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VIR Biotechnology, Inc.

Report: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

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REPORT	
VIR	**Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months**

1.0 PURPOSE

The purpose of this report is to support the expiry extension of VIR-7831 Gen2 62.5 mg/mL DP (GSK provided EUA Material Lot 2T8F) to 30-months. The current shelf-life for this product is 24-months from date of manufacture (ref: Veeva Doc 10892).

2.0 SCOPE

The scope of this report applies to extension of product shelf-life for VIR-7831 Gen2 62.5 mg/mL DP (GSK provided EUA Material Lot 2T8F). The current expiry date of this clinical material is 18-Feb-2023. Upon approval of this report, the expiry date will be extended to 18-Aug-2023 for this drug product lot.

3.0 DEFINITIONS

Term(s)/ Acronym(s)	Definition(s)
DP	Drug Product
Gen1	Generation 1
Gen2	Generation 2
SEC	Size Exclusion Chromatography
HMW	High Molecular Weight
iCIEF	Isoelectric Focusing
CE-SDS (R)	Reduced Capillary Electrophoresis Sodium Dodecylsulfate
CE-SDS (NR)	Non-Reduced Capillary Electrophoresis Sodium Dodecylsulfate
ELISA	Enzyme-linked Immunosorbent Assay
CCIT	Container Closure Integrity Test
CI	Confidence Interval
SLE	Shelf-Life Extension
SVP	Subvisible Particles
NTU	Nephelometric Turbidity Unit
RH	Relative Humidity

4.0 REFERENCE DOCUMENTS

4.1 Change Control QE-000371 on VEEVA, 30M SLE of VIR-7831 DP (GSK provided EUA Material Lot 2T8F)

4.2 Veeva Document #4100, Specification for VIR-7831_WBP2275 Drug Product [Gen 2 DP]

4.3 Veeva Document #5052, Specification for VIR-7831_ WBP2275 Drug Product [Spec for Gen1 DP]

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4.4 Veeva Document #5963, Stability Study Data Summary Table for VIR-7831_WBP2275 Pilot DP; 6 Month, 25C, Upright, Version 2 [Gen1 Pilot DP – 6M @ 25C]

4.5 Veeva Document #5965, Stability Study Data Summary Table for VIR-7831_WBP2275 Pilot DP; 6 Month, 40C, Upright, Version 1 [Gen1 Pilot DP – 6M @ 40C]

4.6 Veeva Document #6437, Stability Data Summary Table for VIR-7831_WBP2275 DP; 6-Month, 25C, Upright, Version 11 [Gen1 DP 202006002 – 6M @ 25C]

4.7 Veeva Document #6438, Stability Data Summary Table for VIR-7831_WBP2275 DP; 6-Month, 40C, Upright, Version 10 [Gen1 DP 202006002 – 6M @ 40C]

4.8 Veeva Document #7226, Stability Data Summary Table for VIR-7831_WBP2275 DP; 3-Month, 40C, Upright, Version 7 [Gen2 DP 202009005 – 3M @ 40C]

4.9 Veeva Document #7259, Stability Data Summary Table for VIR-7831_WBP2275 DP; 6-Month, 25C, Upright, Ver. 8 [Gen 1 DP 202006004 – 6M @ 25C]

4.10 Veeva Document #7260, Stability Data Summary Table for VIR-7831_WBP2275 DP; 6-Month, 40C, Upright, Ver. 7 [Gen 1 DP 202006004 – 6M @ 40C]

4.11 Veeva Document #7540, Stability Study Data Summary Table for VIR-7831_WBP2275 DP; 3-Month, 40C, Upright, Version 7 [Gen2 DP 202010006 – 3M @ 40C]

4.12 Veeva Document #7756, Stability Study Protocol for VIR-7831_WBP2275 Gen2 DP Lot No. 202010006

4.13 Veeva Document #7772, Stability Study Protocol for VIR-7831_WBP2275 Pilot DP Lot No.: 2275S20200501

4.14 Veeva Document #7773, Stability Study Protocol for WBP2275 (VIR-7831) DP (Lot No: 202006002)

4.15 Veeva Document #7774, Stability Study Protocol for WBP2275 (VIR-7831) DP (Lot No.: 202006004)

4.16 Veeva Document #7775, Stability Study Protocol for WBP2275 (VIR-7831) DP (Lot No.: 202006005)

4.17 Veeva Document #8132, Stability Data Summary Table for VIR-7831_WBP2275 DP; 6-Month, 25C, Upright, Report No. 5836 [Gen2 DP 202009005 – 6M @ 25C]

4.18 Veeva Document #8414, Comparability Assessment of Gen 1 and Gen 2 DP Stability Data for SL Assignments of Gen 2 DP Lots

4.19 Veeva Document #8499, Stability Study Data Summary Table for VIR-7831_WBP2275 Pilot DP, 12 Month, 5C, Upright, Report 6529 [Gen1 Pilot DP – 12M @ 5C]

4.20 Veeva Document #8567, Stability Study Data Summary Table for VIR-7831_WBP2275 DP; 6-Month, 25C, Upright, Report No. 6670 [Gen2 DP 202010006 – 6M @ 25C]

4.21 Veeva Document #10369, Stability Data Summary Table for VIR-7831_WBP2275 DP; 18-Month, 5C, Upright, Report No. 11053 [Gen1 DP 202006004 – 18M @ 5C]

4.22 Veeva Document #10366, Shelf Life Reporting Form_VIR-7831 (Gen2) Shelf Life_24 Month

4.23 Veeva Document #11499, Stability Data Summary Table for VIR-7831_WBP2275 DP; 18-Month, 5C, Upright, Report No. 13787 [Gen2 DP 202009005 – 18M @ 5C]

4.24 Veeva Document #11500, Stability Data Summary Table for VIR-7831_WBP2275 DP; 18-Month, 5C, Upright, Report No. 13788 [Gen2 DP 202010006 – 18M @ 5C]

4.25 Veeva Document #11701, Stability Data Summary Table for VIR-7831_WBP2275 DP; 24-Month, 5C, Upright, Report No. 14782 [Gen1 DP 202006002 – 24M @ 5C]

4.26 Veeva Document #11747, Stability Summary Reports _ 12M _ VIR-7831 (GSK4182136) DP Lots

4.27 Veeva Document #11754, GSK Specifications for VIR-7831 (GSK4182136) DP

5.0 RESPONSIBILITIES

5.1 Quality Control Stability and Data Analytics

5.1.1 Receives approved stability summary data and performs statistical analysis using JMP software.

5.1.2 Authors the stability assessment report and uploads to VEEVA for approval.

5.2 Quality Assurance

5.2.1 Reviews and approves the stability assessment report.

6.0 STABILITY SUMMARY AND CONCLUSIONS

6.1 Summary of Stability Studies

Stability studies of VIR-7831 drug product were conducted in accordance with ICH Q1A(R2): *Stability Testing of New Drug Substances and Products* and ICH Q5C: *Stability Testing of Biotechnological/ Biological Products*. Studies were conducted at the long-term (5±3°C), accelerated (25±2°C/60±5% RH), and stressed (40±2°C/75±5% RH) conditions.

The drug product batches tested on stability and data supporting this expiry extension are summarized in Table 1.

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Table 1: Overview of VIR-7831 Drug Product Stability Studies

DP Lot No.		Date of Manufacture	Purpose	DP Manufacturing Site	Source DS Lot No.	Storage Condition(s)		Study Duration	Available Data	Stability Protocol
Gen1 (25 mg/mL) Lots	2275S20200501	08 May 2020	Pilot Lot	WuXi Biologics, Wuxi	2275S200411Y	Long-term	5 ± 3°C	12 months	12 months	Table 2
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C, 75 ± 5% RH	6 months	6 months	
	202006002	06 Jun 2020	Clinical	WuXi Biologics, Wuxi	2275S20Aa	Long-term	5 ± 3°C	36 months	24 months	Table 3
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C, 75 ± 5% RH	6 months	6 months	
	202006004	24 Jun 2020	Clinical	WuXi Biologics, Wuxi	2275S20Ba	Long-term	5 ± 3°C	36 months	18 months	Table 3
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C, 75 ± 5% RH	6 months	6 months	
Gen2 (62.5 mg/mL) Lots	202009005	11 Sep 2020	Clinical	WuXi Biologics, Wuxi	S227520C	Long-term	5 ± 3°C	60 months	18 months	Table 4
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	

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						Stress	40 ± 2°C, 75 ± 5% RH	3 months	3 months	
	202010006	16 Oct 2020	Clinical	WuXi Biologics, Wuxi	S227520D	Long-term	5 ± 3°C	60 months	18 months	Table 4
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	
	202421682	18 Dec 2020	Engineering Batch	GSK, Parma	0000020103	Long-term	5 ± 3°C	36 months	12 months	Table 5
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	
	8H5D	16 Feb 2021	Clinical	GSK, Parma	0000020106	Long-term	5 ± 3°C	36 months	12 months	Table 5
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	
	9G7S	18 Feb 2021	Clinical	GSK, Parma	0000022793	Long-term	5 ± 3°C	36 months	12 months	Table 5
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	
	CF2J	02 Mar 2021	PPQ	GSK, Parma	0000022793	Long-term	5 ± 3°C	36 months	12 months	Table 5

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						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	
	FW9J	16 Mar 2021	PPQ	GSK, Parma	0000022793 0000023662	Long-term	5 ± 3°C	36 months	12 months	Table 5
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	
	FX4A	17 Mar 2021	PPQ	GSK, Parma	0000023662	Long-term	5 ± 3°C	36 months	12 months	Table 5
						Accelerated	25 ± 2°C, 60 ± 5% RH	6 months	6 months	
						Stress	40 ± 2°C. 75 ± 5% RH	3 months	3 months	

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6.2 Design of Stability Studies

The storage conditions, testing frequency, and analytical methods for VIR-7831 DP stability studies are summarized in Table 2, Table 3, and Table 4 below.

Table 2: Stability Study Protocol for VIR-7831 Gen1 (25 mg/mL) Pilot DP lot 2275S20200501, Upright

Test Method	Time Interval (Month)						
	T0	1	2	3	6	9	12
Color	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Clarity	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
pH	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Protein Concentration	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Visible Particles	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Subvisible Particulate Matter	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Charge Variants by iCIEF	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Purity by SEC-HPLC	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Purity by CE-SDS (reduced)	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Purity by CE-SDS (non-reduced)	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Potency by Binding ELISA	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L
Polysorbate 80	R	NT	NT	NT	NT	NT	L
CCIT	L	NT	NT	NT	NT	NT	L

Abbreviations: A = accelerated (25 ± 2°C / 60 ± 5% RH); L = long-term (5 ± 3°C); M = month(s); NT = not tested per protocol; R = Release Testing; S = stressed (40 ± 2°C / 75 ± 5% RH)

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Table 3: Stability Study Design for VIR-7831 Gen1 (25 mg/mL) Clinical DP lots 202006002 and 202006004, Upright

Test Method	Time Interval (Month)									
	T0	**1**	**2**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Color	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Clarity	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
pH	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Protein Concentration	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Visible Particles	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Subvisible Particulate Matter	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Charge Variants by iCIEF	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Purity by SEC-HPLC	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Purity by CE-SDS (reduced)	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Purity by CE-SDS (non-reduced)	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Potency by Binding ELISA	R	L, A, S	L, A, S	L, A, S	L, A, S	L	L	L	L	L
Polysorbate 80	R	NT	NT	NT	L	NT	L	NT	L	L
CCIT	L	NT	NT	NT	NT	NT	L	NT	L	L

Abbreviations: A = accelerated (25 ± 2°C / 60 ± 5% RH); L = long-term (5 ± 3°C); M = month(s); NT = not tested per protocol; R = Release Testing; S = stressed (40 ± 2°C / 75 ± 5% RH)

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Table 4: Stability Study Design for VIR-7831 Gen2 (62.5 mg/mL) Clinical DP lots 202009005 and 202010006, Upright

Test Method	Time Interval (Month)														
	T0	1	2	3	4	6	9	12	18	24	30	36	42	48	60
Color	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Clarity	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
pH	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Protein Concentration	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Visible Particles	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Subvisible Particulate Matter	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Charge Variants by iCIEF	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Purity by SEC-HPLC	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Purity by CE-SDS (reduced)	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Purity by CE-SDS (non-reduced)	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Potency by Binding ELISA	R	L, A, S	L, A, S	L, A, S	L	L, A, S	L	L	L	L	L	L	L	L	L
Polysorbate 80	R	NT	NT	NT	NT	L	NT	L	NT	L	NT	L	NT	L	L
CCIT	L	NT	NT	NT	NT	NT	NT	L	NT	L	NT	L	NT	L	L

Abbreviations: A = accelerated (25 ± 2°C / 60 ± 5% RH); L = long-term (5 ± 3°C); M = month(s); NT = not tested per protocol; R = Release Testing; S = stressed (40 ± 2°C / 75 ± 5% RH)

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Table 5: Test Schedule for Gen2 62.5 mg/mL, Drug Product Batches Manufactured at GSK Parma, Inverted

Test / Attribute	Stability Timepoints												
	T0	14 D [a]	1 M	2 M [b]	3 M	4 M [b]	6 M	9 M	12 M	18 M	24 M	30M	36 M
Color	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Clarity	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
pH	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Protein concentration	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Visible particles	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Subvisible particles	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Charge heterogeneity by cIEF	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Purity by SE-HPLC	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Purity by CE-SDS (reduced)	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Purity by CE-SDS (non-reduced)	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Potency by binding ELISA	R	A, S	L, A, S	L, A, S	L, A, S	L, A	L, A	L	L	L	L	L	L
Polysorbate 80	R	S [c]	L, A [d,e]	L	L, A [e], S [f]	L	L, A[e]	L	L	L	L	L	L
Sterility	R	NT	NT	NT	NT	NT	NT	NT	NT	NT	NT	NT	L [g]
CCIT	NT	NT	NT	NT	NT	NT	NT	NT	L	NT	L	NT	L

Abbreviations: A = accelerated (25 ± 2°C / 60 ± 5% RH); L = long-term (5 ± 3°C); M = month(s); NT = not tested per protocol; R = Release Testing; S = stressed (40 ± 2°C / 75 ± 5% RH)

[a] Testing at this timepoint for DP PPQ batches is only performed at stress conditions.
[b] Testing at this timepoint is not performed for the DP PPQ batches.
[c] Testing at stress conditions is only performed on DP PPQ batches.
[d] Not performed at accelerated condition for the DP engineering batch.
[e] Polysorbate 80 is not tested at accelerated condition (1, 3 and 6 months timepoints) for DP GMP batch 9G7S
[f] Stressed condition is only performed for engineering batch.
[g] Not performed for DP engineering batch.

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6.3 Data Discussion

6.3.1 Statistical Analysis

Stability data were evaluated for trends at a significance level (α) of 0.05 in accordance with ICH Q1E. Attributes which demonstrated statistically and analytically significant trends as a function of time and temperature were subjected to regression analysis and discussed below. Attributes that did not demonstrate statistical and analytical significant trends were not subjected to trend analysis and were not discussed.

Trends were observed in the data for the following attributes: purity by SEC, purity by iCIEF (acidic, basic, and main charge variant), purity by CE-SDS (Reduced and Non-reduced), and potency.

6.3.1.1 Purity by SEC

Purity by SEC data of the VIR-7831 DP lots demonstrated similar trends. A decreasing trend was observed in the monomer content together with an inverse increasing trend in the HMW content. All data met the stability acceptance criteria for DP purity by SEC as depicted in Figure 1 and Figure 2. Extrapolation of the long-term stability data supports extension of the expiry period for VIR-7831 Gen2 DP to 30-months as depicted in Figure 3 and Figure 4.

Figure 1: Stability Data for SEC (Monomer)

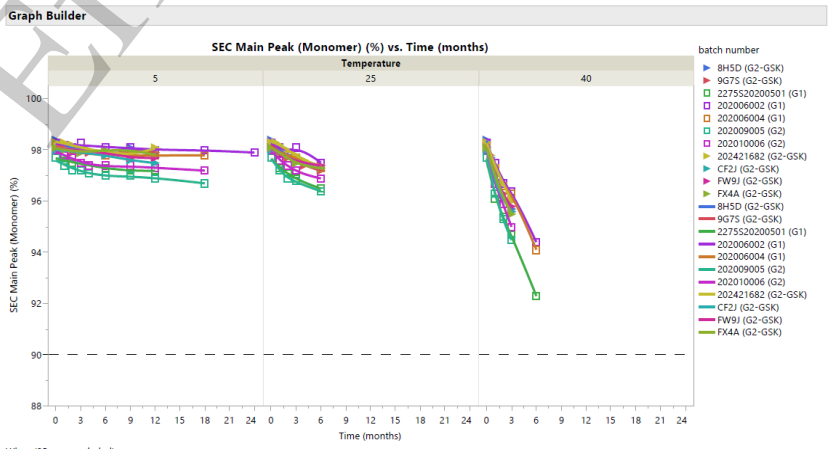

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Figure 2: Stability Data for SEC (HMW)

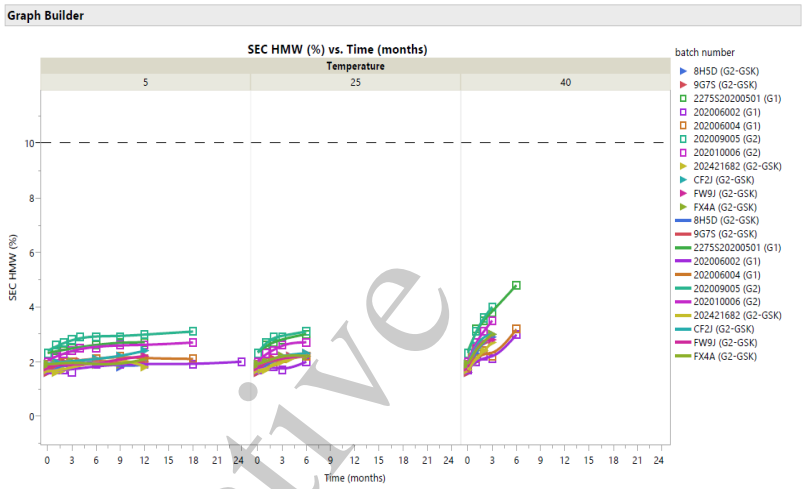

Figure 3: Extrapolation of Long-term Stability Data for SEC (Monomer)

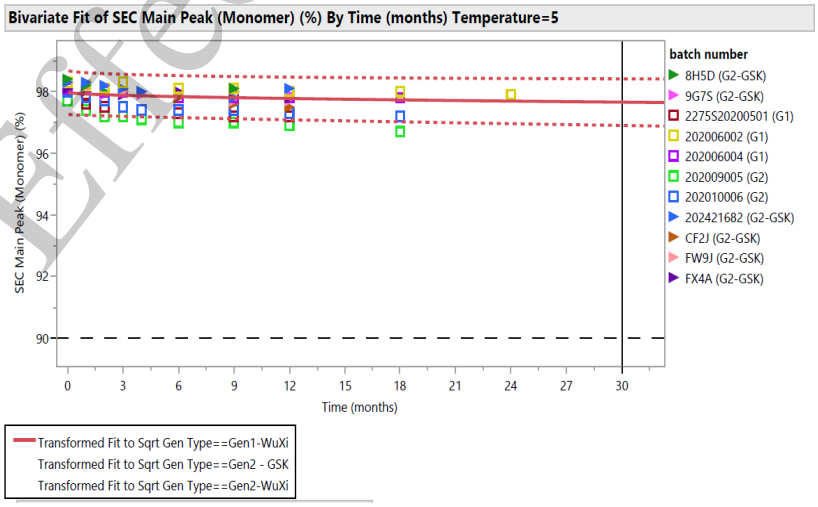

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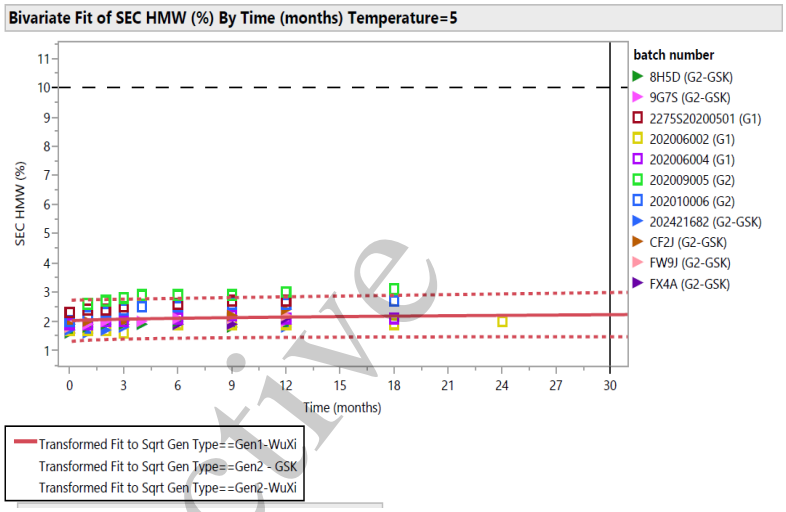
Figure 4: Extrapolation of Long-term Stability Data for SEC (HMW)



6.3.1.2 Purity by iCIEF

Purity by iCIEF data of the VIR-7831 DP lots demonstrated similar trends. A decreasing trend was observed in the main peak together with an inverse increasing trend in the acidic charge variants from analyses of the DP samples stored at accelerated and stressed stability conditions. Datasets for the basic charge variant from analyses of the DP samples at the stressed storage conditions demonstrated a decreasing trend. The long-term and accelerated stability datasets did not exhibit any trend and conformed with stability acceptance criteria as depicted in Figure 5, Figure 6, and Figure 7.

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Figure 5: Stability Data for iCIEF (Main Peak)

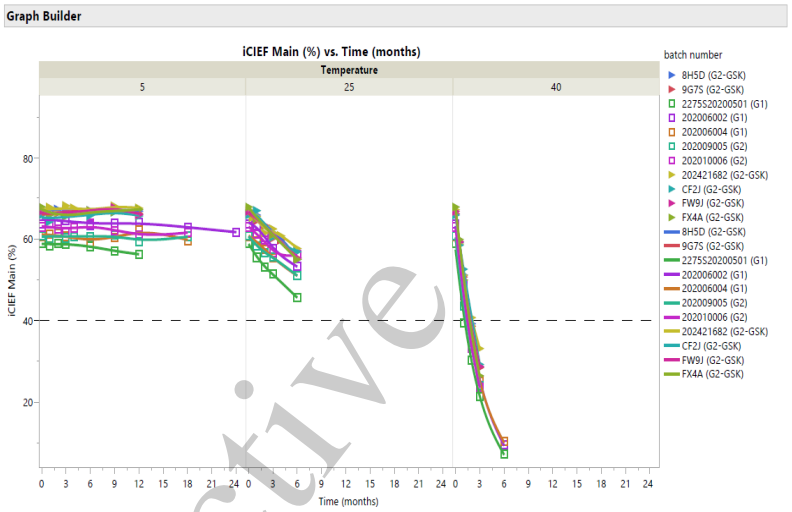

Figure 6: Stability Data for iCIEF (Acidic Species)

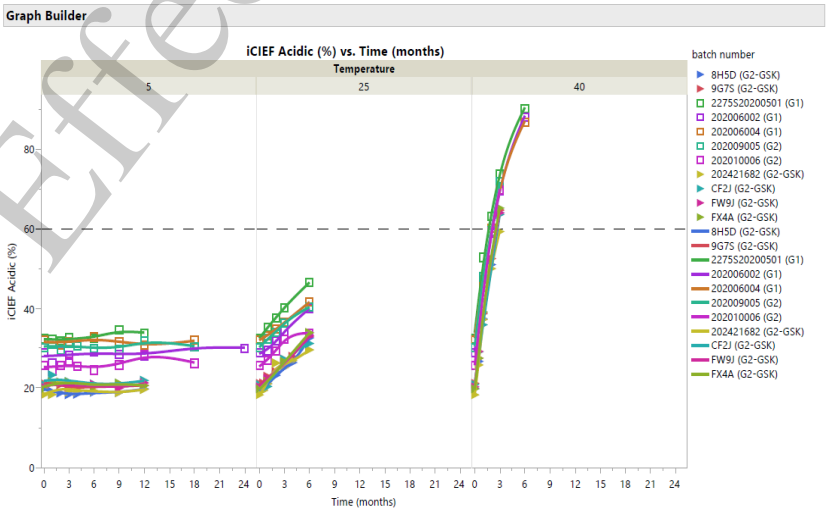

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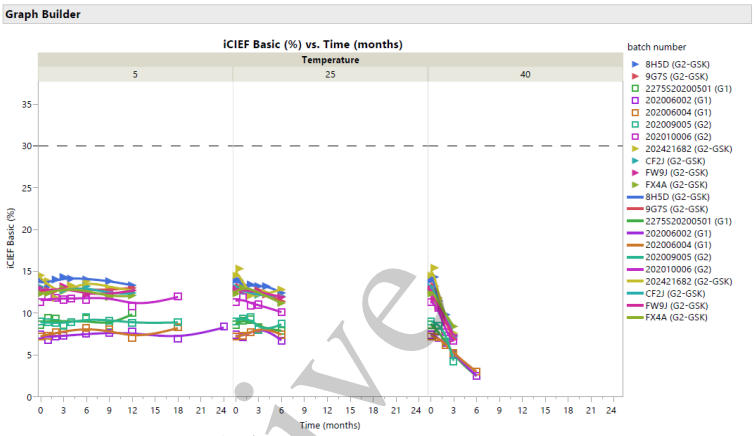
Figure 7: Stability Data for iCIEF (Basic Species)



6.3.1.3 Purity by Reduced CE-SDS (Reduced and Non-reduced)

Purity by CE-SDS (Reduced and Non-reduced) data of the VIR-7831 DP lots at the long-term stability storage condition did not exhibit any trends and have met stability acceptance criteria. Ddata from accelerated and stressed conditions displayed a similar decreasing trend as depicted in Figure 8 and Figure 9.

Figure 8: Stability Data for Reduced CE-SDS

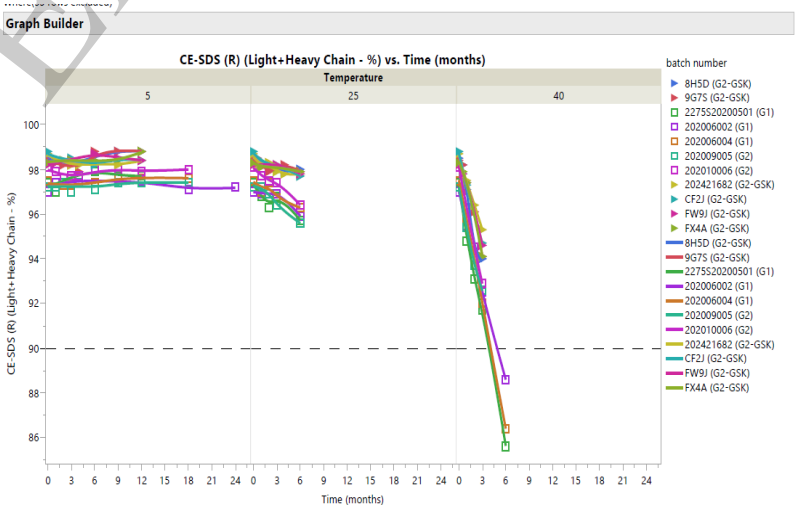


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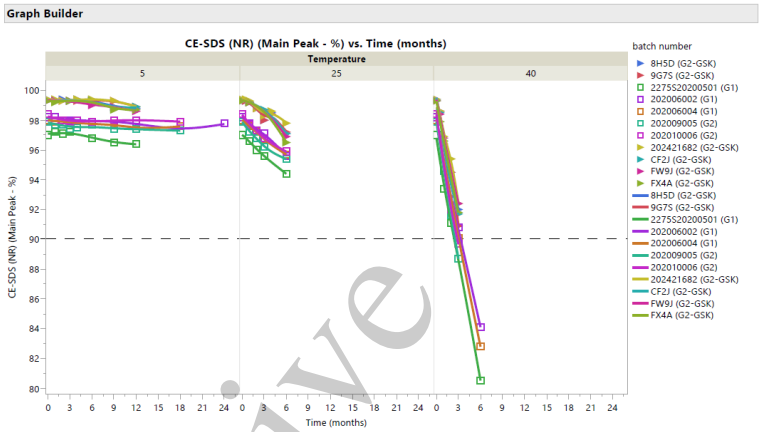
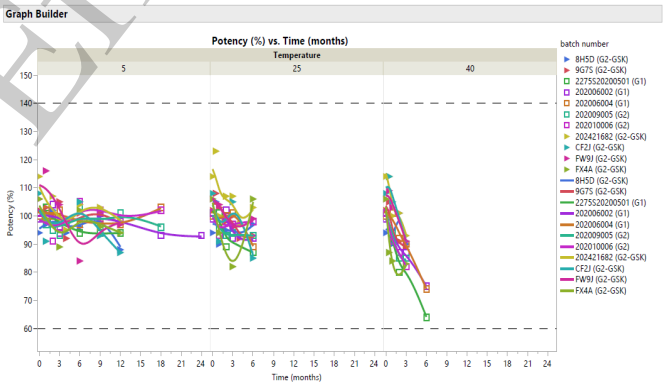
Figure 9: Stability Data for Non-reduced CE-SDS



6.3.1.4 Potency

Potency data sets of the DP samples stored at the accelerated and stressed stability conditions exhibited a downward trend. The decrease was not observed from the datasets from analyses of the DP samples in the long-term storage conditions. All data conformed to stability specifications as depicted in Figure 10.

Figure 10: Stability Data for Potency



6.3.1.5 Other Stability Tests

Data from the other attributes monitored on stability did not indicate any trends with all results conforming to stability acceptance criteria at the long-term storage condition.

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7.0 CONCLUSION

Stability data through 24-months for 7831 Gen1 (25.0 mg/mL) DP lots and 18-months for 7831 Gen2 (62.5 mg/mL) DP lots at the long-term storage condition with all results conforming to acceptance criteria are available. Trends observed in the purity attribute test data were expected for the product.

Based on the availability of the 24-months and 18-months stability data stated in Table 1 and conformance to specifications, an expiry of 30-months will be established for VIR-7831 Gen2 (62.5 mg/mL) drug product (GSK provided EUA Material Lot 2T8F). This 30-month shelf-life extension for EUA Material Lot 2T8F is aligned with the product IMPD in that the shelf-life is extended not more than 6 months past real-time data of the Gen1 DP.

Upon approval of this report, the expiry date for VIR-7831 Gen2 (62.5 mg/mL) DP (GSK provided EUA Material Lot 2T8F) will be extended to 18-Aug-2023 (30 months from date of manufacture).

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8.0 DATA TABLES

8.1 The stability data for VIR-7831 drug product lots are detailed below in Table 6 and Table 7.

Table 6: Summary of VIR-7831 Gen1 (25.0 mg/mL) and Gen2 (62.5 mg/mL) Stability Data Tables (WuXi DP Batches)

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Batch	Purpose	DOM	Stability Start Date	Storage Condition(s)	Study Duration	Available Data	Table
2275S20200501 (Gen1 DP - 25.0 mg/mL)	Pilot	08-May-2020	14-May-2020	5 ± 3°C	12M	12M	Table 8
				25 ± 2°C/ 60 ± 5% RH	6M	6M	Table 9
				40 ± 2°C/ 75 ± 5% RH	6M	6M	Table 10
202006002 (Gen1 DP – 25.0 mg/mL)	Clinical	06-Jun-2020	09-Jun-2020	5 ± 3°C	36M	24M	Table 11
				25 ± 2°C/ 60 ± 5% RH	6M	6M	Table 12
				40 ± 2°C/ 75 ± 5% RH	6M	6M	Table 13
202006004 (Gen1 DP – 25.0 mg/mL)	Clinical	24-Jun-2020	29-Jun-2020	5 ± 3°C	36M	18M	Table 14
				25 ± 2°C/ 60 ± 5% RH	6M	6M	Table 15
				40 ± 2°C/ 75 ± 5% RH	6M	3M	Table 16
202009005 (Gen2 DP – 62.5 mg/mL)	Clinical	11-Sep-2020	19-Sep-2020	5 ± 3°C	60M	18M	Table 17
				25 ± 2°C/ 60 ± 5% RH	6M	6M	Table 18
				40 ± 2°C/ 75 ± 5% RH	3M	3M	Table 19
202010006 (Gen2 DP – 62.5 mg/mL)	Clinical	16-Oct-2020	21-Oct-2020	5 ± 3°C	60M	18M	Table 20
				25 ± 2°C/ 60 ± 5% RH	6M	6M	Table 21
				40 ± 2°C/ 75 ± 5% RH	3M	3M	Table 22

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Table 7: Summary of VIR-7831 Gen2 (62.5 mg/mL) Stability Data Tables (GSK DP Batches)

Batch	Purpose	DOM	Stability Start Date	Storage Condition(s)	Study Duration	Available Data	Table
202121682 (Gen 2 DP – 62.5 mg/mL)	Eng	18-Dec-2020	25-Jan-2021	5 ± 3°C	36M	12M	**Table 23**
				25 ± 2°C/ 60 ± 5% RH	6M	6M	**Table 24**
				40 ± 2°C/ 75 ± 5% RH	3M	3M	**Table 25**
8H5D (Gen 2 DP – 62.5 mg/mL)	Clinical	16-Feb-2021	25-Mar-2021	5 ± 3°C	36M	12M	**Table 26**
				25 ± 2°C/ 60 ± 5% RH	6M	6M	**Table 27**
				40 ± 2°C/ 75 ± 5% RH	3M	3M	**Table 28**
9G7S (Gen 2 DP – 62.5 mg/mL)	Clinical	18-Feb-2021	25-Mar-2021	5 ± 3°C	36M	12M	**Table 29**
				25 ± 2°C/ 60 ± 5% RH	6M	6M	**Table 30**
				40 ± 2°C/ 75 ± 5% RH	3M	3M	**Table 31**
CF2J (Gen 2 DP – 62.5 mg/mL)	PPQ	02-Mar-2021	06-Apr-2021	5 ± 3°C	36M	12M	**Table 32**
				25 ± 2°C/ 60 ± 5% RH	6M	6M	**Table 33**
				40 ± 2°C/ 75 ± 5% RH	3M	3M	**Table 34**
FW9J (Gen 2 DP – 62.5 mg/mL)	PPQ	16-Mar-2021	13-Apr-2021	5 ± 3°C	36M	12M	**Table 35**
				25 ± 2°C/ 60 ± 5% RH	6M	6M	**Table 36**
				40 ± 2°C/ 75 ± 5% RH	3M	3M	**Table 37**
FX4Aa (Gen 2 DP – 62.5 mg/mL)	PPQ	17-Mar-2021	13-Apr-2021	5 ± 3°C	36M	12M	**Table 38**
				25 ± 2°C/ 60 ± 5% RH	6M	6M	**Table 39**
				40 ± 2°C/ 75 ± 5% RH	3M	3M	**Table 40**

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Table 8: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) Pilot Drug Product Lot 2275S20200501 Stored at 5 ± 3°C

Test	Stability Specification[a]	Time Interval (month)						
		0	1	2	3	6	9	12
Color	Report result (Refer to EP)	B8	B8	B8	B8	B8	BY7	BY7
Clarity	Report result (NTU)	5.0	5.7	5.6	5.5	5.2	5.6	6.3
Visible Particles	Essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Sub-visible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	75 2 3000 599	45 0 2649 462	92 5 4077 715	109 2 3334 795	69 7 3524 650	11 0 3867 76	114 7 4119 842
pH	6.0 ± 0.5	6.1	6.0	6.0	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	25.0 ± 2.5 mg/mL	25.0	25.2	25.3	25.4	25.3	25.4	25.3
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 50.0% Basic peaks: ≤ 20.0%	59.0 32.4 8.6	58.3 32.3 9.4	59.0 31.8 9.3	58.8 32.6 8.6	58.2 32.5 9.3	57.0 34.6 8.5	56.3 33.7 10.0
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	97.7 2.3	97.6 2.4	97.5 2.4	97.5 2.5	97.3 2.6	97.2 2.7	97.2 2.7
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	97.4	97.0	97.6	97.7	97.9	97.7	97.7
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	97.0	97.2	97.1	97.2	96.8	96.5	96.4
Potency by Binding ELISA	60 – 140% relative potency	101	103	98	98	94	94	94
Polysorbate 80	Report Result (%) w/v	0.028	NT	NT	NT	NT	NT	< 0.02
CCIT	Pass	Pass	NT	NT	NT	NT	NT	Pass

[a] Specification in effect at time of filling of pilot lot; limits applicable for samples stored in long-term stability conditions.

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Table 9: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) Pilot Drug Product Lot 2275S20200501 Stored at 25 ± 2°C / 60 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B8	B8	BY7	Y7	B7
Clarity	5.0	5.6	5.5	5.4	5.5
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	75	110	69	105	74
≥ 25 µm :	2	2	0	0	4
≥ 2 µm :	3000	3145	3224	5022	5199
≥ 5 µm :	599	639	587	1077	982
pH	6.1	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	25.0	25.1	25.6	25.7	25.2
Charge Variants by iCIEF					
Main peak:	59.0	55.5	53.1	51.5	45.6
Acidic peaks:	32.4	35.3	37.6	40.2	46.5
Basic peaks:	8.6	9.1	9.2	8.3	7.9
Purity by SEC-HPLC					
Main Peak (monomer):	97.7	97.3	97.1	96.9	96.5
HMWS:	2.3	2.6	2.7	2.8	3.0
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.4	96.8	96.3	96.8	95.7
Purity by CE-SDS (Non-Reduced) Mean Peak:	97.0	96.6	96.0	95.6	94.4
Potency by Binding ELISA	101	101	89	92	87

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Table 10: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) Pilot Drug Product Lot 2275S20200501 Stored at 40 ± 2°C / 75 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B8	B7	B6	B6	B5
Clarity	5.0	5.8	5.9	6.6	6.6
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	75	132	135	180	170
≥ 25 µm :	2	2	9	0	4
≥ 2 µm :	3000	3867	3404	5460	7047
≥ 5 µm :	599	990	867	1257	1592
pH	6.1	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	25.0	25.7	25.5	25.4	25.5
Charge Variants by iCIEF					
Main peak:	59.0	39.4	30.3	21.3	7.2
Acidic peaks:	32.4	52.8	63.1	73.7	90.2
Basic peaks:	8.6	7.8	6.6	5.0	2.5
Purity by SEC-HPLC					
Main Peak (monomer):	97.7	96.1	95.4	94.7	92.3
HMWS:	2.3	3.2	3.5	3.8	4.8
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.4	94.8	93.1	91.7	85.6
Purity by CE-SDS (Non-Reduced) Mean Peak:	97.0	93.4	91.1	88.7	80.5
Potency by Binding ELISA	101	92	80	82	64

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Table 11: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) cGMP Drug Product Lot 202006002 Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**2**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Color	Report result (Refer to EP)	B8	B8	B8	B8	B8	B8	B8	B8	B8	X
Clarity	≤ 18.0 NTU	5.6	5.6	5.3	5.3	5.4	5.5	6.0	4.8	5.1	X
Visible Particles	Essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X
Subvisible Particulate Matter	≥ 10 µm : ≤ 6000 particles/container ≥ 25 µm : ≤ 600 particles/container ≥ 2 µm : report result ≥ 5 µm : report result	59 2 2745 499	32 0 2324 358	57 8 2360 400	50 16 2228 485	25 0 2456 378	107 63 3627 619	62 2 4314 780	18 0 3939 458	36 5 4050 509	X
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.1	6.0	6.0	6.1	X
Protein Concentration by UV A_{280}	25.0 ± 2.5 mg/mL	25.5	25.2	25.4	25.3	25.2	25.4	25.8	25.6	25.3	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	63.7 28.9 7.4	66.9 26.3 6.8	63.8 29.1 7.2	64.5 28.2 7.3	63.4 29.2 7.5	63.9 28.5 7.6	64.1 28.1 7.8	62.8 30.4 6.9	61.7 30.0 8.4	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.3 1.7	98.2 1.7	98.1 1.7	98.3 1.6	98.1 1.9	98.1 1.9	98.0 1.9	98.0 1.9	97.9 2.0	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	97.0	97.4	97.4	97.6	97.4	97.4	97.5	97.1	97.2	X
Purity by CE-SDS (Non-reduced)	Main Peak ≥ 90.0%	98.2	98.2	98.0	98.0	97.9	98.0	97.8	97.3	97.8	X
Potency by Binding ELISA	60 - 140% relative potency	99	102	104	94	98	101	98	93	93	X
Polysorbate 80	Report Result (%) (w/v)	0.037	NT	NT	NT	0.036	NT	0.036	NT	0.036	X

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Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**2**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
CCIT	Pass	Pass	NT	NT	NT	NT	NT	Pass	NT	Pass	X

[a] Specification limits applicable for samples stored in long-term stability conditions.

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Table 12: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) cGMP Drug Product Lot 202006002 Stored at 25 ± 2°C / 60 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B8	B8	B8	BY7	BY7
Clarity	5.6	5.7	5.5	5.3	5.7
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	59	62	72	90	72
≥ 25 µm :	2	0	1	5	6
≥ 2 µm :	2745	2822	3246	4166	5773
≥ 5 µm :	499	548	659	846	970
pH	6.0	6.0	6.0	6.0	6.1
Protein Concentration by UV A_{280}	25.5	25.2	25.4	25.4	25.5
Charge Variants by iCIEF					
Main peak:	63.7	63.4	60.5	57.6	53.3
Acidic peaks:	28.9	29.4	31.8	34.3	40.0
Basic peaks:	7.4	7.1	7.7	8.1	6.7
Purity by SEC-HPLC					
Main Peak (monomer):	98.3	98.1	97.9	98.1	97.5
HMWS:	1.7	1.8	1.8	1.7	2.0
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.0	96.9	96.9	96.9	95.9
Purity by CE-SDS (Non-Reduced) Mean Peak:	98.2	97.8	97.3	97.1	95.6
Potency by Binding ELISA	99	98	102	92	92

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Table 13: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) cGMP Drug Product Lot 202006002 Stored at 40 ± 2°C / 75 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B8	BY7	B7	BY6	BY5
Clarity	5.6	5.7	5.6	5.7	6.2
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	59	74	51	98	90
≥ 25 µm :	2	0	1	1	2
≥ 2 µm :	2745	3672	2941	4244	4538
≥ 5 µm :	499	680	584	951	825
pH	6.0	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	25.5	25.2	25.5	25.4	25.7
Charge Variants by iCIEF					
Main peak:	63.7	48.7	34.6	25.4	9.5
Acidic peaks:	28.9	44.3	58.9	69.5	88.1
Basic peaks:	7.4	7.0	6.4	5.1	2.5
Purity by SEC-HPLC					
Main Peak (monomer):	98.3	97.5	96.7	96.4	94.4
HMWS:	1.7	2.0	2.2	2.1	3.0
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.0	95.5	94.0	92.5	88.6
Purity by CE-SDS (Non-Reduced) Mean Peak:	98.2	95.5	92.6	90.8	84.1
Potency by Binding ELISA	99	94	87	87	75

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Table 14: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) cGMP Drug Product Lot 202006004 Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**2**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Color	Report result (Refer to EP)	B8	B8	B8	B8	B8	B8	B8	B8	X	X
Clarity	≤ 18.0 NTU	5.7	5.3	5.5	5.3	5.4	5.4	5.6	5.4	X	X
Visible Particles	Essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X
Subvisible Particulate Matter	≥ 10 µm : ≤ 6000 particles/container ≥ 25 µm : ≤ 600 particles/container ≥ 2 µm : report result ≥ 5 µm : report result	35 2 2009 308	151 3 6433 1156	20 2 2882 444	51 2 3307 575	29 2 4320 492	74 3 4626 788	132 19 5729 1093	66 0 4754 805	X	X
pH	6.0 ± 0.5	6.1	6.0	6.1	6.0	6.0	6.0	6.0	6.1	X	X
Protein Concentration by UV A_{280}	25.0 ± 2.5 mg/mL	25.0	25.1	24.9	25.2	24.9	25.1	25.2	25.2	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	60.7 32.1 7.2	61.3 31.3 7.3	61.4 30.9 7.7	60.7 31.6 7.7	59.1 32.8 8.2	60.4 31.6 8.0	62.2 30.7 7.0	59.6 32.0 8.3	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.9	98.1 1.9	98.0 2.0	98.0 2.0	97.8 2.1	97.8 2.2	97.8 2.1	97.8 2.1	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	97.5	97.2	97.3	97.3	97.4	97.6	97.6	97.6	X	X
Purity by CE-SDS (Non-reduced)	Main Peak ≥ 90.0%	98.0	97.9	98.0	97.8	97.7	97.8	97.4	97.6	X	X
Potency by Binding ELISA	60 - 140% relative potency	100	102	100	102	97	98	97	103	X	X
Polysorbate 80	Report Result (%) (w/v)	0.039	NT	NT	NT	0.034	NT	0.035	NT	X	X

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Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**2**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
CCIT	Pass	Pass	NT	NT	NT	NT	NT	Pass	NT	X	X

[a] Specification limits applicable for samples stored in long-term stability conditions.

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Table 15: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) cGMP Drug Product Lot 202006004 Stored at 25 ± 2°C / 60 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B8	B8	B8	B8	BY7
Clarity	5.7	5.3	5.4	5.8	5.4
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	35	135	18	57	41
≥ 25 µm :	2	2	1	2	3
≥ 2 µm :	2009	4347	2680	3652	4620
≥ 5 µm :	308	741	340	672	712
pH	6.1	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	25.0	25.1	25.0	25.5	25.2
Charge Variants by iCIEF					
Main peak:	60.7	59.5	57.5	55.4	51.0
Acidic peaks:	32.1	33.2	34.8	36.5	41.6
Basic peaks:	7.2	7.3	7.7	8.1	7.4
Purity by SEC-HPLC					
Main Peak (monomer):	98.1	97.9	97.8	97.7	97.3
HMWS:	1.9	2.0	2.0	2.1	2.2
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.5	97.0	97.4	96.7	96.3
Purity by CE-SDS (Non-Reduced) Mean Peak:	98.0	97.6	97.2	96.7	95.7
Potency by Binding ELISA	100	98	100	101	89

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Table 16: Stability Data for VIR-7831 Gen1 (25.0 mg/mL) cGMP Drug Product Lot 202006004 Stored at 40 ± 2°C / 75 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B8	BY7	B7	BY6	B6
Clarity	5.7	5.4	5.7	5.6	6.2
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	35	178	40	124	22
≥ 25 µm :	2	2	1	1	1
≥ 2 µm :	2009	6458	3017	4308	4638
≥ 5 µm :	308	1418	530	1089	610
pH	6.1	6.0	6.1	6.0	6.0
Protein Concentration by UV A_{280}	25.0	25.2	25.0	25.2	25.6
Charge Variants by iCIEF					
Main peak:	60.7	46.2	33.7	25.0	10.2
Acidic peaks:	32.1	46.6	60.1	69.8	86.8
Basic peaks:	7.2	7.1	6.2	5.2	3.0
Purity by SEC-HPLC					
Main Peak (monomer):	98.1	97.3	96.6	96.3	94.1
HMWS:	1.9	2.1	2.4	2.2	3.2
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.5	95.8	94.0	92.0	86.4
Purity by CE-SDS (Non-Reduced) Mean Peak:	98.0	95.4	92.7	90.1	82.8
Potency by Binding ELISA	100	101	92	90	74

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Table 17: Stability Data for VIR-7831 Gen2 (62.5 mg/mL) cGMP Drug Product Lot 202009005 Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)												
		0	**1**	**2**	**3**	**4**	**6**	**9**	**12**	**18**	**24**	**36**	**48**	**60**
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	B6	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	7.4	7.2	7.4	7.7	7.5	7.7	7.5	7.5	7.3	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	62 0 2461 526	53 0 2637 535	108 32 2683 608	36 0 2891 448	34 3 3382 442	18 6 3597 379	70 7 3906 667	44 2 3143 571	19 9 4130 488	X	X	X	X
pH	6.0 ± 0.5	5.9	5.9	6.0	6.0	6.0	5.9	6.0	6.0	5.9	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.7	62.1	61.8	62.1	61.2	62.0	62.8	62.6	62.1	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	60.8 30.2 9.0	60.0 31.1 8.9	61.6 29.6 8.8	60.3 31.2 8.5	60.6 30.5 8.9	60.6 29.9 9.5	61.1 29.8 9.1	59.4 31.9 8.8	60.7 30.4 8.9	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	97.7 2.3	97.4 2.6	97.2 2.7	97.2 2.8	97.1 2.9	97.0 2.9	97.0 2.9	96.9 3.0	96.7 3.1	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	97.2	97.2	97.4	97.0	97.4	97.1	97.4	97.4	97.4	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	97.9	97.7	97.7	97.4	97.5	97.7	97.4	97.4	97.3	X	X	X	X
Potency by Binding ELISA	60 – 140% relative potency	101	97	95	93	98	103	96	101	96	X	X	X	X

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Test	Stability Specification [a]	Time Interval (month)												
		0	**1**	**2**	**3**	**4**	**6**	**9**	**12**	**18**	**24**	**36**	**48**	**60**
Polysorbate 80	Report Result	0.036	NT	NT	NT	NT	0.035	NT	0.033	NT	X	X	X	X
CCIT	Pass	Pass	NT	NT	NT	NT	NT	NT	Pass	NT	X	X	X	X

[a] Specification limits applicable for samples stored in long-term stability conditions.

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 18: Stability Data for VIR-7831 Gen2 (62.5 mg/mL) cGMP Drug Product Lot 202009005 Stored at 25 ± 2°C / 60 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B7	B7	B6	B6	B6
Clarity	7.4	7.5	7.3	7.6	7.7
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	62	40	195	32	39
≥ 25 µm :	0	2	44	0	1
≥ 2 µm :	2461	2230	4420	2987	3831
≥ 5 µm :	526	461	938	508	543
pH	5.9	6.0	6.0	6.0	5.9
Protein Concentration by UV A_{280}	61.7	62.0	61.6	62.4	61.6
Charge Variants by iCIEF					
Main peak:	60.8	58.3	56.6	55.6	51.0
Acidic peaks:	30.2	32.4	33.9	36.4	40.3
Basic peaks:	9.0	9.3	9.5	8.0	8.7
Purity by SEC-HPLC					
Main Peak (monomer):	97.7	97.2	96.9	96.8	96.4
HMWS:	2.3	2.7	2.9	2.9	3.1
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.2	97.2	96.9	96.4	95.6
Purity by CE-SDS (Non-Reduced) Mean Peak:	97.9	97.2	96.8	96.2	95.4
Potency by Binding ELISA	101	95	93	94	93

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 19: Stability Data for VIR-7831 Gen2 (62.5 mg/mL) cGMP Drug Product Lot 202009005 Stored at 40 ± 2°C / 75 ± 5% RH

Test	Time Interval (month)			
	0	**1**	**2**	**3**
Color	B7	B6	B6	BY5
Clarity	7.4	7.6	7.8	8.2
Visible Particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter				
≥ 10 µm :	62	29	89	12
≥ 25 µm :	0	0	12	0
≥ 2 µm :	2461	3635	4092	2719
≥ 5 µm :	526	647	773	339
pH	5.9	5.9	6.0	6.0
Protein Concentration by UV A_{280}	61.7	61.9	61.6	62.7
Charge Variants by iCIEF				
Main peak:	60.8	43.5	33.3	24.0
Acidic peaks:	30.2	47.9	59.4	71.8
Basic peaks:	9.0	8.5	7.3	4.2
Purity by SEC-HPLC				
Main Peak (monomer):	97.7	96.3	95.3	94.5
HMWS:	2.3	3.1	3.6	4.0
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	97.2	95.4	93.7	92.6
Purity by CE-SDS (Non-Reduced) Mean Peak:	97.9	94.6	91.6	88.7
Potency by Binding ELISA	101	94	85	85

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 20: Stability Data for VIR-7831 Gen2 (62.5 mg/mL) cGMP Drug Product Lot 202010006 Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)												
		0	**1**	**2**	**3**	**4**	**6**	**9**	**12**	**18**	**24**	**36**	**48**	**60**
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	B7	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	7.2	7.2	7.6	7.4	7.8	7.4	7.2	7.1	7.0	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	20 0 3178 394	46 3 1971 403	22 1 2141 360	31 1 3868 488	90 2 2643 592	61 2 3465 531	45 1 2984 496	9 0 4657 349	24 1 3604 398	X	X	X	X
pH	6.0 ± 0.5	6.0	6.0	6.0	5.9	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	63.1	62.2	63.4	62.5	62.8	63.0	63.0	62.6	62.2	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	63.0 25.6 11.3	63.8 24.3 11.9	62.5 25.7 11.8	61.6 26.7 11.6	62.8 25.5 11.7	63.9 24.5 11.6	62.1 25.8 12.2	60.9 28.4 10.8	61.7 26.2 12.0	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.0 2.0	97.8 2.2	97.7 2.3	97.5 2.4	97.4 2.5	97.4 2.5	97.4 2.6	97.3 2.6	97.2 2.7	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.1	97.9	97.6	97.7	97.7	98.0	98.0	97.9	98.0	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	98.4	98.0	98.0	97.9	98.0	97.9	98.0	98.0	97.9	X	X	X	X
Potency by Binding ELISA	60 – 140% relative potency	101	99	91	96	98	105	102	99	102	X	X	X	X

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Test	Stability Specification [a]	Time Interval (month)												
		0	1	2	3	4	6	9	12	18	24	36	48	60
Polysorbate 80	Report Result	0.036	NT	NT	NT	NT	0.033	NT	0.036	NT	X	X	X	X
CCIT	Pass	Pass	NT	NT	NT	NT	NT	NT	Pass	NT	X	X	X	X

[a] Specification limits applicable for samples stored in long-term stability conditions.

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 21: Stability Data for VIR-7831 Gen2 (62.5 mg/mL) cGMP Drug Product Lot 202010006 Stored at 25 ± 2°C / 60 ± 5% RH

Test	Time Interval (month)				
	0	**1**	**2**	**3**	**6**
Color	B7	B7	B7	B7	B6
Clarity	7.2	7.1	7.5	7.8	7.6
Visible Particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter					
≥ 10 µm :	20	80	33	43	76
≥ 25 µm :	0	8	0	3	7
≥ 2 µm :	3178	3040	2435	3950	3490
≥ 5 µm :	394	651	434	456	700
pH	6.0	6.0	6.0	5.9	6.0
Protein Concentration by UV A_{280}	63.1	62.0	63.4	62.6	64.2
Charge Variants by iCIEF					
Main peak:	63.0	61.2	59.8	56.7	56.2
Acidic peaks:	25.6	26.9	29.3	32.3	33.7
Basic peaks:	11.3	11.9	10.9	11.0	10.1
Purity by SEC-HPLC					
Main Peak (monomer):	98.0	97.6	97.4	97.2	96.9
HMWS:	2.0	2.3	2.4	2.6	2.7
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	98.1	97.7	97.5	97.4	96.4
Purity by CE-SDS (Non-Reduced) Mean Peak:	98.4	97.7	97.3	96.8	95.9
Potency by Binding ELISA	101	93	98	97	98

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Table 22: Stability Data for VIR-7831 Gen2 (62.5 mg/mL) cGMP Drug Product Lot 202010006 Stored at 40 ± 2°C / 75 ± 5% RH

Test	Time Interval (month)			
	0	**1**	**2**	**3**
Color	B7	B6	B6	B6
Clarity	7.2	7.6	7.9	8.3
Visible Particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter				
≥ 10 µm :	20	58	19	31
≥ 25 µm :	0	5	0	0
≥ 2 µm :	3178	2802	2636	4222
≥ 5 µm :	394	541	399	503
pH	6.0	6.0	6.0	5.9
Protein Concentration by UV A_{280}	63.1	62.3	63.0	62.7
Charge Variants by iCIEF				
Main peak:	63.0	46.1	33.1	23.6
Acidic peaks:	25.6	43.4	59.2	69.7
Basic peaks:	11.3	10.6	7.7	6.7
Purity by SEC-HPLC				
Main Peak (monomer):	98.0	96.7	95.9	95.0
HMWS:	2.0	2.7	3.1	3.5
Purity by CE-SDS (Reduced) Light Chain + Heavy Chain:	98.1	96.3	94.5	92.9
Purity by CE-SDS (Non-Reduced) Mean Peak:	98.4	95.0	92.0	89.7
Potency by Binding ELISA	101	91	87	82

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 23: Stability Data for VIR-7831 Gen2 Engineering Drug Product (GSK) Lot 202421682, Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)											
		0	**1**	**2**	**3**	**4**	**6**	**9**	**12**	**18**	**24**	**30**	**36**
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	6.4	7.1	7.3	7.2	6.9	7.0	6.9	6.8	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container	43	22	27	11	22	14	14	3	X	X	X	X
	≥ 25 µm: ≤ 600 particles/container	0	0	0	0	8	6	0	0	X	X	X	X
	≥ 2 µm: report result	3435	1744	2342	1398	1672	1608	1600	2182	X	X	X	X
	≥ 5 µm: report result	494	171	344	160	235	163	259	195	X	X	X	X
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	63.2	62.6	63.6	62.9	62.8	62.4	62.3	63.2	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0%	67.2	67.8	66.7	68.2	67.6	66.9	68.1	67.6	X	X	X	X
	Acidic peaks: ≤ 60.0%	18.3	18.4	21.5	19.1	19.1	19.3	18.9	19.7	X	X	X	X
	Basic peaks: ≤ 30.0%	14.5	13.8	11.8	12.6	13.3	13.8	13.0	12.7	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0%	98.3	98.3	98.2	98.1	98.0	98.0	97.8	98.1	X	X	X	X
	HMWS ≤ 10.0%	1.7	1.6	1.7	1.8	1.9	1.9	2.1	1.8	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.7	98.4	98.4	98.2	98.2	98.3	98.2	98.4	X	X	X	X

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Test	Stability Specification [a]	Time Interval (month)											
		0	**1**	**2**	**3**	**4**	**6**	**9**	**12**	**18**	**24**	**30**	**36**
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.4	99.4	99.3	99.3	99.4	99.4	99.3	98.9	X	X	X	X
Potency by Binding ELISA	60 - 140% relative potency	114	99	107	99	95	104	103	98	X	X	X	X
Polysorbate 80	0.040% ± 0.030% (w/v)	NT[b]	0.032	0.035	0.035	0.032	0.036	0.035	0.036	X	X	X	X
CCIT	Pass	NT	NT	NT	NT	NT	NT	NT	Pass	NT	X	NT	X

[a] Specification limits applicable for samples stored in long-term stability conditions
[b] Test method was still in development at time of release testing for lot 202421682; thus, was not performed.

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 24: Stability Data for VIR-7831 Gen2 Engineering Drug Product (GSK) Lot 202421682, Stored at 25 ± 2°C/60 ± 5% RH

Test	Stability Specification [a]	Time Interval						
		0	14 days	1 month	2 months	3 months	4 months	6 months
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	B6
Clarity	≤ 18.0 NTU	6.4	6.6	6.8	6.8	6.9	7.1	7.0
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container	43	53	30	35	46	14	27
	≥ 25 µm: ≤ 600 particles/container	0	0	0	0	0	0	0
	≥ 2 µm: report result	3435	3616	2635	2766	2566	1702	1934
	≥ 5 µm: report result	494	685	392	478	456	254	243
pH	6.0 ± 0.5	6.0	5.9	5.9	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	63.2	63.2	62.6	63.2	62.7	62.5	62.9
Charge Variants by iCIEF	Main peak: ≥ 40.0%	67.2	65.3	65.6	61.5	62.5	60.8	57.7
	Acidic peaks: ≤ 60.0%	18.3	19.4	21.1	26.3	25.2	26.9	29.6
	Basic peaks: ≤ 30.0%	14.5	15.3	13.3	12.1	12.2	12.4	12.8
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0%	98.3	98.3	98.2	98.0	97.8	97.6	97.4
	HMWS ≤ 10.0%	1.7	1.7	1.7	1.9	2.0	2.1	2.2
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.7	98.2	98.2	98.3	97.9	97.8	97.8
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.4	99.4	99.3	98.8	98.3	98.6	97.8

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Test	Stability Specification [a]	Time Interval						
		0	14 days	1 month	2 months	3 months	4 months	6 months
Potency by Binding ELISA	60 - 140% relative potency	114	123	100	107	107	97	103
Polysorbate 80	0.040% ± 0.030% (w/v)	NT[b]	NT	NT	NT	0.031	NT	0.031

[a] Specification limits applicable for samples stored in long-term stability conditions
[b] Test method was still in development at time of release testing for lot 202421682; thus, was not performed.

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Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 25: Stability Data for VIR-7831 Gen2 Engineering Drug Product (GSK) Lot 202421682, Stored at 40 ± 2°C/75 ± 5% RH

Test	Stability Specification [a]	Time Interval				
		0	14 days	1 month	2 months	3 months
Color	Report result (Refer to EP)	B7	B7	B6	B6	B6
Clarity	≤ 18.0 NTU	6.4	6.9	7.0	7.6	7.6
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container	43	80	22	6	24
	≥ 25 µm: ≤ 600 particles/container	0	5	0	0	0
	≥ 2 µm: report result	3435	3536	2288	2083	1979
	≥ 5 µm: report result	494	544	270	171	254
pH	6.0 ± 0.5	6.0	6.0	5.9	6.1	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	63.2	63.2	62.9	63.5	63.3
Charge Variants by iCIEF	Main peak: ≥ 40.0%	67.2	58.8	51.1	40.7	33.1
	Acidic peaks: ≤ 60.0%	18.3	25.8	37.2	50.0	59.3
	Basic peaks: ≤ 30.0%	14.5	15.4	11.8	9.3	7.6
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0%	98.3	97.8	97.4	96.7	96.0
	HMWS ≤ 10.0%	1.7	1.9	2.1	2.4	2.7
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.7	97.9	97.5	96.4	95.3
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.4	98.6	96.9	95.4	92.4
Potency by Binding ELISA	60 - 140% relative potency	114	114	100	101	93
Polysorbate 80	0.040% ± 0.030% (w/v)	NT[b]	NT	NT	NT	0.029

[a] Specification limits applicable for samples stored in long-term stability conditions
[b] Test method was still in development at time of release testing for lot 202421682; thus, was not performed.

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 26: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot 8H5D Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)											
		0	1	2	3	4	6	9	12	18	24	30	36
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	6.9	7.0	6.8	6.9	6.8	6.7	7.7	6.7	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	30 0 2270 376	102 0 5432 968	67 0 3651 656	110 0 4846 1075	115 43 4256 774	43 0 3030 507	35 0 3683 555	6 0 2315 291	X	X	X	X
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.6	61.6	61.2	61.0	61.0	61.4	61.6	61.1	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.2 19.9 13.9	67.7 19.1 13.2	67.3 18.8 14.0	67.3 18.4 14.3	67.4 18.5 14.1	67.0 19.0 14.0	67.3 18.9 13.8	66.9 19.8 13.3	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.4 1.6	98.2 1.8	98.0 1.9	98.0 1.9	98.0 1.9	97.9 2.0	98.1 1.8	97.9 1.9	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.5	98.3	98.3	98.3	98.3	98.6	98.8	98.8	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.4	99.3	99.4	99.3	99.4	99.3	98.9	98.8	X	X	X	X
Potency by Binding ELISA	60 - 140% relative potency	94	97	102	97	94	96	100	88	X	X	X	X

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Test	Stability Specification [a]	Time Interval (month)											
		0	1	2	3	4	6	9	12	18	24	30	36
Polysorbate 80	0.040% ± 0.030% (w/v)	0.034	0.035	0.034	0.034	0.036	0.034	0.036	0.037	X	X	X	X
Sterility	No growth	No growth	NT	NT	NT	NT	NT	NT	NT	NT	NT	NT	X
CCIT	Pass	NT	NT	NT	NT	NT	NT	NT	Pass	NT	X	NT	X

[a] Specification limits applicable for samples stored in long-term stability conditions

RPT-QC-11743 1.0 Approved

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 27: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot 8H5D Stored at 25 ± 2°C/60 ± 5% RH

Test	Stability Specification [a]	Time Interval						
		0	14 days	1 month	2 months	3 months	4 months	6 months
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B6	B6
Clarity	≤ 18.0 NTU	6.9	6.7	7.1	6.8	7.0	7.0	7.1
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	30 0 2270 376	104 0 5835 987	54 0 4955 795	64 0 3470 614	139 0 4848 939	22 0 2920 512	59 0 3344 576
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.6	61.7	61.5	61.3	61.4	61.0	61.7
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.2 19.9 13.9	66.5 19.6 13.9	65.9 21.1 13.0	63.3 23.2 13.4	61.6 25.2 13.2	60.4 26.4 13.2	55.0 32.6 12.4
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.4 1.6	98.1 1.8	98.0 1.9	97.8 2.0	97.6 2.1	97.5 2.2	97.3 2.3
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.5	98.5	98.2	98.1	98.1	97.9	98.0
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.4	99.3	99.2	98.8	98.0	98.5	97.1
Potency by Binding ELISA	60 - 140% relative potency	94	105	90	95	96	93	97
Polysorbate 80	0.040% ± 0.030% (w/v)	0.034	NT	0.031	NT	0.030	NT	0.029

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 28: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot 8H5D Stored at 40 ± 2°C/75 ± 5% RH

Test	Stability Specification [a]	Time Interval				
		0	14 days	1 month	2 months	3 months
Color	Report result (Refer to EP)	B7	B7	B6	B6	B6
Clarity	≤ 18.0 NTU	6.9	6.8	7.1	7.3	7.7
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	30 0 2270 376	88 0 4208 827	62 3 4008 752	35 0 3467 627	70 0 5686 963
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.6	61.5	61.5	61.5	61.5
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.2 19.9 13.9	59.1 26.7 14.3	51.2 37.4 11.4	39.2 51.0 9.8	28.6 64.0 7.4
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.4 1.6	97.7 2.1	97.1 2.3	96.3 2.7	95.7 2.9
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.5	98.2	97.1	94.4	94.0
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.4	98.6	96.6	94.5	92.0
Potency by Binding ELISA	60 - 140% relative potency	94	99	90	101	90

[a] Specification limits applicable for samples stored in long-term stability condition

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 29: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot 9G7S Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)											
		0	1	2	3	4	6	9	12	18	24	30	36
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	7.1	6.9	6.9	7.0	7.0	6.7	6.5	6.7	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	43 0 1939 283	30 0 3168 475	22 0 2950 427	22 0 3320 459	30 0 3446 435	51 0 3094 478	0 0 3470 334	11 0 2016 222	X	X	X	X
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.5	61.8	61.4	61.3	61.4	61.8	61.7	60.9	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.2 21.2 12.6	66.0 21.3 12.7	66.4 20.9 12.7	66.9 20.1 13.0	66.9 20.0 13.1	66.7 20.5 12.7	66.8 20.4 12.8	66.3 20.7 13.0	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.3 1.6	98.1 1.9	97.9 2.0	97.9 2.0	97.9 2.0	97.8 2.1	98.0 1.9	97.9 2.0	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.4	98.3	98.2	98.2	97.9	98.8	98.8	98.8	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.3	99.3	99.3	99.3	99.3	99.3	98.9	X	X	X	X
Potency by Binding ELISA	60 - 140% relative potency	102	103	97	105	92	101	101	97	X	X	X	X

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Test	Stability Specification [a]	Time Interval (month)											
		0	1	2	3	4	6	9	12	18	24	30	36
Polysorbate 80	0.040% ± 0.030% (w/v)	0.034	0.035	0.036	0.034	0.036	0.033	0.037	0.035	X	X	X	X
Sterility	No growth	No growth	NT	NT	NT	NT	NT	NT	NT	NT	NT	NT	X
CCIT	Pass	NT	NT	NT	NT	NT	NT	NT	Pass	NT	X	NT	X

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 30: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot 9G7S Stored at 25 ± 2°C/60 ± 5% RH

Test	Stability Specification [a]	Time Interval						
		0	14 days	1 month	2 months	3 months	4 months	6 months
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B6	B6
Clarity	≤ 18.0 NTU	7.1	6.6	7.0	6.6	6.9	7.1	7.3
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conform	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	43 0 1939 283	78 0 4696 662	19 0 3408 440	96 0 3923 643	51 0 3382 552	83 0 3358 534	54 0 2838 451
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.5	61.8	61.9	61.5	61.3	61.8	61.8
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.2 21.2 12.6	65.6 21.2 13.1	64.5 22.9 12.6	63.4 24.1 12.5	60.2 27.2 12.7	59.8 27.9 12.2	55.4 33.2 11.4
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.3 1.6	98.0 1.9	97.9 2.0	97.7 2.1	97.6 2.2	97.4 2.2	97.2 2.3
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.4	98.5	98.1	97.9	98.0	98.2	97.9
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.3	99.2	98.8	98.0	98.4	97.2
Potency by Binding ELISA	60 - 140% relative potency	102	108	103	98	100	92	93

[a] Specification limits applicable for samples stored in long-term stability condition

RPT-QC-11743 1.0 Approved

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 31: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot 9G7S Stored at 40 ± 2°C/75 ± 5% RH

Test	Stability Specification [a]	Time Interval)				
		0	14 days	1 month	2 months	3 months
Color	Report result (Refer to EP)	B7	B7	B6	B6	B6
Clarity	≤ 18.0 NTU	7.1	7.3	7.1	7.3	7.7
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	43 0 1939 283	94 0 4454 686	19 0 4294 528	16 0 3008 400	91 0 5016 739
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.5	61.5	61.5	61.8	61.9
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.2 21.2 12.6	59.4 27.5 13.2	50.7 38.7 10.6	38.6 52.5 8.9	28.4 64.7 6.9
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.3 1.6	97.6 2.1	97.0 2.5	96.3 2.7	95.6 3.0
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.4	98.2	97.0	96.1	94.1
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	98.6	96.4	94.5	90.9
Potency by Binding ELISA	60 - 140% relative potency	102	105	92	91	89

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 32: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot CF2J Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)									
		0	1	3	6	9	12	18	24	30	36
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	6.5	7.1	7.2	6.7	6.8	6.7	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	38 3 2744 475	46 0 2230 419	16 0 2024 278	32 0 1491 312	8 0 1246 150	112 0 5318 840	X	X	X	X
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	62.2	62.1	61.9	61.9	62.2	63.2	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	65.9 20.9 13.1	64.3 23.3 12.4	65.8 21.6 12.7	65.8 21.0 13.2	66.7 21.1 12.2	65.7 21.9 12.4	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.0 1.9	98.0 2.0	97.9 2.0	97.8 2.1	97.6 2.2	97.5 2.4	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.8	98.4	98.5	98.2	98.5	98.4	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.3	99.3	99.3	98.8	98.9	X	X	X	X
Potency by Binding ELISA	60 - 140% relative potency	108	91	97	105	93	87	X	X	X	X

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**3**	**6**	**9**	**12**	**18**	**24**	**30**	**36**
Polysorbate 80	0.040% ± 0.030% (w/v)	0.036	0.036	0.035	0.038	0.037	0.035	X	X	X	X
Sterility	No growth	No growth	NT	NT	NT	NT	NT	NT	NT	NT	X
CCIT	Pass	NT	NT	NT	NT	NT	Pass	NT	X	NT	X

[a] Specification limits applicable for samples stored in long-term stability condition

RPT-QC-11743 1.0 Approved

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 33: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot CF2J Stored at 25 ± 2°C/60 ± 5% RH

Test	Stability Specification [a]	Time Interval			
		0	1 month	3 months	6 months
Color	Report result (Refer to EP)	B7	B7	B7	B6
Clarity	≤ 18.0 NTU	6.5	6.9	7.1	7.3
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	38 3 2744 475	62 0 2955 496	14 3 2216 264	22 0 1662 230
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	62.2	62.3	61.8	61.6
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	65.9 20.9 13.1	67.0 20.4 12.6	60.5 27.2 12.2	56.9 31.2 12.0
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.0 1.9	97.9 2.0	97.5 2.2	97.3 2.3
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.8	98.3	98.2	97.7
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.2	98.7	97.1
Potency by Binding ELISA	60 - 140% relative potency	108	91	105	85
Polysorbate 80	0.040% ± 0.030% (w/v)	0.036	0.035	0.032	0.032

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 34: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot CF2J Stored at 40 ± 2°C/75 ± 5% RH

Test	Stability Specification [a]	Time Interval			
		0	14 days	1 month	3 months
Color	Report result (Refer to EP)	B7	B7	B6	B6
Clarity	≤ 18.0 NTU	6.5	7.1	7.0	7.7
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	38 3 2744 475	16 0 1411 214	32 0 1960 326	14 0 1254 187
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	62.2	61.8	62.4	62.0
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	65.9 20.9 13.1	58.5 29.1 12.4	52.6 35.9 11.5	29.2 63.6 7.2
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.0 1.9	97.5 2.2	96.8 2.6	95.6 3.0
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.8	97.8	97.3	94.7
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	98.5	96.0	91.7
Potency by Binding ELISA	60 - 140% relative potency	108	114	105	91
Polysorbate 80	0.040% ± 0.030% (w/v)	0.036	0.034	NT	NT

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 35: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot FW9J Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)									
		0	1	3	6	9	12	18	24	30	36
Color	Report result (Refer to EP)	B7	B7	B7	B6	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	6.7	6.8	7.0	6.8	6.7	8.0	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	158 0 4176 902	43 0 4894 670	40 0 4030 672	75 0 5136 819	30 0 5024 520	11 0 3728 403	X	X	X	X
pH	6.0 ± 0.5	5.9	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	62.2	61.8	61.0	60.9	61.4	61.2	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.8 20.3 12.9	66.3 21.4 12.4	66.4 20.4 13.2	66.9 20.9 12.2	67.7 20.0 12.3	66.6 21.3 12.7	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.8	98.0 1.9	98.0 1.9	97.9 1.9	97.7 2.1	97.2 2.2	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.2	98.3	98.4	98.7	98.5	98.4	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.3	99.3	99.0	98.9	98.6	X	X	X	X
Potency by Binding ELISA	60 - 140% relative potency	106	116	104	84	98	97	X	X	X	X

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**3**	**6**	**9**	**12**	**18**	**24**	**30**	**36**
Polysorbate 80	0.040% ± 0.030% (w/v)	0.037	0.034	0.035	0.035	0.036	0.034	X	X	X	X
Sterility	No growth	No Growth	NT	NT	NT	NT	NT	NT	NT	NT	X
CCIT	Pass	NT	NT	NT	NT	NT	Pass	NT	X	NT	X

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 36: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot FW9J Stored at 25 ± 2°C/60 ± 5% RH

Test	Stability Specification [a]	Time Interval			
		0	1 month	3 months	6 months
Color	Report result (Refer to EP)	B7	B7	B7	B7
Clarity	≤ 18.0 NTU	6.7	6.8	7.3	7.0
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	158 0 4176 902	64 0 4115 656	62 0 4720 766	104 0 4819 854
pH	6.0 ± 0.5	5.9	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	62.2	61.4	61.3	60.9
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.8 20.3 12.9	64.9 22.4 12.7	61.3 26.2 12.5	55.1 33.0 11.9
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.8	97.8 2.0	97.6 2.1	97.4 2.2
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.2	98.2	98.2	97.8
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.2	98.6	96.9
Potency by Binding ELISA	60 - 140% relative potency	106	104	96	99
Polysorbate 80	0.040% ± 0.030% (w/v)	0.037	0.032	0.031	0.031

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 37: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot FW9J Stored at 40 ± 2°C/75 ± 5% RH

Test	Stability Specification [a]	Time Interval			
		0	14 days	1 month	3 months
Color	Report result (Refer to EP)	B7	B7	B6	B6
Clarity	≤ 18.0 NTU	6.7	7.0	7.4	7.7
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	158 0 4176 902	59 0 4088 736	75 0 4230 790	40 0 3366 536
pH	6.0 ± 0.5	5.9	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	62.2	61.5	61.6	61.4
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	66.8 20.3 12.9	59.3 29.2 11.6	50.0 39.1 11.0	28.7 64.0 7.3
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.8	97.6 2.1	97.0 2.5	95.8 2.8
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.2	97.8	97.4	94.6
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	98.4	96.8	92.4
Potency by Binding ELISA	60 - 140% relative potency	106	109	103	91
Polysorbate 80	0.040% ± 0.030% (w/v)	0.037	0.034	NT	NT

[a] Specification limits applicable for samples stored in long-term stability condition

RPT-QC-11743 1.0 Approved

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 38: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot FX4A Stored at 5 ± 3°C

Test	Stability Specification [a]	Time Interval (month)									
		0	1	3	6	9	12	18	24	30	36
Color	Report result (Refer to EP)	B7	B7	B7	B7	B7	B7	X	X	X	X
Clarity	≤ 18.0 NTU	6.7	6.7	6.9	6.7	6.6	6.6	X	X	X	X
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	X	X	X	X
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	48 3 2958 568	16 0 3763 424	40 0 3459 526	40 3 3267 448	14 0 3638 350	6 3 1816 203	X	X	X	X
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0	6.0	6.0	X	X	X	X
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.8	60.9	61.6	60.9	61.0	60.9	X	X	X	X
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	67.9 19.8 12.3	66.0 21.5 12.4	65.6 21.5 12.9	66.9 20.4 12.7	66.8 21.2 11.9	67.3 20.6 12.1	X	X	X	X
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.9	98.0 1.9	97.9 2.0	98.0 1.9	98.0 1.9	97.8 2.1	X	X	X	X
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.3	98.4	98.4	98.4	98.4	98.8	X	X	X	X
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.2	99.3	99.3	98.7	98.7	X	X	X	X
Potency by Binding ELISA	60 - 140% relative potency	106	99	89	102	96	94	X	X	X	X

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Test	Stability Specification [a]	Time Interval (month)									
		0	**1**	**3**	**6**	**9**	**12**	**18**	**24**	**30**	**36**
Polysorbate 80	0.040% ± 0.030% (w/v)	0.037	0.034	0.037	0.035	0.035	0.033	X	X	X	X
Sterility	No growth	No Growth	NT	NT	NT	NT	NT	NT	NT	NT	X
CCIT	Pass	NT	NT	NT	NT	NT	Pass	NT	X	NT	X

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 39: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot FX4A Stored at 25 ± 2°C/60 ± 5% RH

Test	Stability Specification [a]	Time Interval			
		0	1 month	3 months	6 months
Color	Report result (Refer to EP)	B7	B7	B7	B6
Clarity	≤ 18.0 NTU	6.7	6.8	7.5	6.9
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	48 3 2958 568	19 0 3448 494	86 0 550 3262	27 0 2715 291
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.8	60.2	60.9	60.5
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	67.9 19.8 12.3	65.1 21.6 13.3	61.1 26.6 12.3	55.0 33.9 11.2
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.9	97.9 2.0	97.5 2.2	97.3 2.2
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.3	98.1	98.1	97.9
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	99.2	98.6	96.5
Potency by Binding ELISA	60 - 140% relative potency	106	94	82	106
Polysorbate 80	0.040% ± 0.030% (w/v)	0.037	0.032	0.031	0.030

[a] Specification limits applicable for samples stored in long-term stability condition

RPT-QC-11743 1.0 Approved

REPORT

Title: Expiry Extension Report for VIR-7831 DP (GSK provided EUA Material Lot 2T8F) to 30-months

Table 40: Stability Data for VIR-7831 Gen2 cGMP Drug Product Lot FX4A Stored at 40 ± 2°C/75 ± 5% RH

Test	Stability Specification [a]	Time Interval			
		0	14 days	1 month	3 months
Color	Report result (Refer to EP)	B7	B7	B6	B6
Clarity	≤ 18.0 NTU	6.7	7.4	7.1	7.2
Visible Particles	Liquid, essentially free of visible particles	Conforms	Conforms	Conforms	Conforms
Subvisible Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container ≥ 2 µm: report result ≥ 5 µm: report result	48 3 2958 568	16 0 3635 326	38 0 4448 456	59 0 3360 352
pH	6.0 ± 0.5	6.0	6.0	6.0	6.0
Protein Concentration by UV A_{280}	62.5 ± 6.2 mg/mL	61.8	61.1	60.6	61.1
Charge Variants by iCIEF	Main peak: ≥ 40.0% Acidic peaks: ≤ 60.0% Basic peaks: ≤ 30.0%	67.9 19.8 12.3	59.9 27.5 12.6	49.9 39.1 11.1	26.4 65.2 8.4
Purity by SEC-HPLC	Main Peak (monomer): ≥ 90.0% HMWS ≤ 10.0%	98.1 1.9	97.6 2.2	97.0 2.4	95.5 3.0
Purity by CE-SDS (Reduced)	Purity (Light Chain + Heavy Chain): ≥ 90.0%	98.3	97.9	97.4	94.1
Purity by CE-SDS (Non-Reduced)	Main Peak ≥ 90.0%	99.3	97.9	96.6	91.8
Potency by Binding ELISA	60 - 140% relative potency	106	87	84	83
Polysorbate 80	0.040% ± 0.030% (w/v)	0.037	0.028	NT	NT

[a] Specification limits applicable for samples stored in long-term stability condition

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REPORT	
VIR	**Title: Expiry Extension Report for VIR-7831 Gen2 62.5 mg/mL DP Lots to 30-months**

9.0 APPENDICES/ATTACHMENTS

9.1 Journals from statistical analysis of the data using JMP software (version 16.0.0) is included as attachments

10.0 DOCUMENT HISTORY

Version	Description of Changes
1.0	New document

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Approval Signatures

Document Name: **Expiry Extension Report for VIR-7831 Gen2 62.5 mg/mL EUA DP Lot 2T8F to 30-months**

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