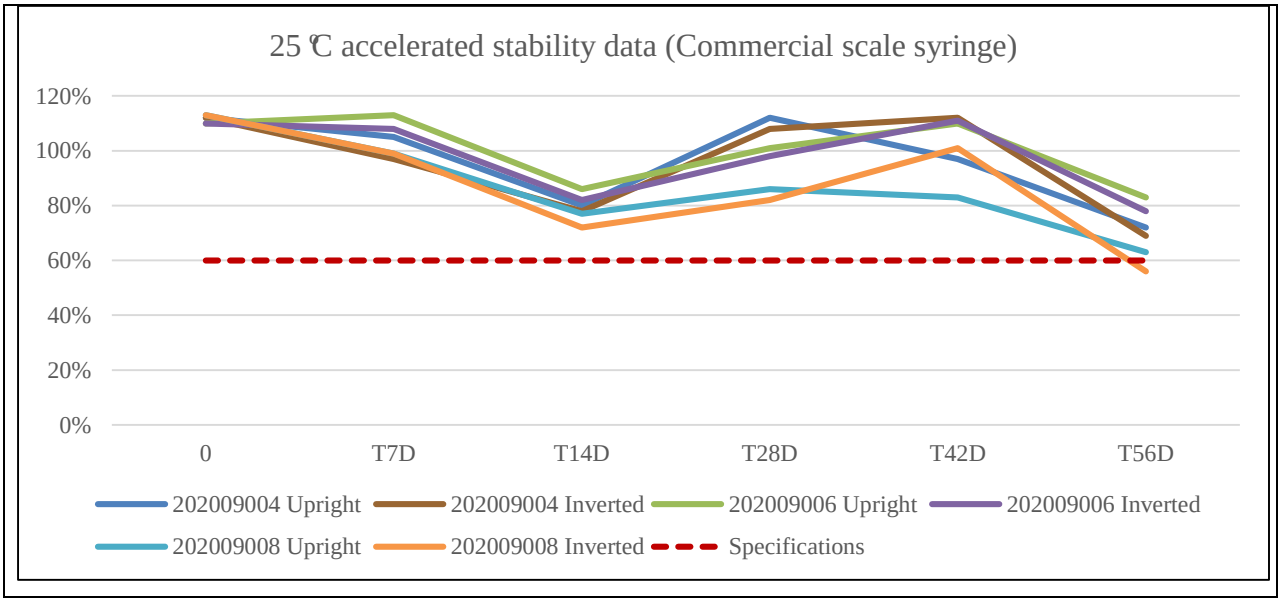
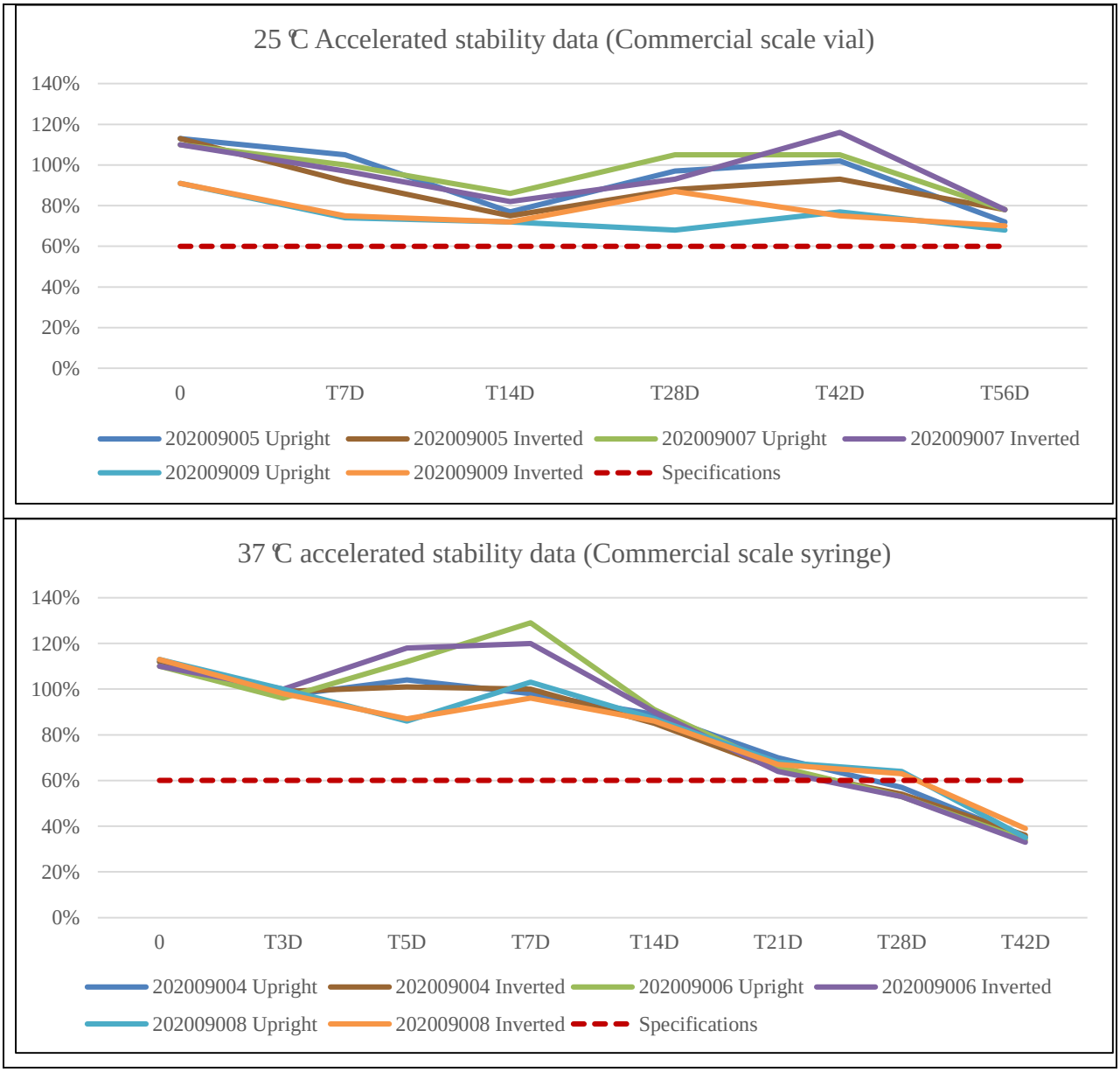


Figure 3.2.P.8.1-1 Post-dissociation antigen content curve under 25 ℃ and 37 ℃ accelerated conditions for 56 days or 42 days




25 ℃ Accelerated stability data (Commercial scale vial)
140%
120%
100%
80%
60%
40%
20%
0%
0
T7D
T14D
T28D
T42D
T56D
202009005 Upright
202009005 Inverted
202009007 Upright
202009007 Inverted
202009009 Upright
202009009 Inverted
Specifications
37 ℃ accelerated stability data (Commercial scale syringe)
140%
120%
100%
80%
60%
40%
20%
0%
0
T3D
T5D
T7D
T14D
T21D
T28D
T42D
202009004 Upright
202009004 Inverted
202009006 Upright
202009006 Inverted
202009008 Upright
202009008 Inverted
Specifications

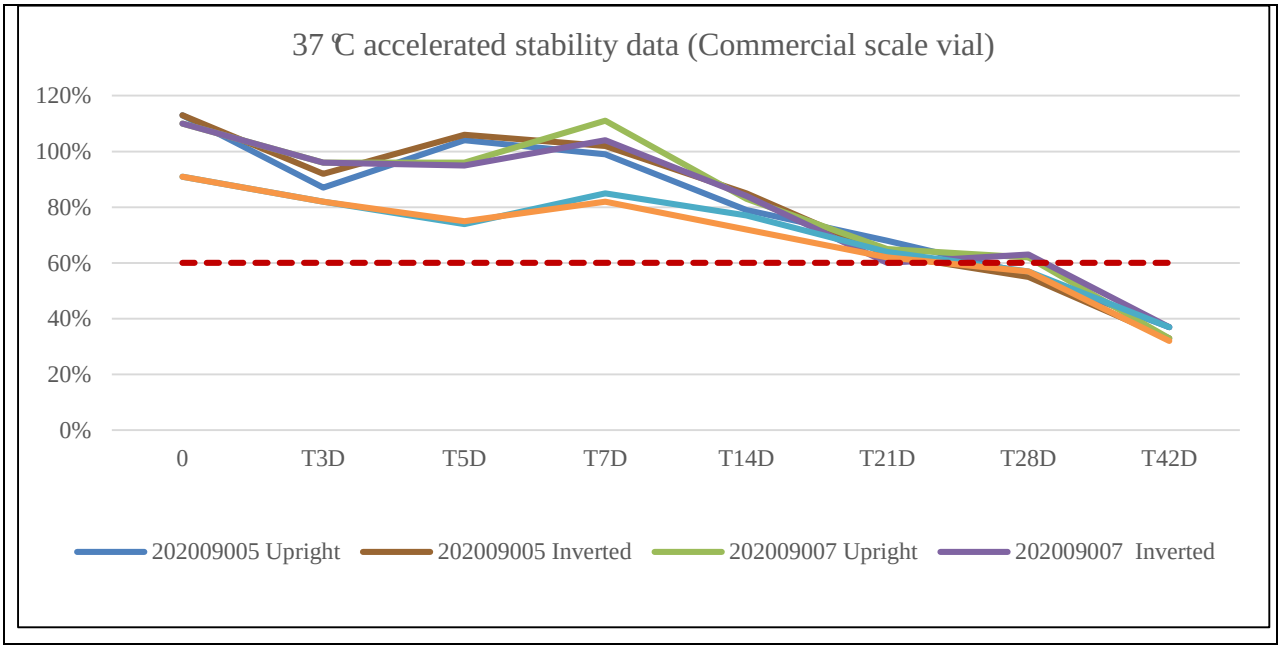


Figure 3.2.P.8.1-2 Commercial batches post-dissociation antigen content curve under 25 ℃ and 37° C accelerated conditions for 56 days or 42 days.

It can be seen from the curves that the post-dissociation antigen content of the vaccine accelerated at 25 ℃ is within the specifications for 42 days, the post-dissociation antigen content of vaccine accelerated at 37 ℃ is within the specifications for 21 days.

For the commercial scale products, as long-term stability is still ongoing with very limited data, the curve on the antigen content will be updated upon completion while preliminary stability data are presented in the 3.2.P.8.3 section.

Base on the designed stability studies, we aim to draw a conclusion by the end of the stability study that the tentative expire date determined for COVID-19 Vaccine is valid and might be extended upon additional data (if any), and the long-term storage conditions 2-8 ℃ can be proved sufficient.

3.2.P.8.2 Post-approval stability protocol and stability commitment

Following the established stability protocol, the T9M vials, T9M syringes long term stability data and T56D/T42D at 25 ℃/37 ℃ data has been obtained. Upon approval, the studies will be on-going as summarized in *Table 3.2.P.8.2-1* to *Table 3.2.P.8.2-4*.

Table 3.2.P.8.2-2 Stability Conditions

Type of product	Stability study	Conditions/Duration	Number of batches
Final bulk	Long-term study	2-8 ℃/15 months	3 commercial batch
	Accelerated study	25 ℃/56 days	3 commercial batch
		37 ℃/28 days	3 commercial batch
Vaccine	Long-term study	2-8 ℃/48 months	9 pilot batch, 6 commercial batch
	Accelerated study	25 ℃/56 days	6 pilot batch, 6 commercial batch
		37 ℃/42 days	6 pilot batch, 6 commercial batch

Table 3.2.P.8.2-2 Interval of stability studies of final bulk – Long-term at 2-8 ℃

Test Item	Time (month)							
	0	1	2	3	6	9	12	15
Sterility	√	√	√	√	√	√	√	√
Antigen adsorption rate	√	√	√	√	√	√	√	√
Post-dissociation antigen content	√	√	√	√	√	√	√	√
pH	√	√	√	√	√	√	√	√
Aluminum content	√	√	√	√	√	√	√	√
Potency	√	√	/	√	/	/	√	√

Notes: "√" means the item is going to be tested and "/" represents that the item is not going to be tested

Table 3.2.P.8.2-3 Interval of stability studies of final bulk – Long-term at 25 ℃

Test Item	Time (Day)			
	0	7	14	56
Sterility	√	√	√	√
Antigen adsorption rate	√	√	√	√
Post-dissociation antigen content	√	√	√	√
pH	√	√	√	√
Aluminum content	√	√	√	√
Potency	√	√	√	√

Notes: "√" means the item is going to be tested and "/" represents that the item is not going to be tested

Table 3.2.P.8.2-4 Interval of stability studies of final bulk – Long-term at 37 ℃

Test Item	Time (Day)						
	0	3	5	7	14	21	28
Sterility	√	√	√	√	√	√	√
Antigen adsorption rate	√	√	√	√	√	√	√
Post-dissociation antigen content	√	√	√	√	√	√	√
pH	√	√	√	√	√	√	√
Aluminum content	√	√	√	√	√	√	√
Potency	√	√	√	√	√	√	√

Notes: "√" means the item is going to be tested and "/" represents that the item is not going to be tested

Table 3.2.P.8.2-5 Interval of stability studies of COVID-19 vaccine - Long-term at 2-8 ℃

Test item	Time for commercial scale (upright/inverted) (Month)												Time for pilot scale (Month)											
	0	1	2	3	6	9	12	18	24	36	42	48	0	1	2	3	6	9	12	18	24	36	42	48
Appearance	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√	√
Extractable volume	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√	√
pH	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√	√
Osmolality	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√	√
Aluminum content	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√	√
Sterility	√	/	/	/	/	/	√	/	√	√	√	√	√	/	/	/	/	/	√	/	/	/	√

Test item	Time for commercial scale (upright/inverted) (Month)												Time for pilot scale (Month)										
	0	1	2	3	6	9	12	18	24	36	42	48	0	1	2	3	6	9	12	18	24	36	48
Abnormal toxicity	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√
Bacterial endotoxin test	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√
Identification	√	/	/	/	√	/	√	√	√	√	√	√	√	/	/	/	√	√	√	√	√	√	√
Post-dissociation antigen content	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Notes: "√" means the item is going to be tested and "/" represents that the item is not going to be tested

Table 3.2.P.8.2-6 Interval of stability studies of COVID-19 vaccine - Accelerated at 25 ℃

Test item	Time for commercial scale (upright/inverted) (day)						Time for pilot scale (Day)					
	0	7	14	28	42	56	0	7	14	28	42	56
Appearance	√	/	√	/	√	√	√	/	/	/	√	/
Extractable volume	√	/	√	/	√	√	√	/	/	/	√	/
pH	√	/	√	/	√	√	√	/	/	/	√	/
Osmolality	√	/	√	/	√	√	√	/	/	/	√	/
Aluminum content	√	/	√	/	√	√	√	/	/	/	√	/
Sterility	√	/	√	/	√	√	√	/	/	/	/	/
Abnormal toxicity	√	/	√	/	√	√	√	/	/	/	√	/
Bacterial endotoxin test	√	/	√	/	√	√	√	/	/	/	√	/
Identification	√	/	√	/	√	√	√	/	/	/	√	/
Post-dissociation antigen content	√	√	√	√	√	√	√	√	√	√	√	√

Notes: "√" means the item is going to be tested and "/" represents that the item is not going to be tested

Table 3.2.P.8.2-7 Interval of stability studies of COVID-19 vaccine - Accelerated at 37 ℃

Test item	Time for commercial scale (upright/inverted) (day)								Time for pilot scale (Day)							
	0	3	5	7	14	21	28	42	0	3	5	7	14	21	28	42
Appearance	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Extractable volume	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
pH	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Osmolality	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Aluminum content	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Sterility	√	/	/	/	√	/	√	√	√	/	/	/	/	/	/	/
Abnormal toxicity	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Bacterial endotoxin test	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Identification	√	/	/	/	√	/	√	√	√	/	/	/	√	/	/	/
Post-dissociation	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Test item	Time for commercial scale (upright/inverted) (day)								Time for pilot scale (Day)							
	0	3	5	7	14	21	28	42	0	3	5	7	14	21	28	42
antigen content																

Notes: "√" means the item is going to be tested and "/" represents that the item is not going to be tested

The stability data is presented in the following part 3.2.P.8.3 and going to be updated gradually when the results become available.

3.2.P.8.3 Stability data

As clarified in the previous section, the stability studies are on-going for the presented batches of COVID-19 Vaccine, preliminary data obtained from both long-term stability and accelerated stability studies as presented as follows.

3.2.S.8.3.1 Long-term stability data

Table 3.2.P.8.3-1 Long-term stability data at 2-8 ℃ (final bulk)

Batch number 202009003-2	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	93%	94%	0.50	Sterile	1.9
T1M	7.4	93%	>99%	0.49	Sterile	1.7
T2M	7.5	91%	>99%	0.46	Sterile	/
T3M	7.5	93%	>99%	0.48	Sterile	0.7
T6M						
T9M						
T12M						
T15M						

Table 3.2.P.8.3-2 Long-term stability data at 2-8 ℃ (final bulk)

Batch number 202009004-2	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	104%	97%	0.40	Sterile	1.7
T1M	7.4	97%	>99%	0.45	Sterile	1.5
T2M	7.4	80%	>99%	0.42	Sterile	/
T3M	7.5	91%	>99%	0.44	Sterile	0.8
T6M						
T9M						
T12M						
T15M						

Table 3.2.P.8.3-3 Long-term stability data at 2-8 ℃ (final bulk)

Batch number 202009009-1	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	114%	>99%	0.43	Sterile	1.3
T1M	7.4	102%	>99%	0.46	Sterile	1.4
T2M	7.4	92%	>99%	0.47	Sterile	/
T3M	On-going	93%	On-going	On-going	On-going	On-going
T6M						
T9M						
T12M						
T15M						

Table 3.2.P.8.3-4 Long-term stability data at 2-8 ℃ (Pilot scale syringe)

Batch number 20200203	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.56	7.2	295	1148 (96%)	Complies	<0.3	0.445	Positive	Sterile	1.1
T1M	/	/	/	/	1123 (84%)	/	/	/	/	/	/
T2M	/	/	/	/	1213 (101%)	/	/	/	/	/	/
T3M	/	/	/	/	1070 (89%)	/	/	/	/	/	/
T6M	/	/	/	/	1100 (92%)	/	/	/	Positive	/	/
T9M	/	/	/	/	1138 (94.8%)	/	/	/	Positive	/	/
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-5 Long-term stability data at 2-8 ℃ (Pilot scale syringe)

Batch number 20200304	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.56	7.3	296	1342(112%)	Complies	<0.3	0.429	Positive	Sterile	1.7
T1M	/	/	/	/	1080 (90%)	/	/	/	/	/	/
T2M	/	/	/	/	1152 (96%)	/	/	/	/	/	/
T3M	/	/	/	/	982 (82%)	/	/	/	/	/	/
T6M	/	/	/	/	1084 (90%)	/	/	/	Positive	/	/
T9M	/	/	/	/	1170 (97.5%)	/	/	/	Positive	/	/
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-6 Long-term stability data at 2-8 ℃ (Pilot scale syringe)

Batch number 20200305	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.56	7.2	294	1156 (96%)	Complies	<0.3	0.420	Positive	Sterile	3.2
T1M	/	/	/	/	1057 (88%)	/	/	/	/	/	/
T2M	/	/	/	/	1299 (108%)	/	/	/	/	/	/
T3M	/	/	/	/	950 (79%)	/	/	/	/	/	/
T6M	/	/	/	/	1098 (92%)	/	/	/	Positive	/	/
T9M	/	/	/	/	1127 (93.9%)	/	/	/	Positive	/	/
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-7 Long-term stability data at 2-8 ℃ (Pilot scale syringe)

Batch number 20200308	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	284	105% (628)	Complies	<0.3	0.453	Positive	Sterile	1.7
T1M	/	/	/	/	118% (710)	/	/	/	/	/	/
T2M	/	/	/	/	102% (614)	/	/	/	/	/	/
T3M	/	/	/	/	98% (588)	/	/	/	/	/	/
T6M	Complies	0.55	7.5	286	131% (788)	Complies	<0.3	0.441	/	/	1.7
T9M											
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-8 Long-term stability data at 2-8 ℃ (Pilot scale syringe)

Batch number 20200412	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	281	142% (850)	Complies	<1.2	0.454	Positive	Sterile	4.0
T1M	/	/	/	/	122% (730)	/	/	/	/	/	/
T2M	/	/	/	/	133% (799)	/	/	/	/	/	/
T3M	/	/	/	/	140% (840)	/	/	/	/	/	/
T6M	Complies	0.56	7.4	280	139% (836)	Complies	<1.2	0.444	Positive	/	3.6
T9M											
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-9 Long-term stability data at 2-8 ℃ (Pilot scale syringe)

Batch number 20200419	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	281	126% (754)	Complies	<0.15	0.452	Positive	Sterile	2.6
T1M	/	/	/	/	148% (886)	/	/	/	/	/	/
T2M	/	/	/	/	145% (872)	/	/	/	/	/	/
T3M	/	/	/	/	134% (805)	/	/	/	/	/	/
T6M	Complies	0.55	7.4	281	134% (805)	Complies	<0.15	0.444	Positive	/	2.9
T9M											
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-10 Long-term stability data at 2-8 ℃ (Pilot scale Vial)

Batch number 20200414	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.52	7.3	283	153% (919)	Complies	<1.2	0.442	Positive	Sterile	2.3
T1M	/	/	/	/	125% (752)	/	/	/	/	/	/
T2M	/	/	/	/	128% (766)	/	/	/	/	/	/
T3M	/	/	/	/	168% (1008)	/	/	/	/	/	/
T6M	Complies	0.54	7.7	284	153% (918)	Complies	<1.2	0.433	Positive	/	2.0
T9M											
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-11 Long-term stability data at 2-8 ℃ (Pilot scale Vial)

Batch number 20200415	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.51	7.3	269	115% (692)	Complies	<1.2	0.437	Positive	Sterile	2.0
T1M	/	/	/	/	94% (562)	/	/	/	/	/	/
T2M	/	/	/	/	102% (614)	/	/	/	/	/	/
T3M	/	/	/	/	114% (684)	/	/	/	/	/	/
T6M	Complies	0.54	7.7	270	95% (572)	Complies	<1.2	0.438	Positive	/	1.7
T9M											
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-12 Long-term stability data at 2-8 ℃ (Pilot scale Vial)

Batch number 20200416	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.52	7.3	250	140% (843)	Complies	<0.3	0.432	Positive	Sterile	3.5
T1M	/	/	/	/	114% (686)	/	/	/	/	/	/
T2M	/	/	/	/	116%(694)	/	/	/	/	/	/
T3M	/	/	/	/	143% (856)	/	/	/	/	/	/
T6M	Complies	0.54	7.6	250	116% (699)	Complies	<0.3	0.438	Positive	/	2.9
T9M											
T12M											
T18M											
T24M											
T36M											
T48M											

Table 3.2.P.8.3-13 Long-term stability data at 2-8 ℃ (Commercial scale syringe)

Batch number 202009004	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	--	Complies	0.53	7.3	283	Complies	112%	Complies	<0.0625	0.5	Positive	Sterile
T1M	Upright	/	/	/	/	/	140%	/	/	/	/	/
	Inverted	/	/	/	/	/	123%	/	/	/	/	/
T2M	Upright	/	/	/	/	/	114%	/	/	/	/	/
	Inverted	/	/	/	/	/	111%	/	/	/	/	/
T3M	Upright	/	/	/	/	/	110%	/	/	/	/	/
	Inverted	/	/	/	/	/	104%	/	/	/	/	/
T6M												
T9M												
T12M												
T18M												
T24M												
T36M												
T42M												
T48M												

Table 3.2.P.8.3-14 Long-term stability data at 2-8 ℃ (Commercial scale syringe)

Batch number 202009006	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	--	Complies	0.55	7.3	283	Complies	110%	Complies	<0.0625	0.49	Positive	Sterile
T1M	Upright	/	/	/	/	/	127%	/	/	/	/	/
	Inverted	/	/	/	/	/	142%	/	/	/	/	/
T2M	Upright	/	/	/	/	/	92%	/	/	/	/	/
	Inverted	/	/	/	/	/	97%	/	/	/	/	/
T3M	Upright	/	/	/	/	/	102%	/	/	/	/	/
	Inverted	/	/	/	/	/	103%	/	/	/	/	/
T6M												
T9M												
T12M												
T18M												
T24M												
T36M												
T42M												
T48M												

Table 3.2.P.8.3-15 Long-term stability data at 2-8 ℃ (Commercial scale syringe)

Batch number 202009008	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	--	Complies	0.56	7.2	292	Complies	113%	Complies	<0.0625	0.5	Positive	Sterile
T1M	Upright	/	/	/	/	/	108%	/	/	/	/	/
	Inverted	/	/	/	/	/	115%	/	/	/	/	/
T2M	Upright	/	/	/	/	/	97%	/	/	/	/	/
	Inverted	/	/	/	/	/	99%	/	/	/	/	/
T3M	Upright	/	/	/	/	/	90%	/	/	/	/	/
	Inverted	/	/	/	/	/	99%	/	/	/	/	/
T6M												
T9M												
T12M												
T18M												
T24M												
T36M												
T42M												
T48M												

Table 3.2.P.8.3-16 Long-term stability data at 2-8 ℃ (Commercial scale vial)

Batch number 202009005	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	--	Complies	0.51	7.4	284	Complies	113%	Complies	<0.0625	0.5	Positive	Sterile
T1M	Upright	/	/	/	/	/	119%	/	/	/	/	/
	Inverted	/	/	/	/	/	123%	/	/	/	/	/
T2M	Upright	/	/	/	/	/	115%	/	/	/	/	/
	Inverted	/	/	/	/	/	110%	/	/	/	/	/
T3M	Upright	/	/	/	/	/	111%	/	/	/	/	/
	Inverted	/	/	/	/	/	105%	/	/	/	/	/
T6M												
T9M												
T12M												
T18M												
T24M												
T36M												
T42M												
T48M												

Table 3.2.P.8.3-17 Long-term stability data at 2-8 ℃ (Commercial scale vial)

Batch number 202009007	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	--	Complies	0.52	7.3	283	Complies	110%	Complies	<0.0625	0.5	Positive	Sterile
T1M	Upright	/	/	/	/	/	124%	/	/	/	/	/
	Inverted	/	/	/	/	/	119%	/	/	/	/	/
T2M	Upright	/	/	/	/	/	107%	/	/	/	/	/
	Inverted	/	/	/	/	/	109%	/	/	/	/	/
T3M	Upright	/	/	/	/	/	112%	/	/	/	/	/
	Inverted	/	/	/	/	/	102%	/	/	/	/	/
T6M												
T9M												
T12M												
T18M												
T24M												
T36M												
T42M												
T48M												

Table 3.2.P.8.3-18 Long-term stability data at 2-8 ℃ (Commercial scale vial)

Batch number 202009009	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	--	Complies	0.51	7.3	294	Complies	91%	Complies	<0.0625	0.5	Positive	Sterile
T1M	Upright	/	/	/	/	/	90%	/	/	/	/	/
	Inverted	/	/	/	/	/	99%	/	/	/	/	/
T2M	Upright	/	/	/	/	/	93%	/	/	/	/	/
	Inverted	/	/	/	/	/	97%	/	/	/	/	/
T3M	Upright	/	/	/	/	/	89%	/	/	/	/	/
	Inverted	/	/	/	/	/	95%	/	/	/	/	/
T6M												
T9M												
T12M												
T18M												
T24M												
T36M												
T42M												
T48M												

3.2.P.8.3.2 Accelerated stability data

Table 3.2.P.8.3-19 Accelerated stability data at 25 ℃ (Final bulk)

Batch number 202009003-2	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	93%	94%	0.50	Sterile	1.9
T7D	7.5	103%	>99%	0.48	Sterile	2.8
T14D	7.5	91%	>99%	0.47	Sterile	1.1
T56D	7.5	75%	>99%	0.47	Sterile	1.3

Table 3.2.P.8.3-20 Accelerated stability data at 25 ℃ (Final bulk)

Batch number 202009004-2	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	104%	97%	0.40	Sterile	1.7
T7D	7.5	116%	>99%	0.44	Sterile	2.0
T14D	7.5	94%	>99%	0.43	Sterile	1.5
T56D	7.5	60%	>99%	0.45	Sterile	1.2

Table 3.2.P.8.3-21 Accelerated stability data at 25 ℃ (Final bulk)

Batch number 202009009-1	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	114%	>99%	0.43	Sterile	1.3
T7D	7.4	108%	>99%	0.46	Sterile	2.1
T14D	7.4	93%	>99%	0.45	Sterile	1.2
T56D	7.5	65%	>99%	0.46	Sterile	1.5

Table 3.2.P.8.3-22 Accelerated stability data at 37 ℃ (Final bulk)

Batch number 202009003-2	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	93%	94%	0.50	Sterile	1.9
T3D	7. 5	159%	＞99%	0. 48	Sterile	1.1
T5D	7. 5	96%	＞99%	0. 45	Sterile	1.2
T7D	7. 6	105%	＞99%	0. 46	Sterile	1.3
T14D	7.6	84%	＞99%	0.47	Sterile	1.1
T21D	7.6	66%	＞99%	0.44	Sterile	0.7
T28D	7.7	38%	＞99%	0.48	Sterile	1.0

Table 3.2.P.8.3-23 Accelerated stability data at 37 ℃ (Final bulk)

Batch number 202009004-2	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	104%	97%	0.40	Sterile	1.7
T3D	7. 5	112%	＞99%	0. 47	Sterile	1
T5D	7. 4	90%	＞99%	0. 45	Sterile	1.1
T7D	7. 6	83%	＞99%	0. 45	Sterile	1.6
T14D	7.6	77%	＞99%	0.43	Sterile	1.1
T21D	7.6	53%	＞99%	0.44	Sterile	0.7
T28D	7.6	30%	＞99%	0.46	Sterile	1.0

Table 3.2.P.8.3-24 Accelerated stability data at 37℃ (Final bulk)

Batch number 202009009-1	**Test Item**					
Specifications	**pH**	**Post-dissociation antigen content**	**Antigen adsorption rate**	**Aluminum content**	**Sterility**	**Potency**
Time	6.8-7.8	≥60% of the indicated content	≥ 85%	0.3-0.6mg/mL	Sterile	≥0.5 of the reference vaccine at same dosage
0	7.2	114%	>99%	0.43	Sterile	1.3
T3D	7.4	107%	＞99%	0.47	Sterile	2
T5D	7.4	84%	＞99%	0.46	Sterile	1.3
T7D	7.5	99%	＞99%	0.46	Sterile	1.7
T14D	7.5	66%	＞99%	0.45	Sterile	1.0
T21D	7.5	57%	＞99%	0.48	Sterile	1.1
T28D	7.6	35%	＞99%	0.48	Sterile	1.4

Table 3.2.P.8.3-25 Accelerated stability data at 25 ℃ (Pilot scale Syringe)

Batch number 20200308	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	284	105% (628)	Complies	<0.3	0.453	Positive	Sterile	1.7
T7D	/	/	/	/	122% (732)	/	/	/	/	/	/
T14D	/	/	/	/	119% (714)	/	/	/	/	/	/
T28D	/	/	/	/	70% (418)	/	/	/	/	/	/
T42D	Complies	0.54	7.6	286	69% (415)	Complies	<0.6	0.447	Positive	/	0.8
T56D	/	/	/	/	44% (262)	/	/	/	/	/	/

Table 3.2.P.8.3-26 Accelerated stability data at 25 ℃ (Pilot scale Syringe)

Batch number 20200412	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	281	142% (850)	Complies	<1.2	0.454	Positive	Sterile	4.0
T7D	/	/	/	/	147% (884)	/	/	/	/	/	/
T14D	/	/	/	/	135% (812)	/	/	/	/	/	/
T28D	/	/	/	/	71% (424)	/	/	/	/	/	/
T42D	Complies	0.55	7.5	280	57% (345)	Complies	<2.4	0.438	Positive	/	0.9
T56D	/	/	/	/	37% (220)	/	/	/	/	/	/

Table 3.2.P.8.3-27 Accelerated stability data at 25 ℃ (Pilot scale Syringe)

Batch number 20200419	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	281	126% (754)	Complies	<0.15	0.452	Positive	Sterile	2.6
T7D	/	/	/	/	110% (658)	/	/	/	/	/	/
T14D	/	/	/	/	112% (669)	/	/	/	/	/	/
T28D	/	/	/	/	64% (381)	/	/	/	/	/	/
T42D	Complies	0.54	7.5	280	64% (387)	Complies	<3	0.444	Positive	/	1.5
T56D	/	/	/	/	49% (295)	/	/	/	/	/	/

Table 3.2.P.8.3-28 Accelerated stability data at 25 ℃ (Pilot scale Vial)

Batch number 20200414	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.52	7.3	283	153% (919)	Complies	<1.2	0.442	Positive	Sterile	2.3
T7D	/	/	/	/	145% (869)	/	/	/	/	/	/
T14D	/	/	/	/	128% (770)	/	/	/	/	/	/
T28D	/	/	/	/	71% (424)	/	/	/	/	/	/
T42D	Complies	0.53	7.7	281	70% (420)	Complies	<1.2	0.457	Positive	/	1.9
T56D	/	/	/	/	48% (288)	/	/	/	/	/	/

Table 3.2.P.8.3-29 Accelerated stability data at 25℃ (Pilot scale Vial)

Batch number 20200415	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.51	7.3	269	115% (692)	Complies	<1.2	0.437	Positive	Sterile	2.0
T7D	/	/	/	/	111% (664)	/	/	/	/	/	/
T14D	/	/	/	/	109% (656)	/	/	/	/	/	/
T28D	/	/	/	/	69% (413)	/	/	/	/	/	/
T42D	Complies	0.52	7.6	267	68% (406)	Complies	<1.2	0.457	Positive	/	1.5
T56D	/	/	/	/	44% (264)	/	/	/	/	/	/

Table 3.2.P.8.3-30 Accelerated stability data at 25 ℃ (Pilot scale Vial)

Batch number 20200416	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.52	7.3	250	140% (843)	Complies	<0.3	0.432	Positive	Sterile	3.5
T7D	/	/	/	/	138% (828)	/	/	/	/	/	/
T14D	/	/	/	/	137% (824)	/	/	/	/	/	/
T28D	/	/	/	/	66% (394)	/	/	/	/	/	/
T42D	Complies	0.53	7.6	251	60% (361)	Complies	<0.3	0.444	Positive	/	1.9
T56D	/	/	/	/	47% (283)	/	/	/	/	/	/

Table 3.2.P.8.3-31 Accelerated stability data at 25 ℃ (Commercial scale syringe)

Batch number 202009004	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.53	7.3	283	Complies	112%	Complies	<0.0625	0.5	Positive	Sterile
T7D	Upright	/	/	/	/	/	105%	/	/	/	/	/
	Inverted	/	/	/	/	/	97%	/	/	/	/	/
T14D	Upright	Complies	0.51	7.6	283	Complies	80%	Complies	<5	0.49	Positive	Sterile
	Inverted	Complies	0.52	7.6	283	Complies	78%	Complies	<5	0.49	Positive	Sterile
T28D	Upright	/	/	/	/	/	112%	/	/	/	/	/
	Inverted	/	/	/	/	/	108%	/	/	/	/	/
T42D	Upright	Complies	0.52	7.5	303	Complies	97%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.52	7.4	300	Complies	112%	Complies	<5	0.48	Positive	Sterile
T56D	Upright	Complies	0.51	7.6	288	Complies	72%	Complies	<5	0.47	Positive	Sterile
	Inverted	Complies	0.51	7.6	288	Complies	69%	Complies	<5	0.46	Positive	Sterile

Table 3.2.P.8.3-32 Accelerated stability data at 25 ℃ (Commercial scale syringe)

Batch number 202009006	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.55	7.3	283	Complies	110%	Complies	<0.0625	0.49	Positive	Sterile
T7D	Upright	/	/	/	/	/	113%	/	/	/	/	/
	Inverted	/	/	/	/	/	108%	/	/	/	/	/
T14D	Upright	Complies	0.52	7.6	284	Complies	86%	Complies	<5	0.49	Positive	Sterile
	Inverted	Complies	0.51	7.6	281	Complies	82%	Complies	<5	0.48	Positive	Sterile
T28D	Upright	/	/	/	/	/	101%	/	/	/	/	/
	Inverted	/	/	/	/	/	98%	/	/	/	/	/
T42D	Upright	Complies	0.52	7.5	309	Complies	110%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.52	7.5	298	Complies	111%	Complies	<5	0.47	Positive	Sterile
T56D	Upright	Complies	0.51	7.6	286	Complies	83%	Complies	<5	0.47	Positive	Sterile
	Inverted	Complies	0.51	7.6	287	Complies	78%	Complies	<5	0.45	Positive	Sterile

Table 3.2.P.8.3-33 Accelerated stability data at 25 ℃ (Commercial scale syringe)

Batch number 202009008	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.56	7.2	292	Complies	113%	Complies	<0.0625	0.5	Positive	Sterile
T7D	Upright	/	/	/	/	/	99%	/	/	/	/	/
	Inverted	/	/	/	/	/	99%	/	/	/	/	/
T14D	Upright	Complies	0.51	7.5	292	Complies	77%	Complies	<5	0.45	Positive	Sterile
	Inverted	Complies	0.51	7.5	292	Complies	72%	Complies	<5	0.45	Positive	Sterile
T28D	Upright	/	/	/	/	/	86%	/	/	/	/	/
	Inverted	/	/	/	/	/	82%	/	/	/	/	/
T42D	Upright	Complies	0.51	7.5	302	Complies	83%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.52	7.5	306	Complies	101%	Complies	<5	0.45	Positive	Sterile
T56D	Upright	Complies	0.51	7.5	302	Complies	63%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.51	7.6	293	Complies	56%	Complies	<5	0.43	Positive	Sterile

Table 3.2.P.8.3-34 Accelerated stability data at 25 ℃ (Commercial scale vial)

Batch number 202009005	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.51	7.4	284	Complies	113%	Complies	<0.0625	0.5	Positive	Sterile
T7D	Upright	/	/	/	/	/	105%	/	/	/	/	/
	Inverted	/	/	/	/	/	92%	/	/	/	/	/
T14D	Upright	Complies	0.50	7.7	288	Complies	77%	Complies	<5	0.44	Positive	Sterile
	Inverted	Complies	0.50	7.7	288	Complies	75%	Complies	<5	0.45	Positive	Sterile
T28D	Upright	/	/	/	/	/	97%	/	/	/	/	/
	Inverted	/	/	/	/	/	88%	/	/	/	/	/
T42D	Upright	Complies	0.50	7.6	313	Complies	102%	Complies	<5	0.43	Positive	Sterile
	Inverted	Complies	0.50	7.7	310	Complies	93%	Complies	<5	0.44	Positive	Sterile
T56D	Upright	Complies	0.51	7.7	292	Complies	72%	Complies	<5	0.42	Positive	Sterile
	Inverted	Complies	0.50	7.8	295	Complies	78%	Complies	<5	0.43	Positive	Sterile

Table 3.2.P.8.3-35 Accelerated stability data at 25 ℃ (Commercial scale vial)

Batch number 202009007	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.52	7.3	283	Complies	110%	Complies	<0.0625	0.5	Positive	Sterile
T7D	Upright	/	/	/	/	/	100%	/	/	/	/	/
	Inverted	/	/	/	/	/	97%	/	/	/	/	/
T14D	Upright	Complies	0.50	7.6	283	Complies	86%	Complies	<5	0.49	Positive	Sterile
	Inverted	Complies	0.50	7.6	281	Complies	82%	Complies	<5	0.49	Positive	Sterile
T28D	Upright	/	/	/	/	/	105%	/	/	/	/	/
	Inverted	/	/	/	/	/	93%	/	/	/	/	/
T42D	Upright	Complies	0.50	7.5	305	Complies	105%	Complies	<5	0.47	Positive	Sterile
	Inverted	Complies	0.50	7.5	305	Complies	116%	Complies	<5	0.43	Positive	Sterile
T56D	Upright	Complies	0.50	7.7	287	Complies	78%	Complies	<5	0.46	Positive	Sterile
	Inverted	Complies	0.50	7.7	286	Complies	78%	Complies	<5	0.47	Positive	Sterile

Table 3.2.P.8.3-36 Accelerated stability data at 25 ℃ (Commercial scale vial)

Batch number 202009009	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.51	7.3	294	Complies	91%	Complies	<0.0625	0.5	Positive	Sterile
T7D	Upright	/	/	/	/	/	74%	/	/	/	/	/
	Inverted	/	/	/	/	/	75%	/	/	/	/	/
T14D	Upright	Complies	0.51	7.6	289	Complies	72%	Complies	<5	0.45	Positive	Sterile
	Inverted	Complies	0.51	7.6	290	Complies	72%	Complies	<5	0.45	Positive	Sterile
T28D	Upright	/	/	/	/	/	68%	/	/	/	/	/
	Inverted	/	/	/	/	/	87%	/	/	/	/	/
T42D	Upright	Complies	0.52	7.6	316	Complies	77%	Complies	<5	0.44	Positive	Sterile
	Inverted	Complies	0.50	7.6	310	Complies	75%	Complies	<5	0.42	Positive	Sterile
T56D	Upright	Complies	0.51	7.8	294	Complies	68%	Complies	<5	0.42	Positive	Sterile
	Inverted	Complies	0.50	7.9	293	Complies	70%	Complies	<5	0.45	Positive	Sterile

Table 3.2.P.8.3-37 Accelerated stability data at 37 ℃ (Pilot scale Syringe)

Batch number 20200308	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	284	105% (628)	Complies	<0.3	0.453	Positive	Sterile	1.7
T3D	/	/	/	/	128% (765)	/	/	/	/	/	/
T5D	/	/	/	/	128% (770)	/	/	/	/	/	/
T7D	/	/	/	/	127% (761)	/	/	/	/	/	/
T14D	Complies	0.56	7.6	286	77% (463)	Complies	<0.3	0.451	Positive	/	1.1
T21D	/	/	/	/	69% (416)	/	/	/	/	/	/
T28D	/	/	/	/	63% (378)	/	/	/	/	/	/
T42D	/	/	/	/	42% (254)	/	/	/	/	/	/

Table 3.2.P.8.3-38 Accelerated stability data at 37 ℃ (Pilot scale Syringe)

Batch number 20200412	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	281	142% (850)	Complies	<1.2	0.454	Positive	Sterile	4.0
T3D	/	/	/	/	141% (844)	/	/	/	/	/	/
T5D	/	/	/	/	153% (916)	/	/	/	/	/	/
T7D	/	/	/	/	144% (865)	/	/	/	/	/	/
T14D	Complies	0.57	7.5	281	88% (530)	Complies	<1.2	0.448	Positive	/	1.9
T21D	/	/	/	/	81% (484)	/	/	/	/	/	/
T28D	/	/	/	/	59% (354)	/	/	/	/	/	/
T42D	/	/	/	/	50% (301)	/	/	/	/	/	/

Table 3.2.P.8.3-39 Accelerated stability data at 37 ℃ (Pilot scale Syringe)

Batch number 20200419	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/dose)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.57	7.2	281	126% (754)	Complies	<0.15	0.452	Positive	Sterile	2.6
T3D	/	/	/	/	110% (658)	/	/	/	/	/	/
T5D	/	/	/	/	117% (700)	/	/	/	/	/	/
T7D	/	/	/	/	113% (679)	/	/	/	/	/	/
T14D	Complies	0.56	7.5	281	123% (740)	Complies	<0.15	0.453	Positive	/	1.1
T21D	/	/	/	/	87% (524)	/	/	/	/	/	/
T28D	/	/	/	/	60% (360)	/	/	/	/	/	/
T42D	/	/	/	/	47% (284)	/	/	/	/	/	/

Table 3.2.P.8.3-40 Accelerated stability data at 37 ℃ (Pilot scale Vial)

Batch number 20200414	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.52	7.3	283	153% (919)	Complies	<1.2	0.442	Positive	Sterile	2.3
T3D	/	/	/	/	158% (947)	/	/	/	/	/	/
T5D	/	/	/	/	164% (984)	/	/	/	/	/	/
T7D	/	/	/	/	152% (912)	/	/	/	/	/	/
T14D	Complies	0.54	7.7	283	78% (469)	Complies	<1.2	0.451	Positive	/	2.4
T21D	/	/	/	/	70% (422)	/	/	/	/	/	/
T28D	/	/	/	/	59% (354)	/	/	/	/	/	/
T42D	/	/	/	/	50% (301)	/	/	/	/	/	/

Table 3.2.P.8.3-41 Accelerated stability data at 37 ℃ (Pilot scale Vial)

Batch number 20200415	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.51	7.3	269	115% (692)	Complies	<1.2	0.437	Positive	Sterile	2.0
T3D	/	/	/	/	110% (662)	/	/	/	/	/	/
T5D	/	/	/	/	107% (640)	/	/	/	/	/	/
T7D	/	/	/	/	111% (666)	/	/	/	/	/	/
T14D	Complies	0.54	7.6	289	69% (414)	Complies	<1.2	0.437	Positive	/	1.9
T21D	/	/	/	/	72% (430)	/	/	/	/	/	/
T28D	/	/	/	/	65% (392)	/	/	/	/	/	/
T42D	/	/	/	/	40% (241)	/	/	/	/	/	/

Table 3.2.P.8.3-42 Accelerated stability data at 37 ℃ (Pilot scale Vial)

Batch number 20200416	**Test Item**										
Specifications	**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**	**Potency**
Time	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.5-8.0	250-400 mOsmol/Kg	≥50% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile	≥0.5 of the reference vaccine at same dosage
0	Complies	0.52	7.3	250	140% (843)	Complies	<0.3	0.432	Positive	Sterile	3.5
T3D	/	/	/	/	135% (811)	/	/	/	/	/	/
T5D	/	/	/	/	152% (913)	/	/	/	/	/	/
T7D	/	/	/	/	139% (834)	/	/	/	/	/	/
T14D	Complies	0.55	7.6	252	78% (465)	Complies	<0.3	0.445	Positive	/	2.6
T21D	/	/	/	/	67% (402)	/	/	/	/	/	/
T28D	/	/	/	/	68% (408)	/	/	/	/	/	/
T42D	/	/	/	/	49% (294)	/	/	/	/	/	/

Table 3.2.P.8.3-43 Accelerated stability data at 37 ℃ (Commercial scale syringe)

Batch number 202009004	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.53	7.3	283	Complies	112%	Complies	<0.0625	0.5	Positive	Sterile
T3D	Upright	/	/	/	/	/	97%	/	/	/	/	/
	Inverted	/	/	/	/	/	99%	/	/	/	/	/
T5D	Upright	/	/	/	/	/	104%	/	/	/	/	/
	Inverted	/	/	/	/	/	101%	/	/	/	/	/
T7D	Upright	/	/	/	/	/	98%	/	/	/	/	/
	Inverted	/	/	/	/	/	100%	/	/	/	/	/
T14D	Upright	Complies	0.53	7.6	283	Complies	89%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.53	7.6	282	Complies	85%	Complies	<5	0.48	Positive	Sterile
T21D	Upright	/	/	/	/	/	70%	/	/	/	/	/
	Inverted	/	/	/	/	/	65%	/	/	/	/	/
T28D	Upright	Complies	0.51	7.5	301	Complies	57%	Complies	<5	0.46	Positive	Sterile
	Inverted	Complies	0.52	7.5	298	Complies	54%	Complies	<5	0.46	Positive	Sterile
T42D	Upright	Complies	0.51	7.5	308	Complies	35%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.51	7.5	308	Complies	36%	Complies	<5	0.48	Positive	Sterile

Table 3.2.P.8.3-44 Accelerated stability data at 37 ℃ (Commercial scale syringe)

Batch number 202009006	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.55	7.3	283	Complies	110%	Complies	<0.0625	0.49	Positive	Sterile
T3D	Upright	/	/	/	/	/	96%	/	/	/	/	/
	Inverted	/	/	/	/	/	100%	/	/	/	/	/
T5D	Upright	/	/	/	/	/	112%	/	/	/	/	/
	Inverted	/	/	/	/	/	118%	/	/	/	/	/
T7D	Upright	/	/	/	/	/	129%	/	/	/	/	/
	Inverted	/	/	/	/	/	120%	/	/	/	/	/
T14D	Upright	Complies	0.51	7.6	283	Complies	91%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.51	7.6	281	Complies	90%	Complies	<5	0.48	Positive	Sterile
T21D	Upright	/	/	/	/	/	66%	/	/	/	/	/
	Inverted	/	/	/	/	/	64%	/	/	/	/	/
T28D	Upright	Complies	0.52	7.6	292	Complies	53%	Complies	<5	0.45	Positive	Sterile
	Inverted	Complies	0.52	7.5	292	Complies	53%	Complies	<5	0.45	Positive	Sterile
T42D	Upright	Complies	0.51	7.5	303	Complies	34%	Complies	<5	0.47	Positive	Sterile
	Inverted	Complies	0.52	7.5	302	Complies	33%	Complies	<5	0.48	Positive	Sterile

Table 3.2.P.8.3-45 Accelerated stability data at 37 ℃ (Commercial scale syringe)

Batch number 202009008	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.56	7.2	292	Complies	113%	Complies	<0.0625	0.5	Positive	Sterile
T3D	Upright	/	/	/	/	/	100%	/	/	/	/	/
	Inverted	/	/	/	/	/	98%	/	/	/	/	/
T5D	Upright	/	/	/	/	/	86%	/	/	/	/	/
	Inverted	/	/	/	/	/	87%	/	/	/	/	/
T7D	Upright	/	/	/	/	/	103%	/	/	/	/	/
	Inverted	/	/	/	/	/	96%	/	/	/	/	/
T14D	Upright	Complies	0.51	7.6	288	Complies	87%	Complies	<5	0.5	Positive	Sterile
	Inverted	Complies	0.51	7.6	288	Complies	86%	Complies	<5	0.45	Positive	Sterile
T21D	Upright	/	/	/	/	/	68%	/	/	/	/	/
	Inverted	/	/	/	/	/	67%	/	/	/	/	/
T28D	Upright	Complies	0.52	7.5	298	Complies	64%	Complies	<5	0.42	Positive	Sterile
	Inverted	Complies	0.51	7.6	296	Complies	63%	Complies	<5	0.42	Positive	Sterile
T42D	Upright	Complies	0.52	7.5	312	Complies	35%	Complies	<5	0.46	Positive	Sterile
	Inverted	Complies	0.52	7.5	307	Complies	39%	Complies	<5	0.45	Positive	Sterile

Table 3.2.P.8.3-46 Accelerated stability data at 37 ℃ (Commercial scale vial)

Batch number 202009005	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.51	7.4	284	Complies	113%	Complies	<0.0625	0.5	Positive	Sterile
T3D	Upright	/	/	/	/	/	87%	/	/	/	/	/
	Inverted	/	/	/	/	/	92%	/	/	/	/	/
T5D	Upright	/	/	/	/	/	104%	/	/	/	/	/
	Inverted	/	/	/	/	/	106%	/	/	/	/	/
T7D	Upright	/	/	/	/	/	99%	/	/	/	/	/
	Inverted	/	/	/	/	/	102%	/	/	/	/	/
T14D	Upright	Complies	0.52	7.3	289	Complies	79%	Complies	<5	0.45	Positive	Sterile
	Inverted	Complies	0.50	7.8	288	Complies	85%	Complies	<5	0.45	Positive	Sterile
T21D	Upright	/	/	/	/	/	68%	/	/	/	/	/
	Inverted	/	/	/	/	/	63%	/	/	/	/	/
T28D	Upright	Complies	0.51	7.6	294	Complies	56%	Complies	<5	0.43	Positive	Sterile
	Inverted	Complies	0.51	7.7	301	Complies	55%	Complies	<5	0.43	Positive	Sterile
T42D	Upright	Complies	0.50	7.6	321	Complies	37%	Complies	<5	0.43	Positive	Sterile
	Inverted	Complies	0.50	7.6	317	Complies	33%	Complies	<5	0.45	Positive	Sterile

Table 3.2.P.8.3-47 Accelerated stability data at 37 ℃ (Commercial scale vial)

Batch number 202009007	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.52	7.3	283	Complies	110%	Complies	<0.0625	0.5	Positive	Sterile
T3D	Upright	/	/	/	/	/	96%	/	/	/	/	/
	Inverted	/	/	/	/	/	96%	/	/	/	/	/
T5D	Upright	/	/	/	/	/	96%	/	/	/	/	/
	Inverted	/	/	/	/	/	95%	/	/	/	/	/
T7D	Upright	/	/	/	/	/	111%	/	/	/	/	/
	Inverted	/	/	/	/	/	104%	/	/	/	/	/
T14D	Upright	Complies	0.51	7.6	285	Complies	83%	Complies	<5	0.48	Positive	Sterile
	Inverted	Complies	0.51	7.6	282	Complies	84%	Complies	<5	0.48	Positive	Sterile
T21D	Upright	/	/	/	/	/	65%	/	/	/	/	/
	Inverted	/	/	/	/	/	60%	/	/	/	/	/
T28D	Upright	Complies	0.51	7.6	290	Complies	62%	Complies	<5	0.46	Positive	Sterile
	Inverted	Complies	0.51	7.6	293	Complies	63%	Complies	<5	0.45	Positive	Sterile
T42D	Upright	Complies	0.50	7.5	314	Complies	33%	Complies	<5	0.47	Positive	Sterile
	Inverted	Complies	0.50	7.5	312	Complies	37%	Complies	<5	0.48	Positive	Sterile

Table 3.2.P.8.3-48 Accelerated stability data at 37 ℃ (Commercial scale vial)

Batch number 202009009	**Position**	**Test Item**										
Specifications		**Appearance**	**Extractable volume (mL)**	**pH**	**Osmolality (mOsmol/kg)**	**Air tightness**	**Post-dissociation antigen content (SU/mL)**	**Abnormal toxicity**	**Bacteria endotoxin (EU/dose)**	**Aluminum content**	**Identity test**	**Sterility**
Time		Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Not less than the indicated volume	6.8-7.8	250-400 mOsmol/Kg	**Air tight**	≥60% of the indicated content	Complies	≤5EU/dose	0.3-0.6mg/mL	Contains SARS-CoV-2 antigen	Sterile
0	Upright	Complies	0.51	7.3	294	Complies	91%	Complies	<0.0625	0.5	Positive	Sterile
T3D	Upright	/	/	/	/	/	82%	/	/	/	/	/
	Inverted	/	/	/	/	/	82%	/	/	/	/	/
T5D	Upright	/	/	/	/	/	74%	/	/	/	/	/
	Inverted	/	/	/	/	/	75%	/	/	/	/	/
T7D	Upright	/	/	/	/	/	85%	/	/	/	/	/
	Inverted	/	/	/	/	/	82%	/	/	/	/	/
T14D	Upright	Complies	0.5	7.7	291	Complies	77%	Complies	<5	0.45	Positive	Sterile
	Inverted	Complies	0.51	7.8	291	Complies	72%	Complies	<5	0.45	Positive	Sterile
T21D	Upright	/	/	/	/	/	64%	/	/	/	/	/
	Inverted	/	/	/	/	/	62%	/	/	/	/	/
T28D	Upright	Complies	0.51	7.8	299	Complies	57%	Complies	<5	0.42	Positive	Sterile
	Inverted	Complies	0.5	7.7	298	Complies	57%	Complies	<5	0.42	Positive	Sterile
T42D	Upright	Complies	0.50	7.6	312	Complies	37%	Complies	<5	0.42	Positive	Sterile
	Inverted	Complies	0.50	7.6	315	Complies	32%	Complies	<5	0.42	Positive	Sterile

REFERENCES

[1] Research Progress on New Coronavirus SARS-CoV-2, XIA Liqiu*, (Hunan Provincial Key Laboratory for Microbial Molecular Biology, State Key Laboratory of Developmental Biology of Freshwater Fish, College of Life Science, Hunan Normal University, Changsha 410081, China)