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1 INTRODUCTION

This report is to evaluate whether the changes made in the Sotrovimab Drug Product (DP) manufacturing sites and manufacturing processes between the clinical and commercial results in biochemically and biophysically comparable Sotrovimab. Process changes are detailed in Appendix 1. The comparability protocol is provided in VQD-PRTL-01883.

This evaluation consists of the release, extended characterization, and stability experiments, data, data analysis and the conclusions in the assessment of analytical comparability between the Gen2 drug product clinical process at WuXi and the Gen2 drug product clinical and commercial process at Parma. The release data demonstrate that the drug products manufactured at WuXi and Parma are within acceptance criteria per current release specification (VQD-SPEC-027213) at the time of testing. Assessment of release data indicate that there are no impactful differences on product quality attributes. Characterization assays are performed side-by-side, if assay set-up can accommodate, to confirm that the primary structure, secondary structure, tertiary structure, glycosylation profile, and binding activities produced from the two processes are comparable.

The investigated biochemical and biophysical attributes are chosen based on the critical quality attributes (CQA) of Sotrovimab identified to date (VQD-RPT-052783).

2 GENERAL INFORMATION

Internal Company Code:	GSK4182136
Alternative Names:	Sotrovimab, Vir-7831, WBP2275
Host cell line:	CHO host cell line (CHO-K1)
Production cell line:	CHO-K1
Biochemical and Structural Information:	Sotrovimab is a neutralizing IgG1 targeted against the spike (S) protein of SARS-CoV-2.
Molecular Mass:	The total molecular weight is 149,032.6 Da (includes G0F/G0F glycosylation, N-terminal pyroglutamylation and C-terminal lysine cleavage on both heavy chains)
Size (No. amino acids):	1342 amino acids (214 per light chain, 457 per heavy chain)
Glycosylation:	N-linked glycosylation on each heavy chain on N307
pI:	~8.9
Extinction Coefficient at 280nm:	1.49 (mg/mL) ⁻¹ cm ⁻¹

3 MATERIALS/SAMPLES

3.1 Reference Standard

Reference standard (RS) 2275S200411Y-RS was used for system suitability and controls for this comparability and characterization study. The RS was manufactured on 06 May 2020 from Sotrovimab Gen1 process non-clinical batch 2275S200411Y-RS. The concentration is 25.3 mg/mL (RoA No: R2275-2020003-03).

3.2 Samples

3.2.1 Drug Products

Sotrovimab DP clinical batches 202009005 and 202010006 were manufactured at WuXi Biologics Co., Ltd. (Shanghai) in China. The aliquots of material used in this evaluation were stored at 2-8°C from the date of preparation until the time of testing. The concentrations are presented in [Table 1](#).

Sotrovimab DP intended commercial process batches, Engineering batch (202421682), Parma GMP batch 1 (8H5D) and Parma GMP batch 3 (9G7S), were manufactured at GSK Parma facility in Italy. The aliquots of material used in this evaluation were stored at 2-8°C from the date of preparation until the time of testing. The concentrations are presented in [Error! Reference source not found. Table 1](#).

3.2.2 Rejected drug product vials

Some vials from Sotrovimab DP clinical process (Gen2, WuXi) batch 202010006 were rejected due to minor defects in stopper appearance. Upon detailed checking of the cold chain and storage information for the rejected vials, the material inside these vials was acceptable for pseudovirus neutralization characterization assay in the comparability study. See Appendix 1 for the justification of using rejecting vials in testing.

3.3 Formulation Buffer

The formulation buffer for all DP samples is 20 mM Histidine, 7% (w/v) sucrose, 5mM Methionine, 0.04% (w/v) PS-80, pH 6.0.

Table 1. Sample Information

DP Batch Number	Process	Date of Manufacture	Concentration (mg/mL)	Vials used for aliquoted sample
202009005	Gen2, WuXi	Sep 11, 2020	61.7	1 mL Nalgene™ Polypropylene Cryogenic Vial, Thermo Scientific, Supplier Catalog Number 5000-1012;
202010006	Gen2, WuXi	Oct 16, 2020	63.1	

202421682	Gen2, Parma	Dec 18, 2020	63.2	1.5 mL Nalgene™ Polypropylene Cryogenic Vial, Thermo Scientific, Supplier Catalog Number 5000-1020; 5 mL Nalgene™ Polypropylene Cryogenic Vial, Thermo Scientific, Supplier Catalog Number 5000-0050.
8H5D	Gen2, Parma	Feb 16, 2021	61.6	
9G7S	Gen2, Parma	Feb 18, 2021	61.5	

4 SUMMARY OF TESTING

4.1 Release Testing Results

A summary of the release data is presented in [Table 2](#). The release testing for two clinical batches (202009005 and 202010006) was performed at WuXi Shanghai against DP specification VQD-SPEC-032754, while the intended commercial process batches (engineering batch: 202421682, batch 1: 8H5D, and batch 3: 9G7S) are release tested at PPD/Parma per VQD-SPEC-027213. The noticeable shift towards higher percentage of main peak and lower percentage of acidic peak in iCIEF was observed for the drug products produced at two sites. Since there is no significant change between parent DS batch and DP filled with that parent DS batch, the differences are “inherited”, which is likely due to the combination of analytical variability and process improvement at the DS stage.

Overall, the release results support a conclusion that the product quality of the two clinical batches manufactured at WuXi and three intended commercial process batches manufactured at Parma) are comparable.

Table 2. Comparison of Release Data for Sotrovimab Drug Product Gen2 (WuXi) Batches with Gen2 (GSK Parma) Batches

Test Method ^a	Specification	Gen2 (WuXi)		Gen2 (GSK Parma)		
		202009005	202010006	202421682	8H5D	9G7S
Color	Report result (Refer to Ph. Eur.)	B7	B7	B7	B7	B7
Clarity	≤ 18.0 NTU	7.4 NTU	7.2 NTU	6.4 NTU	6.9 NTU	7.1 NTU
Visible Particles ^b	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
Sub-visible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container	62 p/c	20 p/c	43 p/c ^c	30 p/c ^d	43 p/c ^e
	≥ 25 µm: ≤ 600 particles/container	0 p/c	0 p/c	0 p/c ^c	0 p/c ^f	0 p/c ^g
	≥ 2µm: Report result (particles/container)	2461 p/c	3178 p/c	3435 p/c	2270 p/c	1939 p/c
	≥ 5µm: Report result (particles /container)	526 p/c	394 p/c	494 p/c	376 p/c	283 p/c
pH	6.0 ± 0.5	5.9	6.0	6.0	6.0	6.0
Osmolality	290±50 mOsmol/kg	289 mOsmol/kg	288 mOsmol/kg	288 mOsm/kg	288 mOsm/kg	290 mOsm/kg
Extractable Volume	>8 mL/vial	> 8 mL /vial	> 8 mL /vial	> 8 mL/vial	> 8 mL/vial	> 8 mL/vial
Protein Concentration	62.5 ± 6.2 mg/mL	61.7 mg/mL	63.1 mg/mL	63.2 mg/mL	61.6 mg/mL	61.5 mg/mL
Identity by ELISA	Positive for ID	Positive for ID	Positive for ID	Positive for ID	Positive for ID	Positive for ID

Table 2: Comparison of Release Data for Sotrovimab Drug Product Gen2 (WuXi) Batches with Gen2 (GSK Parma) Batches (Continued)

Test Method ^a	Specification	Gen2 (WuXi)		Gen2 (GSK Parma)		
		202009005	202010006	202421682	8H5D	9G7S
Identity by cIEF	Conforms to profile of the Reference Standard. The difference in main peak pI value between sample and RS ≤ 0.2	Conforms	Conforms	Conforms	Conforms	Conforms
Charge Variants by cIEF	Main peak %: $\geq 40.0\%$	60.8 %	63.0 %	67.2 %	66.2 %	66.2 %
	Acidic peaks %: $\leq 60.0\%$	30.2 %	25.6 %	18.3 %	19.9 %	21.2 %
	Basic peaks %: $\leq 30.0\%$	9.0 %	11.3 %	14.5 %	13.9 %	12.6 %
Purity by SEC-HPLC	Main peak (monomer): $\geq 90.0\%$	97.7 %	98.0 %	98.3 %	98.4 %	98.3 %
	HMWS: $\leq 10.0\%$	2.3 %	2.0 %	1.7 %	1.6 %	1.6 %
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): $\geq 90.0\%$	97.2 %	98.1 %	98.7 %	98.5 %	98.4 %
Purity by CE-SDS (Non-Reduced)	Main peak: $\geq 90.0\%$	97.9 %	98.4 %	99.4 %	99.4 %	99.3 %
Endotoxin	WuXi: < 0.15 EU/mg GSK Parma: < 9.0 EU/mL	< 0.0017 EU/mg	< 0.010 EU/mg	NT ^h	< 1.0 EU/mL	< 1.0 EU/mL

Table 2: Comparison of Release Data for Sotrovimab Drug Product Gen2 (WuXi) Batches with Gen2 (GSK Parma) Batches (Continued)

Test Method ^a	Specification	Gen2 (WuXi)		Gen2 (GSK Parma)		
		202009005	202010006	202421682	8H5D	9G7S
Sterility	No growth	No growth	No growth	NT ^h	No growth	No growth
Potency by Binding ELISA	60 – 140% relative potency	101%	101%	114%	94%	102%
Polysorbate 80 by HPLC-FLD (WuXi) HPLC-ELSD (GSK Parma) ^e	0.040% ± 0.030% (w/v)	0.036%	0.036%	NT ⁱ	0.034%	0.034%

Abbreviations: CE-SDS = capillary electrophoresis sodium dodecyl sulfate; cIEF = capillary isoelectric focusing; ELISA = enzyme-linked immunosorbent assay; EU = endotoxin unit; HMWS = high molecular weight species; NTU = nephelometric turbidity unit; SEC-HPLC = size exclusion- high performance liquid chromatography; HPLC-FLD = high performance liquid chromatography-fluorescence detector; HPLC-ELSD = high performance liquid chromatography-evaporative light scattering detection; LOD = Limit of Detection; NT = Not Tested; p/c = particles/container

^a Test methods are product release method.

^b Refer to USP <790>, Ph. Eur. 2.9.20: "Essentially free of particles" is equivalent to "Practically free of Particles"

^c Reporting of subvisible particulate matter was originally listed on the CoA as "< LOD" and the particle count; however, the use of "LOD" is a reference to the PDL (practical detection limit) that was set at a signal to noise ratio (S/N) of 6 (10µm) and 4 (25µm), which is higher than the typically accepted LOD S/N of 3, in order to show that the method was fit for purpose (able to detect well below the specification limits). The PDL does not represent the true limit of detection of the test method. Therefore, only the number of particles is reported here.

^h The Engineering Batch (batch 202421682) was not tested for Endotoxin or Sterility due to the intended use of the batch (engineering and process transfer)

ⁱ Although Polysorbate 80 by HPLC-ELSD is a release assay, it was not included in the testing panel due to the method still being in development at the time of release testing for batch 202421682

4.2 Stability Testing Results

The stability testing for 2 clinical batches (202009005 and 202010006) is at WuXi Shanghai following stability protocol VQD-PRTL-028287 and SH-S20052-DP-01, respectively. The stability testing for batches 202421682 (Engineering, stability proforma # VQD-PRTL-017649), 8H5D (Parma GMP batch 1, stability pro forma # VQD-PRTL-018916) and 9G7S (Parma GMP batch 3, stability pro forma # VQD-PRTL-018916) are performed at PPD. Results from the drug product stability study under recommended storage condition (5°C), accelerated (25°C), and stressed (40°C) conditions from those batches are summarized in [Table 3](#) and [Table 4](#), respectively. Stability data up to 1 month were reported herein and will continue to be monitored for the lifetime of the product under recommended storage condition.

Under storage and accelerated conditions, the product quality for all lots is comparable up to one month. The product stabilities of all lots follow same trending at stressed temperatures. The stability testing show that stabilities of 2 clinical batches manufactured at WuXi are comparable to the 3 batches produced at GSK Parma.

Table 3. Stability Data from Sotrovimab Drug Product Clinical Process (Gen2, WuXi)

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202009005	Batch 202010006
Color	Report Result	5 °C ± 3 °C	T0	B7	B7
			1M	B7	B7
		25 °C ± 2 °C	T0	B7	B7
			1M	B7	B7
		40 °C ± 2 °C	T0	B7	B7
			1M	B6	B6
Clarity	≤ 18.0 NTU	5 °C ± 3 °C	T0	7.4	7.2
			1M	7.2	7.2
			T0	7.4	7.2

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202009005	Batch 202010006
pH	5.5 – 6.5	25 °C ± 2 °C	1M	7.5	7.1
			T0	7.4	7.2
		40 °C ± 2 °C	1M	7.6	7.6
			T0	5.9	6.0
			1M	5.9	6.0
			T0	5.9	6.0
Protein concentration	56.3 – 68.7 mg/mL	25 °C ± 2 °C	T0	61.7	63.1
			1M	62.1	62.2
		40 °C ± 2 °C	T0	61.7	63.1
			1M	62.0	62.0
			T0	61.7	63.1
			1M	61.9	62.3
Visible Particles	Liquid, essentially free of visible particles	5 °C ± 3 °C	T0	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
			1M	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
		25 °C ± 2 °C	T0	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
			1M	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202009005	Batch 202010006
		40 °C ± 2 °C	T0	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
			1M	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
Sub-visible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container	5 °C ± 3 °C	T0	62	20
			1M	53	46
		25 °C ± 2 °C	T0	62	20
			1M	40	80
		40 °C ± 2 °C	T0	62	20
			1M	29	58
	≥ 25 µm: ≤ 600 particles/container	5 °C ± 3 °C	T0	0	0
			1M	0	3
		25 °C ± 2 °C	T0	0	0
			1M	2	8
		40 °C ± 2 °C	T0	0	0
			1M	0	5
	≥ 5µm: Report result (particles /container)	5 °C ± 3 °C	T0	526	394
			1M	535	403
		25 °C ± 2 °C	T0	526	394
			1M	461	651
		40 °C ± 2 °C	T0	526	394
			1M	647	541

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202009005	Batch 202010006
	$\geq 2\mu\text{m}$: Report result (particles/container)	$5\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$	T0	2461	3178
			1M	2637	1971
		$25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	2461	3178
			1M	2230	3040
		$40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	2461	3178
			1M	3635	2802
cIEF	Main Peak $\geq 40.0\%$	$5\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$	T0	60.8%	63.0%
			1M	60.0%	63.8%
		$25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	60.8%	63.0%
			1M	58.3%	61.2%
		$40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	60.8%	63.0%
			1M	43.5%	46.1%
	Acidic Species $\leq 60.0\%$	$5\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$	T0	30.2%	25.6%
			1M	31.1%	24.3%
		$25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	30.2%	25.6%
			1M	32.4%	26.9%
		$40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	30.2%	25.6%
			1M	47.9%	43.4%
	Basic Species $\leq 30.0\%$	$5\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$	T0	9.0%	11.3%
			1M	8.9%	11.9%
		$25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	T0	9.0%	11.3%
			1M	9.3%	11.9%

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202009005	Batch 202010006
SE-HPLC	Main Peak (monomer) \geq 90.0%	40 °C \pm 2 °C	T0	9.0%	11.3%
			1M	8.5%	10.6%
		5 °C \pm 3 °C	T0	97.7%	98.0%
			1M	97.4%	97.8%
		25 °C \pm 2 °C	T0	97.7%	98.0%
			1M	97.2%	97.6%
		40 °C \pm 2 °C	T0	97.7%	98.0%
			1M	96.3%	96.7%
	HMW species \leq 10.0%	5 °C \pm 3 °C	T0	2.3%	2.0%
			1M	2.6%	2.2%
		25 °C \pm 2 °C	T0	2.3%	2.0%
			1M	2.7%	2.3%
		40 °C \pm 2 °C	T0	2.3%	2.0%
			1M	3.1%	2.7%
Reduced CE-SDS	Purity (LC+HC) \geq 90.0%	5 °C \pm 3 °C	T0	97.2%	98.1%
			1M	97.2%	97.9%
		25 °C \pm 2 °C	T0	97.2%	98.1%
			1M	97.2%	97.7%
		40 °C \pm 2 °C	T0	97.2%	98.1%
			1M	95.4%	96.3%
Non-reduced CE-SDS	Main Peak \geq 90.0%	5 °C \pm 3 °C	T0	97.9%	98.4%
			1M	97.7%	98.0%

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202009005	Batch 202010006
		25 °C ± 2 °C	T0	97.9%	98.4%
			1M	97.2%	97.7%
		40 °C ± 2 °C	T0	97.9%	98.4%
			1M	94.6%	95.0%
Potency by Binding ELISA	60%-140% relative potency	5 °C ± 3 °C	T0	101%	101%
			1M	97%	99%
		25 °C ± 2 °C	T0	101%	101%
			1M	95%	93%
		40 °C ± 2 °C	T0	101%	101%
			1M	94%	91%
PS80	Report result % (w/v)	5 °C ± 3 °C	T0	0.036	0.036
			1M	NT ^a	
		25 °C ± 2 °C	T0	0.036	0.036
			1M	NT ^a	
		40 °C ± 2 °C	T0	0.036	0.036
			1M	NT ^a	
CCIT	Pass	5 °C ± 3 °C	T0	Pass	Pass
			12M	NA ^c	
		25 °C ± 2 °C	T0	Pass	Pass
			12M	NA ^c	
		40 °C ± 2 °C	T0	Pass	Pass
			12M	NA ^c	

Abbreviations: NA = not available, NT = not tested

^a PS80 testing for 1M is not required in stability protocol.

^b Per stability protocol, PS80 is not tested at 1M accelerated and stressed conditions for other batches except that batch 8H5D is tested for 1M 25°C.

^c Per stability protocol, CCIT is tested annually and data is not available yet.

Table 4. Stability Data from Sotrovimab Drug Product Clinical and Commercial Process (Gen2, Parma)

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202421682	Batch 8H5D	Batch 9G7S
Color	Report Result	5 °C ± 3 °C	T0	B7	B7	B7
			1M	B7	B7	B7
		25 °C ± 2 °C	T0	B7	B7	B7
			1M	B7	B7	B7
		40 °C ± 2 °C	T0	B7	B7	B7
			1M	B6	B6	B6
Clarity	≤ 18.0 NTU	5 °C ± 3 °C	T0	6.4	6.9	7.1
			1M	7.1	7.0	6.9
		25 °C ± 2 °C	T0	6.4	6.9	7.1
			1M	6.8	7.1	7.0
		40 °C ± 2 °C	T0	6.4	6.9	7.1
			1M	7.0	7.1	7.1
pH	5.5 – 6.5	5 °C ± 3 °C	T0	6.0	6.0	6.0
			1M	6.0	6.0	6.0
		25 °C ± 2 °C	T0	6.0	6.0	6.0
			1M	5.9	6.0	6.0

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202421682	Batch 8H5D	Batch 9G7S
Protein concentration	56.3 – 68.7 mg/mL	40 °C ± 2 °C	T0	6.0	6.0	6.0
			1M	5.9	6.0	6.0
		5 °C ± 3 °C	T0	63.2	61.6	61.5
			1M	62.6	61.6	61.8
		25 °C ± 2 °C	T0	63.2	61.6	61.5
			1M	62.6	61.5	61.9
		40 °C ± 2 °C	T0	63.2	61.6	61.5
			1M	62.9	61.5	61.5
		5 °C ± 3 °C	T0	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
			1M	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
Visible Particles	Liquid, essentially free of visible particles	25 °C ± 2 °C	T0	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
			1M	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
		40 °C ± 2 °C	T0	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
			1M	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles	Liquid, essentially free of visible particles
		5 °C ± 3 °C	T0	43	30	43
			1M	22	102	30
Sub-visible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container	25 °C ± 2 °C	T0	43	30	43
			1M	30	54	19

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202421682	Batch 8H5D	Batch 9G7S
		40 °C ± 2 °C	T0	43	30	43
			1M	22	62	19
	≥ 25 µm: ≤ 600 particles/container	5 °C ± 3 °C	T0	0	0	0
			1M	0	0	0
		25 °C ± 2 °C	T0	0	0	0
			1M	0	0	0
		40 °C ± 2 °C	T0	0	0	0
			1M	0	3	0
	≥ 5µm: Report result (particles /container)	5 °C ± 3 °C	T0	494	376	283
			1M	171	968	475
		25 °C ± 2 °C	T0	494	376	283
			1M	392	795	440
		40 °C ± 2 °C	T0	494	376	283
			1M	270	752	528
	≥ 2µm: Report result (particles/container)	5 °C ± 3 °C	T0	3435	2270	1939
			1M	1744	5432	3168
		25 °C ± 2 °C	T0	3435	2270	1939
			1M	2635	4955	3408
		40 °C ± 2 °C	T0	3435	2270	1939
			1M	2288	4008	4294
cIEF	Main Peak ≥ 40.0%	5 °C ± 3 °C	T0	67.2	66.2	66.2
			1M	67.8	67.7	66.0

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202421682	Batch 8H5D	Batch 9G7S
		25 °C ± 2 °C	T0	67.2	66.2	66.2
			1M	65.6	65.9	64.5
		40 °C ± 2 °C	T0	67.2	66.2	66.2
			1M	51.1	51.2	50.7
	Acidic Species ≤ 60.0%	5 °C ± 3 °C	T0	18.3	19.9	21.2
			1M	18.4	19.1	21.3
		25 °C ± 2 °C	T0	18.3	19.9	21.2
			1M	21.1	21.1	22.9
		40 °C ± 2 °C	T0	18.3	19.9	21.2
			1M	37.2	37.4	38.7
	Basic Species ≤ 30.0%	5 °C ± 3 °C	T0	14.5	13.9	12.6
			1M	13.8	13.2	12.7
		25 °C ± 2 °C	T0	14.5	13.9	12.6
			1M	13.3	13.0	12.6
		40 °C ± 2 °C	T0	14.5	13.9	12.6
			1M	11.8	11.4	10.6
SE-HPLC	Main Peak (monomer) ≥ 90.0%	5 °C ± 3 °C	T0	98.3	98.4	98.3
			1M	98.3	98.2	98.1
		25 °C ± 2 °C	T0	98.3	98.4	98.3
			1M	98.2	98.0	97.9
			T0	98.3	98.4	98.3

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202421682	Batch 8H5D	Batch 9G7S
	HMW species \leq 10.0%	40 °C \pm 2 °C	1M	97.4	97.1	97.0
		5 °C \pm 3 °C	T0	1.7	1.6	1.6
		25 °C \pm 2 °C	1M	1.6	1.8	1.9
			T0	1.7	1.6	1.6
			1M	1.7	1.9	2.0
			T0	1.7	1.6	1.6
		40 °C \pm 2 °C	1M	2.1	2.3	2.5
Reduced CE-SDS	Purity (LC+HC) \geq 90.0%	5 °C \pm 3 °C	T0	98.7	98.5	98.4
			1M	98.4	98.3	98.3
		25 °C \pm 2 °C	T0	98.7	98.5	98.4
			1M	98.2	98.2	98.1
		40 °C \pm 2 °C	T0	98.7	98.5	98.4
			1M	97.5	97.1	97.0
Non-reduced CE-SDS	Main Peak \geq 90.0%	5 °C \pm 3 °C	T0	99.4	99.4	99.3
			1M	99.4	99.3	99.3
		25 °C \pm 2 °C	T0	99.4	99.4	99.3
			1M	99.3	99.2	99.2
		40 °C \pm 2 °C	T0	99.4	99.4	99.3
			1M	96.9	96.6	96.4
Potency by Binding ELISA	60%-140% relative potency	5 °C \pm 3 °C	T0	114	94	102
			1M	99	97	103
			T0	114	94	102

Analytical Test	Comparability Acceptance Criteria	Condition	Time Point	Batch 202421682	Batch 8H5D	Batch 9G7S
		25 °C ± 2 °C	1M	100	90	103
		40 °C ± 2 °C	T0	114	94	102
			1M	100	90	0.035
PS80	Report result % (w/v)	5 °C ± 3 °C	T0	NT ^a	0.034	0.034
			1M	0.032	0.035	0.035
		25 °C ± 2 °C	T0	NT ^b	0.034	0.034
			1M		0.031	NT ^b
		40 °C ± 2 °C	T0		0.034	0.034
			1M		NT ^b	
		CCIT	Pass	5 °C ± 3 °C	T0	NT ^c
12M	NA ^d					
25 °C ± 2 °C	T0			NT ^c		
	12M			NA ^d		
40 °C ± 2 °C	T0			NT ^c		
	12M			NA ^d		

Abbreviations: NA = not available, NT = not tested

^a PS80 by HPLC-ELSD was in development at the time of release testing for batch 202421682.

^b Per stability protocol, PS80 is not tested at 1M accelerated and stressed conditions for other batches except that batch 8H5D is tested for 1M 25°C.

^c The CCIT test method in PPD is not ready at the time of testing

^d Per stability protocol, CCIT is tested annually and data is not available yet.

4.3 Characterization Testing Results

To provide further assurance that two clinical drug product batches manufactured WuXi are comparable in quality to the three drug product batches manufactured at Parma, the extended characterization assays were included as part of this comparability evaluation. The assays were performed side-by-side when possible. The acceptance criteria and rationale for the inclusion of each method are described in subsequent sections. The results are summarized in [Table 5](#). The extended characterization results demonstrate that the quality of the drug products produced at WuXi is comparable to that manufactured at Parma.

Table 5. Comparison of Extended Characterization Data from Sotrovimab two clinical (Gen2, WuXi) batches and three commercial (Gen2, Parma) batches

Analytical Test	Comparability Acceptance Criteria	Gen2 WuXi DP		Gen2 Parma GSK DP		
		202009005	202010006	202421682	8H5D	9G7S
Near- and Far UV CD	Spectra should be visually comparable based on number, relative intensity, and wavelength of spectral minima and maxima	Comparable	Comparable	Comparable	Comparable	Comparable
Differential Scanning Calorimetry (DSC)	Absolute difference in apparent transition temperatures (T _m) is comparable (≤ 1.0 °C) between Gen2 WuXi batches and Gen2 Parma GSK batches)	T _{m1} = 68.8°C T _{m2} = 74.9°C T _{m3} = 79.2°C	T _{m1} = 69.0°C T _{m2} = 75.0°C T _{m3} = 79.7°C	T _{m1} = 68.8°C T _{m2} = 75.1°C T _{m3} = 79.5°C	T _{m1} = 68.8°C T _{m2} = 75.0°C T _{m3} = 79.6°C	T _{m1} = 69.0°C T _{m2} = 75.0°C T _{m3} = 79.9°C
	Visual comparability of the DSC profile, T _{m1} and T _{m2}	Comparable	Comparable	Comparable	Comparable	Comparable

Analytical Test	Comparability Acceptance Criteria	Gen2 WuXi DP		Gen2 Parma GSK DP		
		202009005	202010006	202421682	8H5D	9G7S
SEC-MALS	Comparable molecular weight of the monomer peak between Gen2 WuXi batches and Gen2 Parma GSK batches	Monomer = 144.1 kDa	Monomer = 144.4 kDa	Monomer = 144.1 kDa	Monomer = 144.2 kDa	Monomer = 144.1 kDa
	Comparable molecular weight of aggregate peaks should be observed between Gen2 WuXi batches and Gen2 Parma GSK batches for aggregate peaks with reliable MW measurements	HMW1 = 328.2 kDa HMW2 = n/a ^a	HMW1 = 346.3 kDa HMW2 = n/a ^a	HMW1 = 348.8 kDa HMW2 = n/a ^a	HMW1 = 387.4 kDa HMW2 = n/a ^a	HMW1 = 380.1 kDa HMW2 = n/a ^a
Sub-visible particles by MFI	Comparable level of sub-visible particles between Gen2 WuXi DP batches and Gen2 Parma GSK DP batches	$\geq 2 \mu\text{m} < 100 \mu\text{m}$ = 5185 p/mL	$\geq 2 \mu\text{m} < 100 \mu\text{m}$ = 8944 p/mL	$\geq 2 \mu\text{m} < 100 \mu\text{m}$ = 1228 p/mL	$\geq 2 \mu\text{m} < 100 \mu\text{m}$ = 1880 p/mL	$\geq 2 \mu\text{m} < 100 \mu\text{m}$ = 5521 p/mL
		$\geq 5 \mu\text{m} < 100 \mu\text{m}$ = 342 p/mL	$\geq 5 \mu\text{m} < 100 \mu\text{m}$ = 311 p/mL	$\geq 5 \mu\text{m} < 100 \mu\text{m}$ = 156 p/mL	$\geq 5 \mu\text{m} < 100 \mu\text{m}$ = 219 p/mL	$\geq 5 \mu\text{m} < 100 \mu\text{m}$ = 180 p/mL
		$\geq 10 \mu\text{m} < 100 \mu\text{m}$ = 3 p/mL	$\geq 10 \mu\text{m} < 100 \mu\text{m}$ = 3 p/mL	$\geq 10 \mu\text{m} < 100 \mu\text{m}$ = 8 p/mL	$\geq 10 \mu\text{m} < 100 \mu\text{m}$ = 8 p/mL	$\geq 10 \mu\text{m} < 100 \mu\text{m}$ = 10 p/mL
		$\geq 25 \mu\text{m} < 100 \mu\text{m}$ = 0 p/mL	$\geq 25 \mu\text{m} < 100 \mu\text{m}$ = 0 p/mL	$\geq 25 \mu\text{m} < 100 \mu\text{m}$ = 0 p/mL	$\geq 25 \mu\text{m} < 100 \mu\text{m}$ = 0 p/mL	$\geq 25 \mu\text{m} < 100 \mu\text{m}$ = 0 p/mL
Pseudovirus neutralization	Comparable relative potency levels observed between Gen2 WuXi DP batches and Gen2 Parma GSK DP batches	97%	91%	81%	100%	109%

^a Molecular weight values not reported for HMW2 due to relatively low abundance and observed high standard deviations across the peak

4.3.1 Size Exclusion Chromatography with Multi-Angle Light Scattering (SEC-MALS)

4.3.1.1 Method Description

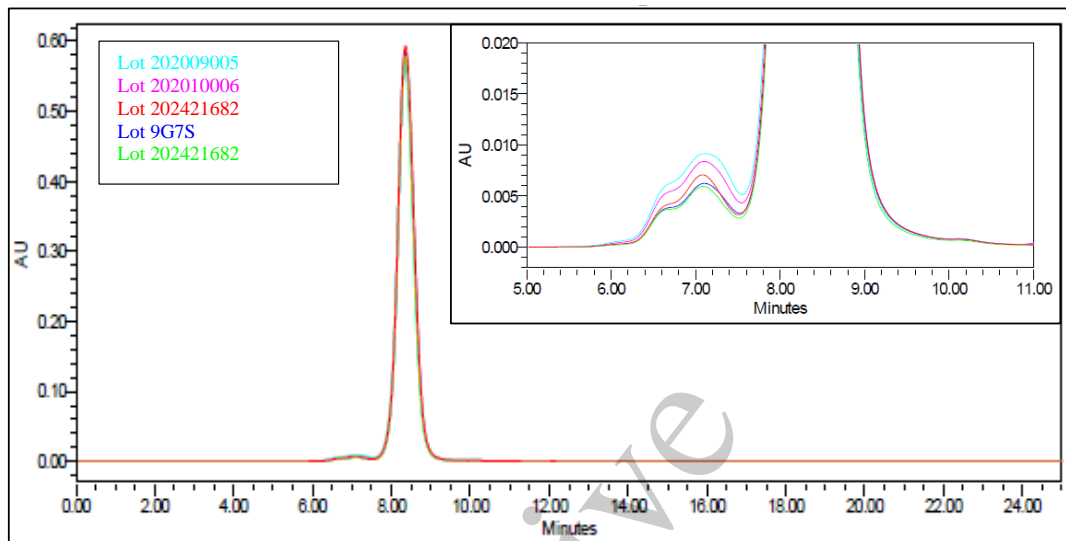
The molecular weight for each component in Sotrovimab samples is determined by SEC-MALS with UV and DAWN-HELEOS II MALS coupled with QELS photometer in series with an Optilab T-rEX refractive index detector. The separation was conducted at 30 °C using isocratic flow of a mobile phase (consisting of phosphate/arginine buffered saline containing 10% IPA) at 1 ml/min. MALS analysis was performed continuously on the SEC column eluate as it passed through the photometer. Data were analyzed using Astra software version 6.1.2.84

4.3.1.2 Results

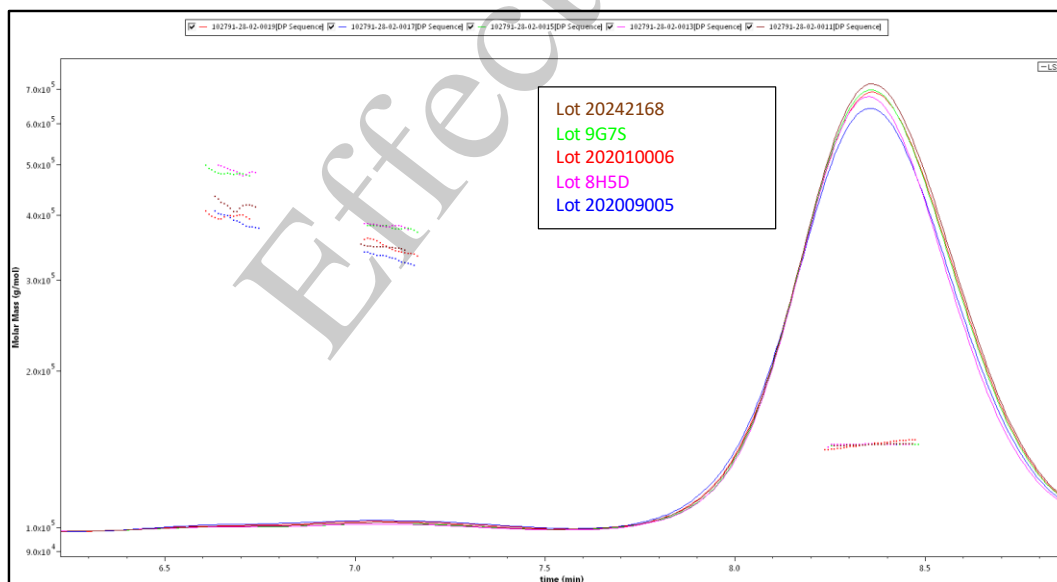
The average molecular weights (MWs) for monomer and HMW1 are summarized in Table 5. SEC chromatograms and molar mass distribution for each peak are shown in The average molecular weights of monomer for all batches are highly similar. The average MWs of HMW1 from two clinical batches produced at WuXi range from 328.2 kDa to 346.3 kDa while the MWs of HMW1 from three clinical and commercial batches produced at Parma range from 348.8 to 387.2 kDa. The difference in molecular weights for HMW1 is likely due to relatively lower abundance resulting in larger assay variability. The chromatograms and mass distribution profiles are comparable for all batches. Overall, SEC-MALS results support the conclusion of analytical comparability between batches manufactured at WuXi and those manufactured at Parma.

. The average molecular weights of monomer for all batches are highly similar. The average MWs of HMW1 from two clinical batches produced at WuXi range from 328.2 kDa to 346.3 kDa while the MWs of HMW1 from three clinical and commercial batches produced at Parma range from 348.8 to 387.2 kDa. The difference in molecular weights for HMW1 is likely due to relatively lower abundance resulting in larger assay variability. The chromatograms and mass distribution profiles are comparable for all batches. Overall, SEC-MALS results support the conclusion of analytical comparability between batches manufactured at WuXi and those manufactured at Parma.

Figure 1. Overlaid SEC Chromatograms and molar mass distributions of Sotrovimab Gen2 WuXi batches and Gen2 Parma GSK batches



M-files IDs: 1697326



4.3.2 Differential Scanning Calorimetry (DSC)

4.3.2.1 Method Description

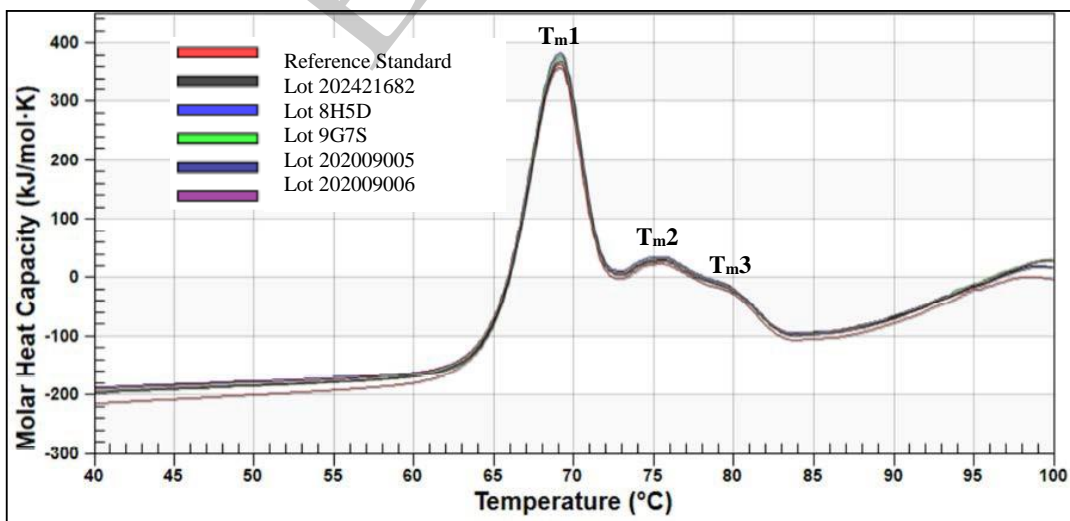
Differential Scanning Calorimetry (DSC) is used to measure thermal stability of Sotrovimab samples and assess conformational differences between them. Proteins unfold when subjected to heat enough to disrupt the non-covalent, hydrophobic and electrostatic

interactions responsible for maintaining their structure. The temperature at which the transition from folded to unfolded state occurs is typically reflective of the protein's stability in the formulation. A typical thermogram consists of a plot of the specific heat capacity of the system (C_p) as function of temperature. In case of multidomain proteins the DSC data are fitted to a non-two state model accounting for the number of the observed thermal transitions in the sample. Apparent transition temperatures (T_m) are determined directly from the individual peak maxima in the DSC melting curve. Samples are considered comparable if the difference in apparent T_m is $\leq 1^\circ\text{C}$.

4.3.2.2 Results

The melting temperature for all batches are summarized in [Table 5](#) and representative thermograms are shown in **Error! Reference source not found.**. The reported values are averages of multiple measurements. The first transition temperatures (T_{m1}) at approximately 68°C were attributed to the unfolding of the Fab domain of the Fc fragment. The second transition temperatures (T_{m2}) at approximately 76°C were likely attributed to the unfolding of both CH2 and CH3 domain of the Fc fragment. The thermograms are visually similar for all Sotrovimab batches. All samples meet the acceptance criteria that the absolute difference in apparent transition temperatures (T_m s) are $\leq 1.0^\circ\text{C}$ when compared to the reference standard. These results indicate the heat induced conformational transitions between Sotrovimab Gen2 drug product clinical batches produced at WuXi and Gen2 drug product clinical and commercial batches manufactured at Parma are comparable.

Figure 2. Overlaid DSC thermograms of Sotrovimab Gen2 WuXi batches and Gen2 Parma GSK batches



4.3.3 Near- and Far- UV Circular Dichroism (CD)

4.3.3.1 Method Description

Circular dichroism (CD) spectroscopy measured the difference in absorbance of the right- and the left- circularly polarized light by the drug substance. Far- and Near-UV Circular dichroism (CD) spectroscopy is used to characterize the secondary and tertiary structure of Sotrovimab samples. A plot of mean residue ellipticity is calculated as a function of the wavelength. The near UV region from 250 to 350 nm and Far-UV CD between 190 nm – 250 nm are examined qualitatively for comparability.

4.3.3.2 Results

Results of near- and Far-UV CD analysis are shown in [Table 5](#) and representative spectra are shown in [Figure 3](#) and [Figure 4](#). The CD spectra exhibit visually comparable profiles for Sotrovimab Gen2 WuXi batches and Gen2 Parma GSK batches. When compared against the reference standard, all samples met the acceptance criteria of comparable spectra. These results indicate that the secondary and tertiary structures of Sotrovimab Gen2 WuXi batches and Gen2 GSK Parma batches are comparable.

Figure 3. Overlaid Near-UV CD spectra of Sotrovimab Gen2 WuXi batches and Gen2 Parma GSK batches

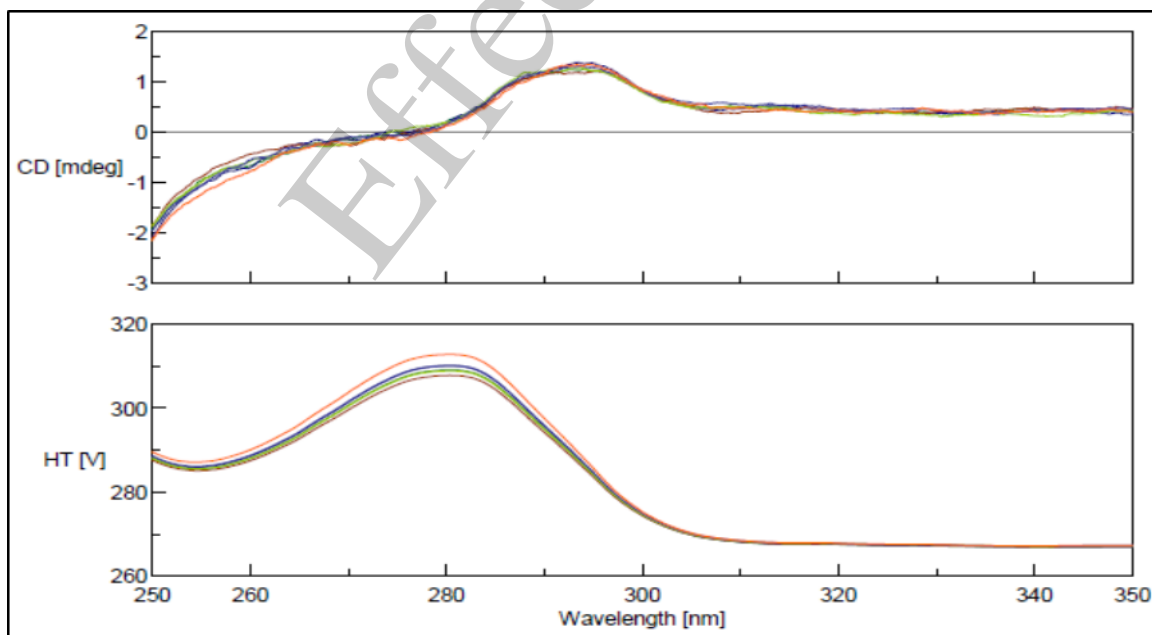
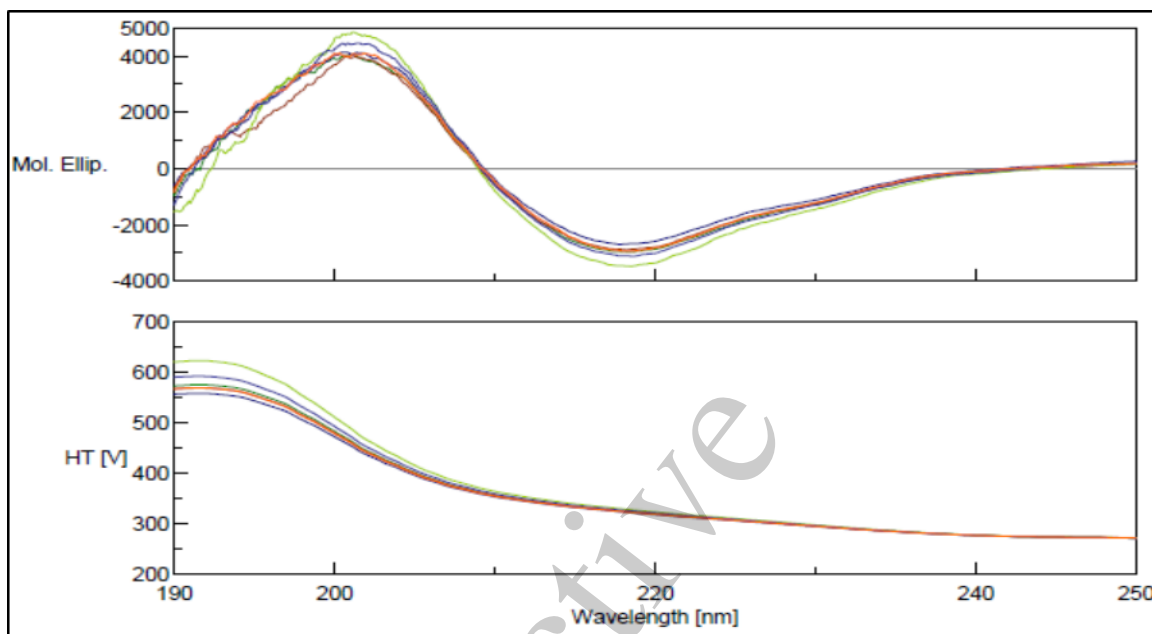


Figure 4. Far-UV CD spectra of Sotrovimab Gen2 WuXi batches and Gen2 Parma GSK batches



4.3.4 Pseudovirus Neutralization

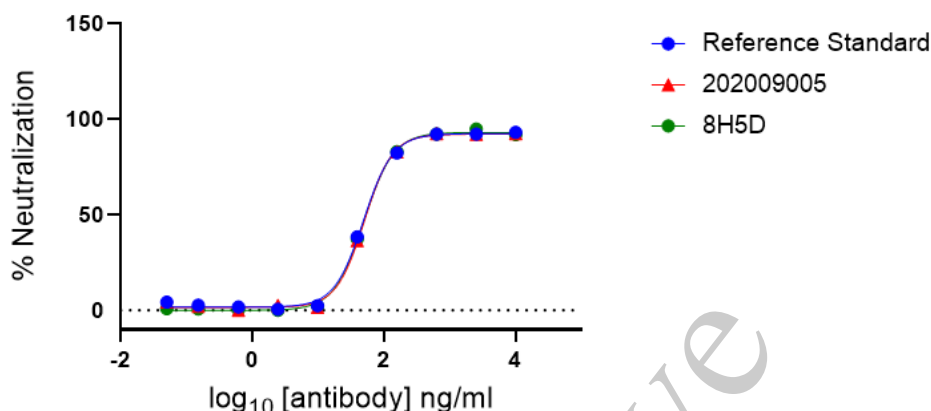
4.3.4.1 Method Description

A cell-based viral neutralization assay is used to determine if an antibody is capable of inhibiting virus replication (or in other words, an antibody that can prevent virus infection). Vero E6 cells are infected with a fixed amount of pseudovirus (a vesicular stomatitis virus expressing luciferase and CoV-2 spike protein) in the presence of the Sotrovimab antibody in increasing concentrations. Neutralization is determined by quantifying the amount of luminescence post-infection.

4.3.4.2 Results

The relative potency levels for all batches are summarized in [Table 5](#) and the representative *in vitro* pseudovirus neutralization curves are shown in [Figure 5](#). Relative potency level between two clinical batches produced at WuXi and three clinical and commercial batches manufactured at Parma are comparable. The *in vitro* pseudovirus neutralization curves profile for all batches are highly similar. Overall, the Gen2 WuXi batches and Gen2 Parma GSK batches have comparable pseudovirus neutralization potency.

Figure 5. Representative pseudovirus neutralization curves of Comparison between Sotrovimab Gen2 WuXi batches and Gen2 GSK Parma batches by Pseudovirus Neutralization Assays



4.3.5 Subvisible particles MFI

4.3.5.1 Method Description

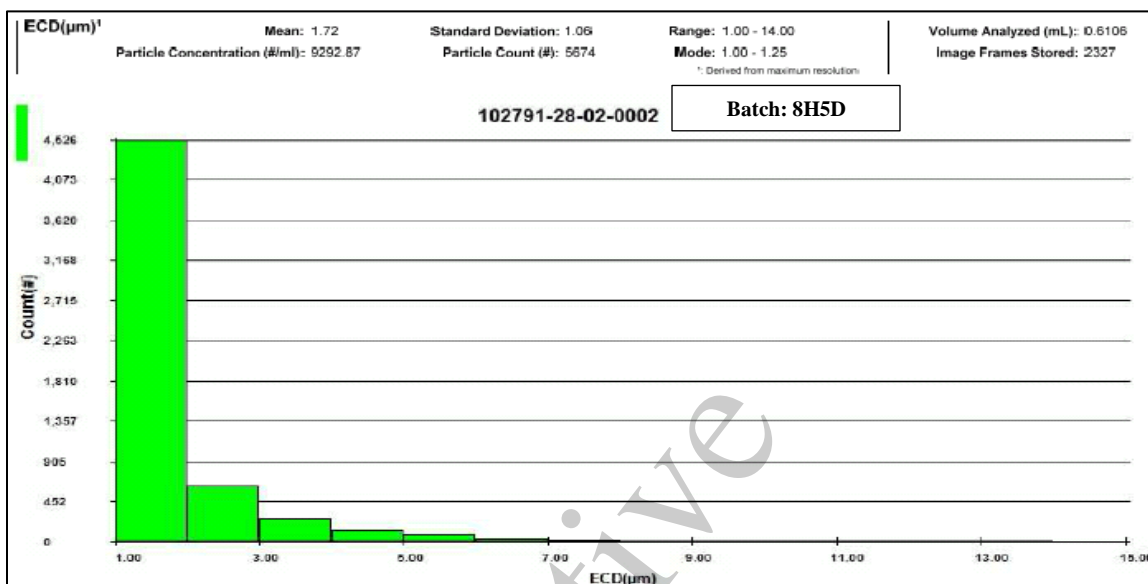
MFI is a flow microscopy technology, where bright field images are captured in successive frames as a continuous sample stream passes through a flow cell centered in the field-of-view of a custom magnification system having a well-characterized and extended depth-of-field.

MFI protein Simple DPA 5200 or equivalent instrument was used to visualize each sample run. SP3_100 flow cells were manually focused using certified polystyrene standard beads in citrate buffer and the instrument segmentation threshold values were set for each particle type. Particle duplicates or particle fragments were manually removed from the data prior to analysis even after optimizing segmentation threshold settings. The final data were analyzed with MFI view system software and MFI view analysis software (MVAS v1.3).

4.3.5.2 Results

The particle counts for MFI analysis are shown in [Table 5](#) and representative spectra are shown in Error! Reference source not found.. Comparable level of sub-visible particles between Gen2 WuXi DP batches and Gen2 Parma GSK DP batches, which indicate that the Sub-visible particle levels by MFI of Sotrovimab Gen2 WuXi DP batches and Gen2 Parma GSK DP batches are comparable.

Figure 6. Representative particle distribution for MFI analysis of Sotrovimab Gen2 GSK Parma batch



5 SOTROVIMAB GEN2 WUXI BATCHES AND GEN2 PARMA GSK BATCHES COMPARABILITY STUDY CONCLUSIONS

Analysis of release data demonstrate a high level of product quality consistency between drug products manufactured at WuXi and those produced at GSK Parma. Although slightly higher percentage of main peak and lower percentage of acidic peak were observed in GSK Parma batches, the minor difference is inherited from DS batches and has no negative impact on the product quality, instead, it is an indication of improvement on product quality. Extended characterization data indicate that no impactful difference in primary, secondary, or tertiary structures are observed between two processes and manufacturing sites. The drug product stressed stability study showed comparable results at recommended conditions and similar trend at stressed conditions up to 1 month. The stability under the recommended storage condition will continue to be monitored during the lifetime of the product. Taken together, the analytical results from the 3 components of the comparability assessment (release data, extended characterization and stressed stability) have shown that drug products manufactured from WuXi clinical process are comparable to those manufactured from GSK Parma clinical and commercial process.

6 REFERENCES

VQD-SPEC-027213 Specifications for VIR-7831/Sotrovimab Drug Product

VQD-RPT-052783	Vir-7831 CQA Assessment (MC# 1100-00776-AD)
VQD-OPS-022179	Certificate of Analysis for Vir-7831 Drug Product 62.6mg/ml Batch 8H5D
VQD-OPS-022180	Certificate of Analysis for Vir-7831 Drug Product 62.6mg/ml Batch 9G7S
GUI_00000150099_CQA	Points to Consider in Determining Critical Quality Attributes for Therapeutic Monoclonal Antibodies
VQD-PRTL-017649	Stability Pro Forma for VIR-7831 Drug Product 62.5 mg/mL Engineering Batch Manufactured at GSK Parma
VQD-PRTL-018916	Stability Pro Forma for VIR-7831 Drug Product 62.5 mg/mL GMP Batches Manufactured at GSK Parma
PPD SOP UD009	Out of Specification Laboratory Investigations
M20279 (PPD)	Characterization of VIR-7831 Binding Affinity to Fc Receptors by Surface Plasmon Resonance (SPR)
M20158 (PPD)	Ultra High Performance Liquid Chromatographic Method for the Carbohydrate Analysis by N-Glycan Profiling of VIR-7831 Drug Substance
M20412 (PPD)	Quantitation of Free Thiols in VIR-7831 Using Measure-iT™ Thiol Assay Kit
M19930 (PPD)	Purity Analysis of VIR-7831 Drug Substance and Drug Product by Reduced Capillary Electrophoresis

7 CHANGES AND REASONS

Changes	Reasons
New document	New document

Appendix 1 Overview of the Changes to the Sotrovimab DP Manufacturing Process.

Drug Product Manufacturing Process	Gen2 (Clinical) - 9000 Vial Process	Gen2 (Clinical and Commercial) - 45000 Vial Process
Manufacturing Site	WuXi Biologics, WuXi City (China)	GSK, Parma (Italy)
Vial	10R type I glass Schott (Vendor)	10R type 1 glass Ompi (Vendor)

Drug Product Manufacturing Process	Gen2 (Clinical) - 9000 Vial Process	Gen2 (Clinical and Commercial) - 45000 Vial Process
Stopper	20mm/Chlorobutyl Rubber Serum Stopper with compound film, 20mm/Grey (Drawing 791)	20mm/Chlorobutyl Rubber Serum Stopper with compound film, 20mm/Grey (Drawing 1343)
Diluent Manufacture	35-40L	170L (Scale increase)
Mixing Bag	Millipore Mobius Mix 100 – 100L	Sartorius LevMix Flexel 400L
Peristaltic Pump	Bosch	Bosch
Filling line	Bosch (Wuxi City, China) (3.5mm Needle ID)	Bosch (Parma, Italy) (2.1 - 3.0mm Needle ID)
Maximum Batch Size	80L (~9000 vials)	400L (~45000 vials) ^a
Sterilization by Filtration ^b	Millipak 200 (1000 cm ² surface area)	Opticap XL4 (0.19 m ² surface area)
Crimping	Metal aluminum overseal with blue flip off cap (colour)	Metal aluminum overseal with white flip off cap (colour)
BDS Concentration (primary container)	100 mg/mL (2L PC bottles)	100 mg/mL (2L PC bottles, 12L FFT bags)
Drug Product Concentration	62.5 mg/mL	62.5 mg/mL
Filling and Stoppering	8.5mL nominal fill volume	8.6 mL nominal fill volume

Appendix 2 Justification of testing the rejected vials from Sotrovimab DP clinical process (Gen2, WuXi) batch 202010006 for comparability study

According to the comparability protocol (VQD-PRTL-018831) for Sotrovimab DP comparability between Gen2, WuXi and Gen2, Parma, DP clinical process (Gen2, WuXi) batch 202010006 is included in the comparability study panel. A rejected vial from batch 202010006 was used for the pseudovirus characterization testing after assessing that the minor stopper vial defect would not be expected to impact product quality and confirming that the vial had been shipped and stored appropriately. Further details are provided.

The rejected vials are naked vials labelled as “SD” for rejected reason on the cap. The “SD” is the defect symbol for any of the following three defects:

- Black Spot in the Stopper: Black spot in the stopper, and it will not drop off when investigating /rotating vial.
- Stopper appearance: Appearance deformation or out-of-shape condition of the stopper, such as pitted, dented, deep scratch marks, cut offs, deformed.
- Cosmetic Defects: Other defects which can affect the stopper cosmetic appearance.

The detailed tracing of the cold chain and storage information after manufacturing confirms that the vials were stored at the appropriate long-term storage condition 2-8 °C after rejection and during/after shipment.

Therefore, upon detailed checking of the cold chain and storage information for the rejected vials, the material inside these vials are appropriate to use for pseudovirus neutralization assay in the comparability characterization study.

Appendix 3 Sotrovimab Sequence as Predicted by cDNA

Heavy Chain

1 QVQLVQSGAE VKKPGASVKV SCKASGYPT SYGISWVRQA PGQGLEWMGW
 51 ISTYQGNTRY AOKFQGRVTM TTDSTTTGY MELRRLRSDD TAVYYCARDY
 101 TRGAWFGESL IGGFDNWGQG TLVTVSSAST KGPSVFPLAP SSKSTSGGTA
 151 ALGCLVKDYF PEPVTVSWNS GALTSGVHTF PAVLQSSGLY SLSSVVTGPS
 201 SSLGTQTYIC NVNHKPSNTK VDKKVEPKSC DKTHTCPPCP APELLGGPSV
 251 FLFPPKPKDT LMISRTPEVT CVVVDVSHED PEVKFNWYVD GVEVHNAKTK
 301 PREEQYNSTY RVVSVLTVLH QDWLNGKEYK CKVSNKALPA PIEKTISKAK
 351 GQPREPQVYT LPPSRDELTK NQVSLTCLVK GFYPSDIAVE WESNGQPENN
 401 YKTTTPVLDS DGSFFLYSKL TVDKSRWQQG NVFSCSVLHE ALHSHYTQKS
 451 LSLSPGK

Light Chain

1 EIVLTQSPGT LSLSPGERAT LSCRASQTVS STSLAWYQQK PGQAPRLLIY
 51 GASSRATGIP DRFSGSGSGT DFTLTISRLE PEDFAVYYCQ QHDTSLTTFGG
 101 GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNIFY PREAKVQWKV
 151 DNALQSGNSQ ESVTEQDSKD STYLSSTLT LSKADYEKHK VYACEVTHQG
 201 LSSPVTKSFN RGEC

CDRs are underlined

Appendix 4 Abbreviations

Acronym	Description
CD	Circular Dichroism
CoA	Certificate of Analysis
CQA	Critical Quality Attribute
CTM	Clinical Trial Material
DSC	Differential Scanning Calorimetry
DP	Drug Product

Acronym	Description
FIO	For Information Only
HC	Heavy Chain
HMW	High Molecular Weight
LC	Light Chain
LMW	Low Molecular Weight
MFI	Micro-flow imaging
Near UV-CD	Near-Ultraviolet Circular Dichroism
NGHC	Nonglycosylated Heavy Chain
PPD	PPD Laboratories
PTMs	Post Translational Modifications
PTM	Pivotal Trial Material
RS, PRS, WRS	Reference Standard (Primary Reference Standard and Working Reference Standard)
SEC-MALS	Size Exclusion Chromatography - Multi-Angle Light Scattering
Sotrovimab	Vir-7831, WBP2275
TBD	To Be Determined
UHPLC	Ultra High Performance Liquid Chromatography
UV	Ultraviolet

Sotrovimab DP Comparability Report 2000L vs 6x2000L

Document Approvals by Electronic Signature

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Verdict: Approve	Sheetal Girase sg552863 (sheetal.x.girase@gsk.com) Quality Assurance Approval 29-Jul-2021 15:59:32 GMT+0000