GSK

Sotrovimab (VIR-7831/GSK4182136) Drug Product Stability Trend Report for Clinical and EUA Batches

Purpose:

The purpose of this study is to evaluate the stability of Sotrovimab (VIR-7831/GSK4182136) drug product batches (manufactured at WuXi Biologics, China using Gen1 and Gen2 2000 L DS) and commercial scale DP batches (manufactured at GSK Parma, Italy using Gen2 6 x 2000 L DS) at a concentration of 25 mg/mL and 62.5 mg/mL in a 10 mL vial, in accordance with ICH guideline Q1A (R2) "*Stability Testing of New Drug Substances and Products*", and ICH Q5C "*Stability Testing of Biotechnological/Biological Products*". The data will be collected to support the recommended storage condition and the drug product shelf life for regulatory filing for clinical and EUA.

Statement:

This report should be considered a historical document and statements made are accurate, at the time the report was authored. Any proposals (storage condition, retest date/shelf-life statements, and label claims) in this report are recommendations based on the available data. All GMP storage conditions, retest date/shelf lives, and label claims are supported by the appropriate documentation and change controls. The official drug product storage condition, expiry date/shelf life, and label claims are documented in the appropriate controlled specification document (VQD-SPEC-027213).

Scope:

This study is designed to evaluate the stability of VIR-7831(GSK4182136) drug product, stored at the long-term 2°C – 8°C (5°C), and accelerated 25°C/60% RH (25°C) conditions. The vials are stored in the inverted orientation. These stability data presented in this report supports a recommended storage condition of "store at 2°C – 8°C" and a proposed shelf life of 48 months. The official shelf life is documented on the appropriate specification document (VQD-SPEC-027213) using the appropriate documentation and change control.

Summary:

The stability data for the VIR-7831(GSK4182136) drug product (62.5 mg/mL) batches (manufactured using the early-stage process and commercial process), described in **Table 1** and **Table 2**, were entered into Statistica Statistical Analysis Software. The data for each batch and storage condition was plotted using scatterplots versus time to generate trend plots. These trend plots can be used to assess changes in the results over time, in terms of empirical relationships. In addition, degradation model (Statistica 13.5.0) was used since the data for the batches manufactured using the early-stage process and the commercial process could be pooled.

The data collected at the long-term (2°C – 8°C) storage condition and the accelerated (25°C/60% RH) condition are used to support the expiry date (clinical) and shelf life (EUA) of the material, according to ICH guidance Q1E "Evaluation for Stability Data" and Q5C "Stability Testing of Biological Products." This guidance applies to drug substance and drug product for use in humans.

The drug product process specification (VQD-SPEC-027213) is provided in **Table 3**. The details of the stability container are provided in **Table 4**.

The trend plots in **Figure 21 - Figure 30** demonstrate that VIR-7831(GSK4182136) drug product (62.5 mg/mL) manufactured at WuXi and Parma in a 10 mL vial, have stability indicating attributes that are demonstrated to remain within specifications, at the recommended storage condition of "store at 2°C – 8°C" up to 48 months for Clinical studies and 42 months for EUA studies.

Table 1: Summary of VIR-7831 (GSK4182136) 25mg/mL and 62.5 mg/mL Drug Product Gen1 and Gen2 Scale Process Drug Product in a 10 mL Vial Manufactured at WuXi

Batch #	Description	Storage Conditions	Study Condition	Available Data	Length of Study	Stability Report
202006002	Clinical Gen1 25 mg/mL	5 ± 3°C 25 ± 2°C/60 ± 5% RH 40 ± 2°C/75 ± 5% RH	Long Term Accelerated Stress	36 Months Study Complete Study Complete	36 Months 6 Months 6 Months	Report Number: 11034
202006004	Clinical Gen1 25 mg/mL	5 ± 3°C 25 ± 2°C/60 ± 5% RH 40 ± 2°C/75 ± 5% RH	Long Term Accelerated Stress	36 Months Study Complete Study Complete	36 Months 6 Months 6 Months	Report Number: 11053
202009005	Clinical Gen2 62.5 mg/mL	5 ± 3°C 25 ± 2°C/60 ± 5% RH 40 ± 2°C/75 ± 5% RH	Long Term Accelerated Stress	30 Months Study Complete Study Complete	60 Months 6 Months 3 Months	Report Number: 5836
202010006	Clinical Gen2 62.5 mg/mL	5 ± 3°C 25 ± 2°C/60 ± 5% RH 40 ± 2°C/75 ± 5% RH	Long Term Accelerated Stress	30 Months Study Complete Study Complete	60 Months 6 Months 3 Months	Report Number: 6671
Clinical trial material has been demonstrated to be comparable to the commercial-scale material as described in the filing and supporting documentation.						

Table 2: Summary of VIR-7831 (GSK4182136) Commercial Scale Process Drug Product (62.5 mg/mL) Batches in a 10 mL Vial Manufactured at Parma						
Batch #	**Description**	**Storage Conditions**	**Study Condition**	**Available Data**	**Length of Study**	**Stability Report**
202421682	Engineering batch	2 – 8°C 25 ± 2°C/60 ± 5%RH 40 ± 2°C/75 ± 5%RH	Long Term Accelerated Stress	24 Months Study Complete Study Complete	36 Months 6 Months 3 Months	VQD-RPT-056817
8H5D	GMP1 Clinical Emergency use	2 – 8°C 25 ± 2°C/60 ± 5%RH 40 ± 2°C/75 ± 5%RH	Long Term Accelerated Stress	24 Months Study Complete Study Complete	36 Months 6 Months 3 Months	VQD-RPT-065745
9G7S	GMP3 Clinical Emergency use	2 – 8°C 25 ± 2°C/60 ± 5%RH 40 ± 2°C/75 ± 5%RH	Long Term Accelerated Stress	24 Months Study Complete Study Complete	36 Months 6 Months 3 Months	VQD-RPT-065746
CF2J	PPQ1 Clinical Emergency use	2 – 8°C 25 ± 2°C/60 ± 5%RH 40 ± 2°C/75 ± 5%RH	Long Term Accelerated Stress	24 Months Study Complete Study Complete	36 Months 6 Months 3 Months	VQD-RPT-123341
FW9J	PPQ2 Clinical Emergency use	2 – 8°C 25 ± 2°C/60 ± 5%RH 40 ± 2°C/75 ± 5%RH	Long Term Accelerated Stress	24 Months Study Complete Study Complete	36 Months 6 Months 3 Months	VQD-RPT-123342
FX4A	PPQ3 Clinical Emergency use	2 – 8°C 25 ± 2°C/60 ± 5%RH 40 ± 2°C/75 ± 5%RH	Long Term Accelerated Stress	24 Months Study Complete Study Complete	36 Months 6 Months 3 Months	VQD-RPT-123343

Table 3: VIR-7831 (GSK4182136) Drug Product Specifications	
Attribute	**VQD-SPEC-027213[1]**
Appearance	Liquid essentially free of visible particles
Color	≤ B5
Clarity	≤ 15.0 NTU
pH	5.5 – 6.5
Protein Conc.	56.3 – 68.7
SEC Monomer	≥ 95.0%
SEC HMW	≤ 5.0%
CE-SDS Reduced	(LC + HC)[2] ≥ 95.0%
CE-SDS Non Reduced	≥ 95.0%
cIEF Main Peak	≥ 50.0%
cIEF Acidic Species	≤ 45.0%
cIEF Basic Species	≤ 20.0%
Potency (ELISA)	70 – 130%
Potency (PNA)	60 – 140%
Particulate Matter	≥ 10 µm: ≤ 6000 particles/container ≥ 25 µm: ≤ 600 particles/container
PS-80	0.02 – 0.06% (w/v)
1. According to the shelf life (Universal) specification VQD-SPEC-027213 Rev.9.0 2. LC = light chain, HC = heavy chain HMW = high molecular weight PNA = Pseudovirus Neutralization Assay	

Table 4: VIR-7831(GSK4182136) Drug Product Container Closure Information		
Container Closure Component	**Description**	**Manufacturer**
Primary (vial)	10 mL Borosilicate glass injection vial (Type I glass)	Nuova Ompi SAP Code 62000000056322
Stopper	20mm/Chlorobutyl Rubber Serum Stopper with compound film, 20mm/Grey	West (SAP code 62000000055225)
Cap	20 mm Aluminum-plastic cap	West (SAP code 10000000095544)

STABILITY ANALYSIS

Data presented within this section will include the following:

- Scatterplots profiling the stability test attributes for the VIR-7831 drug product batches evaluated at the long-term and accelerated stability storage conditions listed in **Table 1 and Table 2**.
- Evaluation of product quality attributes that demonstrate statistically significant change with time.
- Extrapolation analysis of the stability data as function of storage time for product quality attributes demonstrating statistically significant change with time. This analysis is intended to determine if the width of the predicted confidence interval at the 36-month time point conforms to stability acceptance criteria for the VIR-7831 Gen2 GMP DP batches.
- Statistica Stability Reports have been uploaded to the Veeva system, reference VQD-RPT-242787.

Stability Profiles of VIR-7831 DP Batches Using Statistica

- Stability plots for the following test attributes did not indicate any trend and meet the acceptance limits specified in Table 2: Subvisible 10 and 25 μm (**Figure 3**) and Protein Concentration (**Figure 9**).

- Stability plots for pH (**Figure 2**) indicate for the lot 8H5D the results would exceed the 95% confidence interval at the high specification before the 48 month proposed clinical expiry. This is due to the fact that lot 8H5D have only 24 months of data. Lots with additional intervals past the 24 month interval indicate that the product would remain within the specifications well past the current expiration period. With additional data from lot 8H5D it would be expected that this lot would also be within the specification range through the 48 month proposed clinical expiry.

- Stability plots for the following test attributes indicate a downward trend and results meet the acceptance limits specified in **Table 3**: PS80 (**Figure 4**). The statistical analysis shows that lot FX4A would not meet the specification at the lower 95% confidence interval before 36 month timepoint. Lot FX4A has 24 months of data presented. At the accelerated condition it is observed that there is logarithmic trend where there is a large downtrend trend at the 0 through 3 month interval and then the trend levels off at the 6 month interval. Also, it is expected that with additional results generated for later intervals that the downtrend in the results will level and remain within the lower specification.

- Stability plots of Potency data from the long-term and accelerated storage conditions (**Figure 5**) did not exhibit any consistent trends. The stability plot of Potency data generated for the stressed storage condition displayed a clear and similar downward trend for all DP batches listed in **Table 1** and **Table 2**. All potency data have met the acceptance limit specified in **Table 3**.

- Purity by CE-SDS (Reduced and Non-Reduced) in **Figure 6** did not exhibit trends at 5°C storage condition while data plots from the accelerated and stressed conditions both displayed a downward trend similar to each other. All long-term stability data to date have met the acceptance criteria specified in **Table 3**.

- Purity by cIEF (Main Peak, Acidic species, Basic species) in **Figure 7** did exhibit similar trends across the VIR-7831 DP batches. The main peak and basic charge exhibit clear decreases while the acidic charge variants increase as a function of storage time at the stressed condition (40°C). Samples stored at the long-term temperature condition analyzed to date have met the acceptance limits specified in **Table 3** for DP purity by cIEF.

- Purity by SEC (Monomer and HMW) in **Figure 8** demonstrated similar trends across the VIR-7831 DP batches. A downward trend was observed in Monomer content together with an inverse increasing trend in HMW content. All data met the stability acceptance criteria listed in **Table 3** for DP purity by SEC.

- The protein concentration attribute did not exhibit trends across the DP batches as summarized in **Figure 9**. VIR-7831 Gen 1 and Gen 2 DP are formulated at different protein concentrations. Data for all batches of DP analyzed in this report met the acceptance limits as specified in **Table 3.**

Stability Profiles of VIR-7831 (GSK4182136) DP at 5C and 25C

Figure 1: Clarity for VIR-7831 DP (GSK4182136)
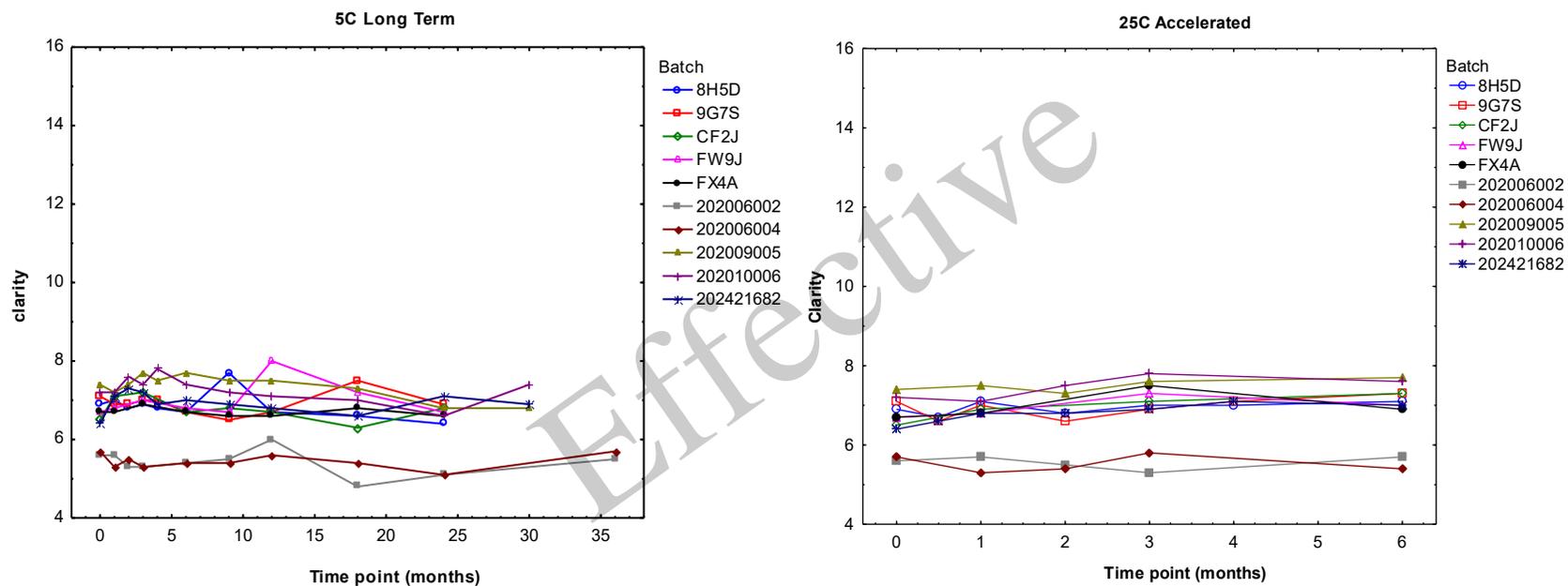
Figure 2: pH for VIR-7831 DP (GSK4182136)
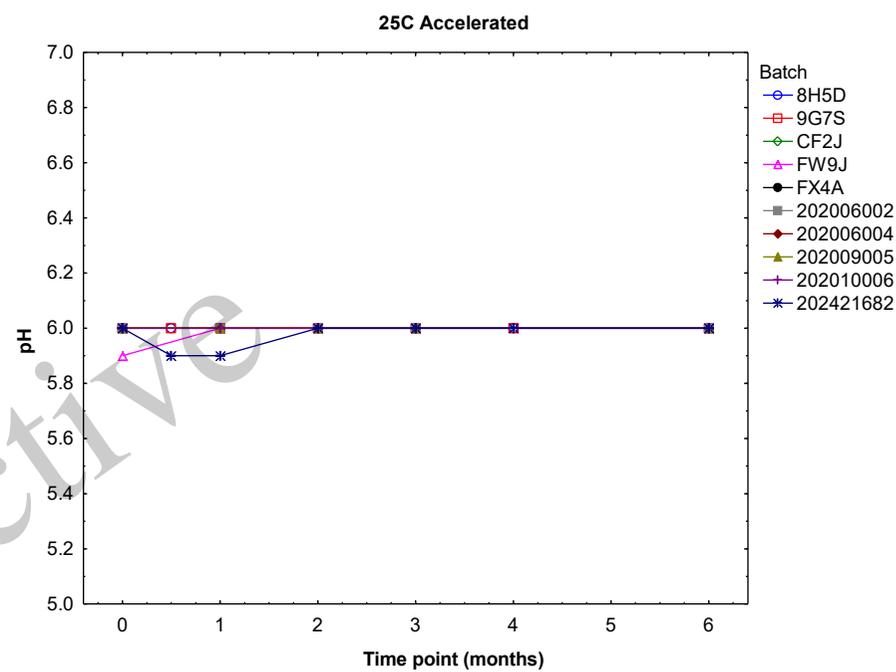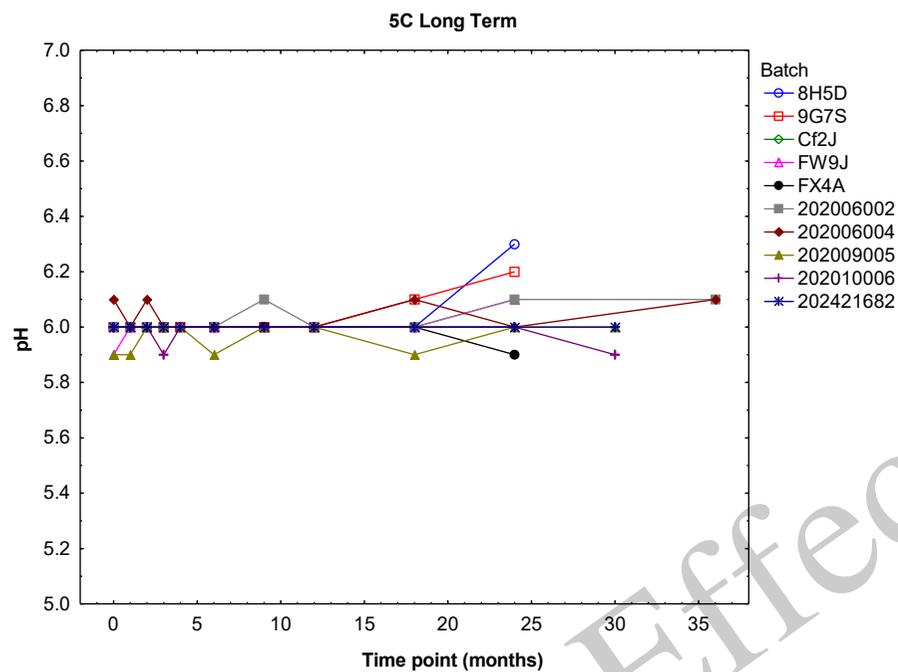
Figure 3: Subvisible Particulate for VIR-7831 (GSK4182136) DP
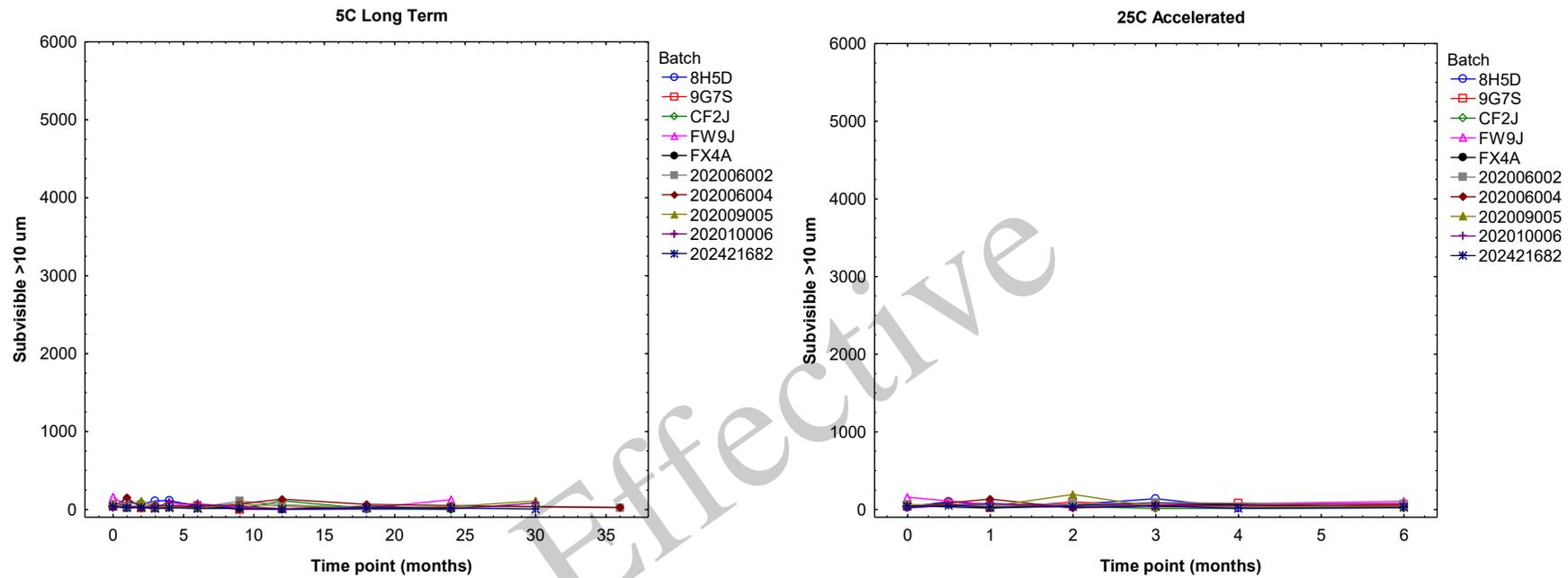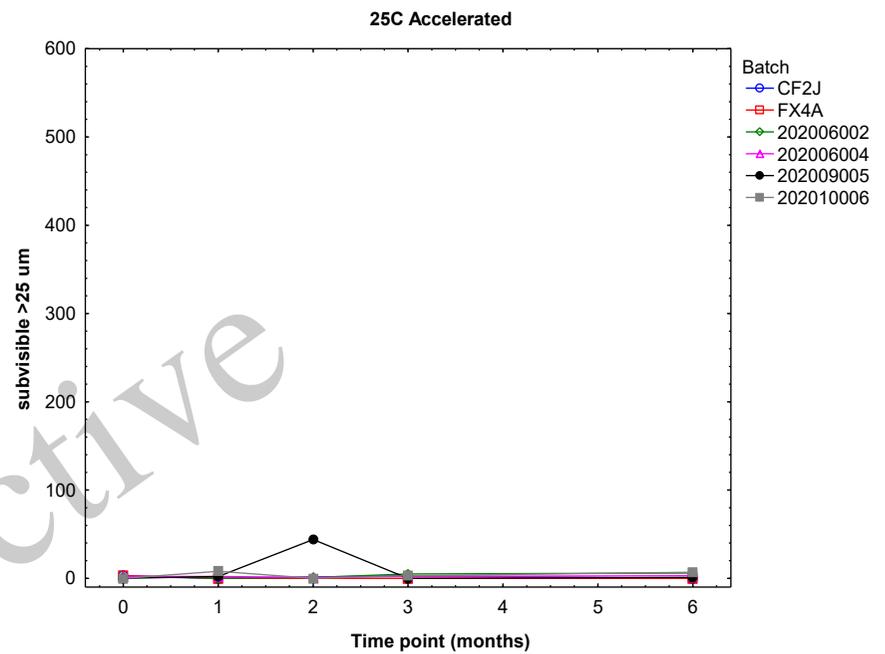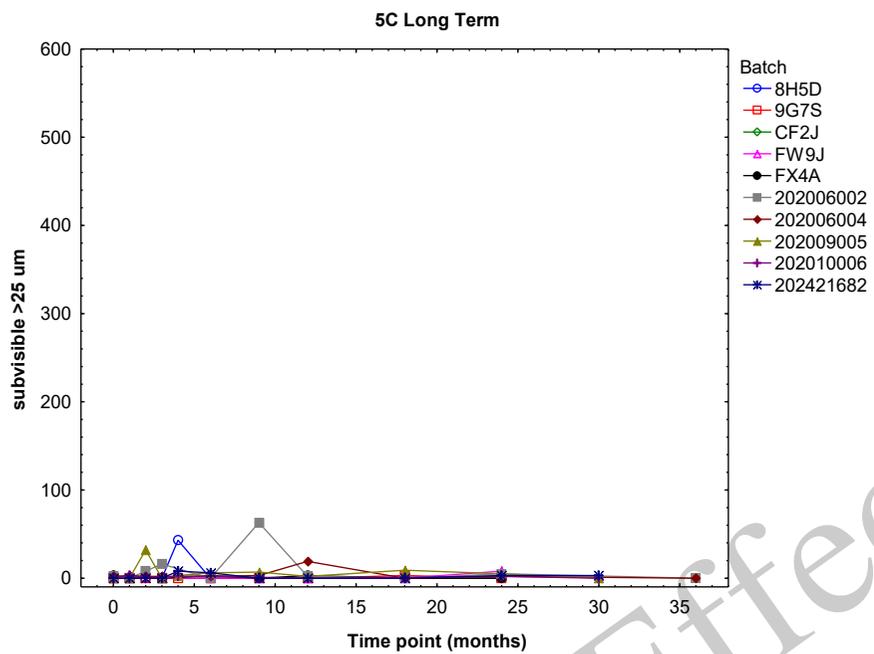
Batches that are not included had values that are all Zero and are not able to be graphed in Statistica.

**Figure 4: Polysorbate 80 for VIR-7831 (GSK4182136) DP**
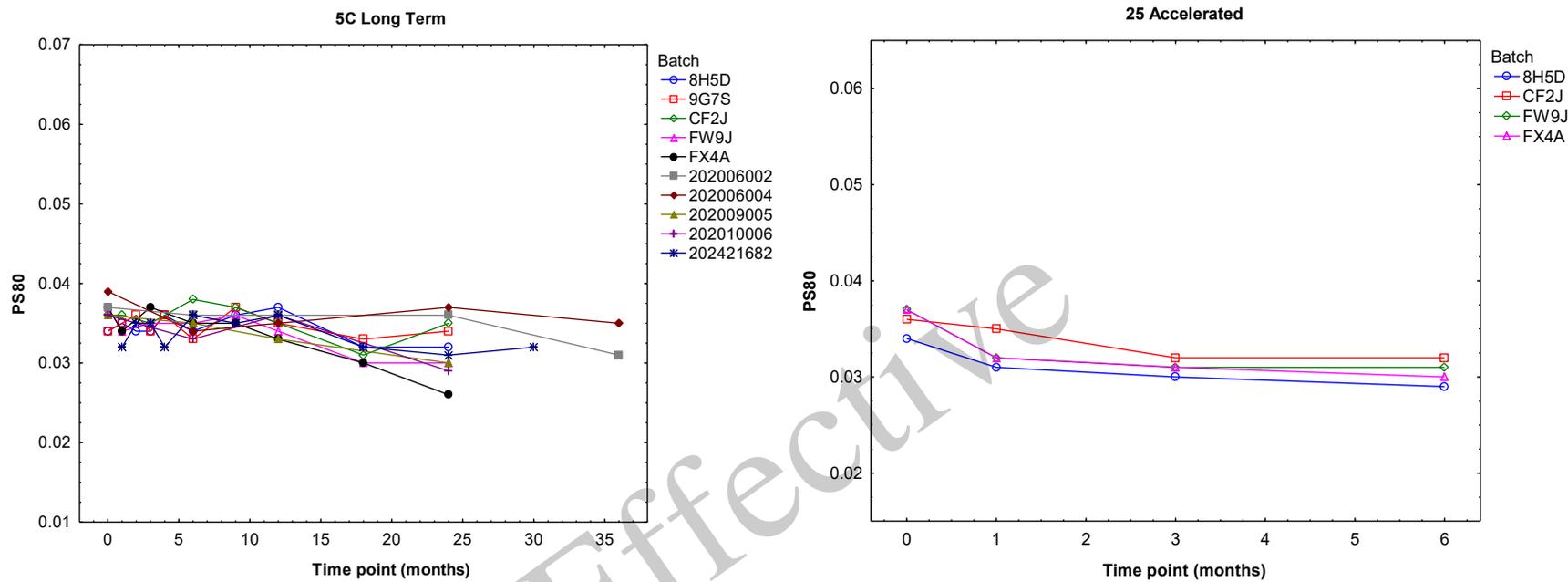
Figure 5: Potency for VIR-7831 (GSK4182136) DP
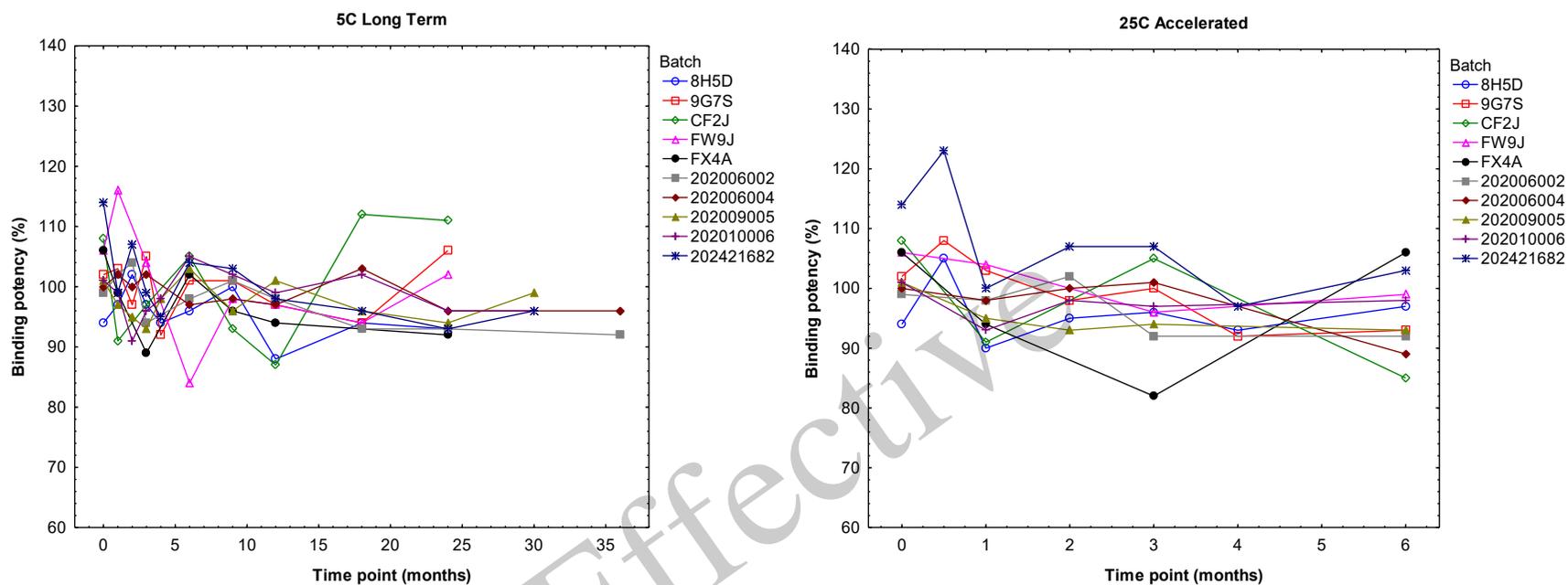
**Figure 6: CE-SDS (Reduced and Non-Reduced) for VIR-7831 (GSK4182136) DP**

VIR-7831 Drug Product Stability Trend Report
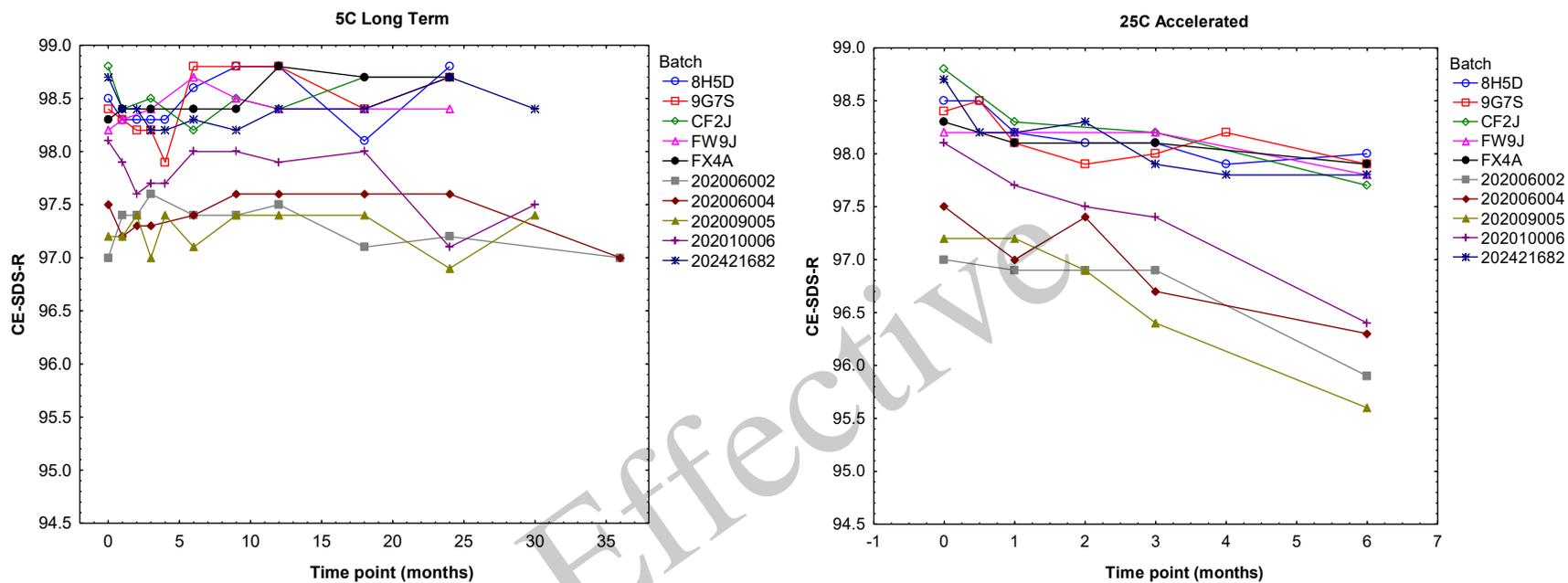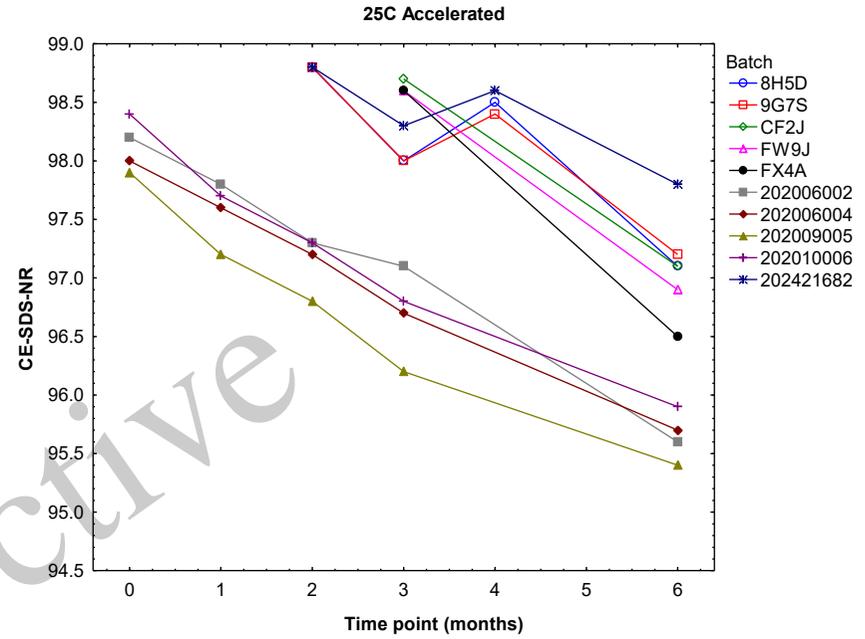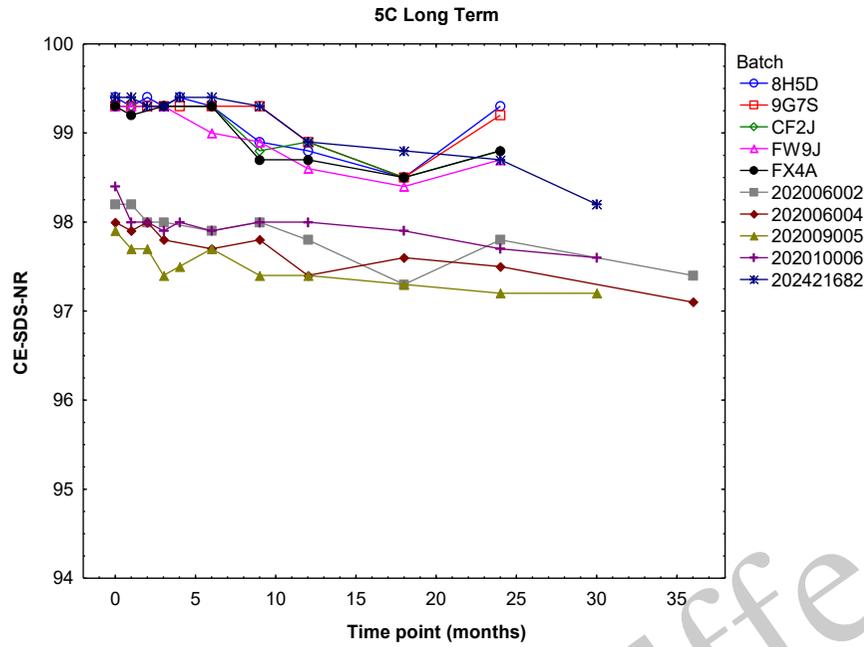
**Figure 7: Charge Variant Analysis for VIR-7831 (GSK4182136) DP**

# VIR-7831 Drug Product Stability Trend Report

VIR-7831 Drug Product Stability Trend Report
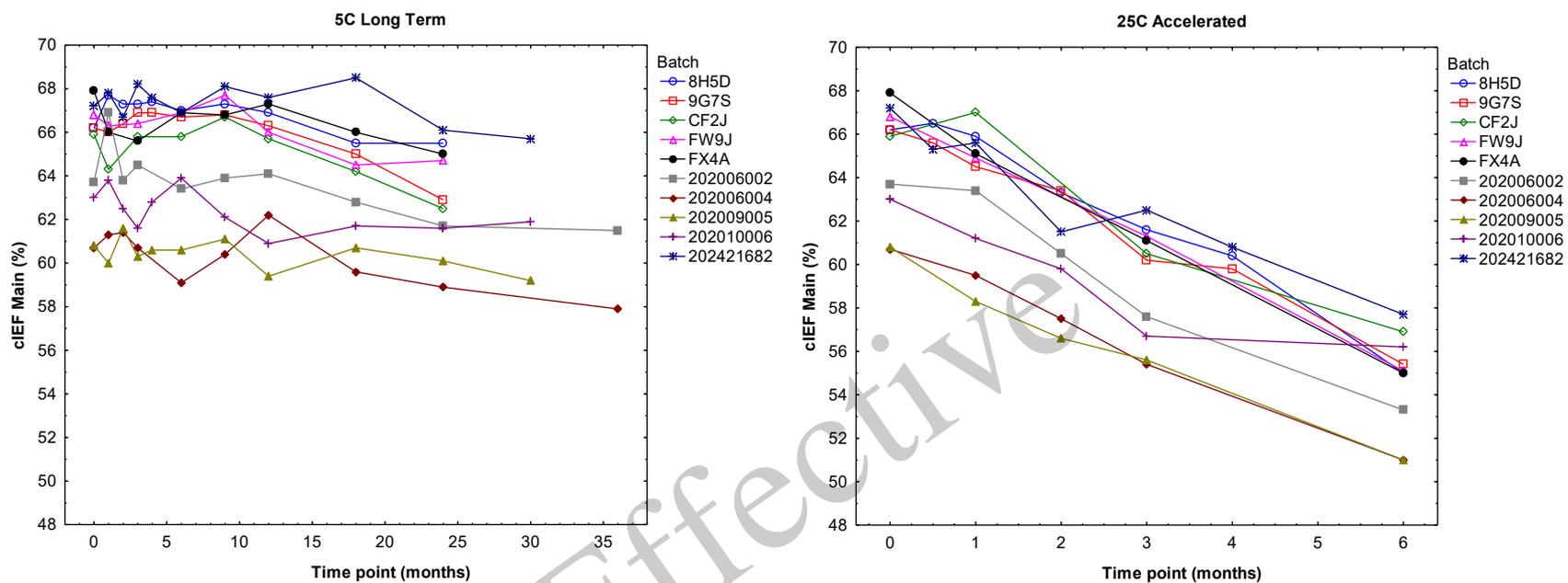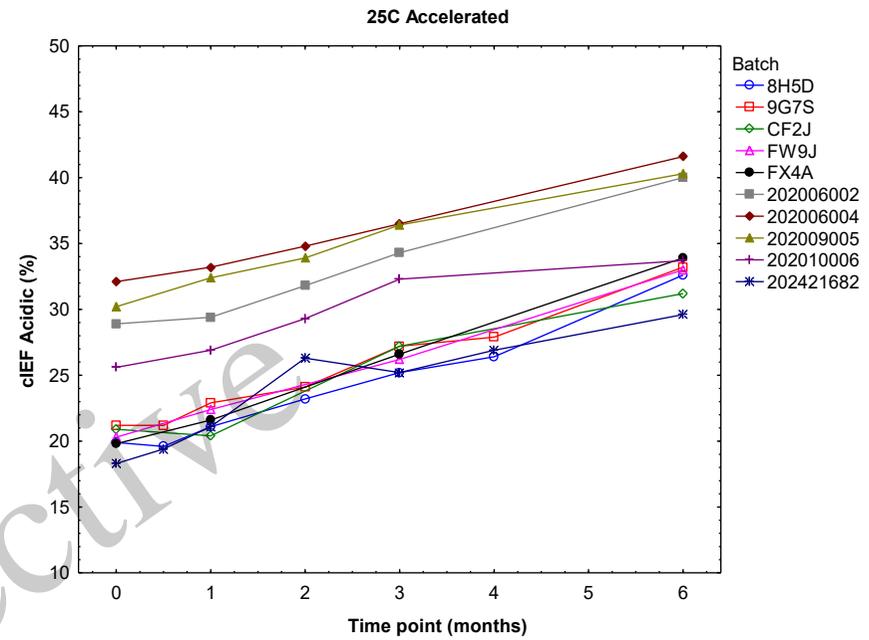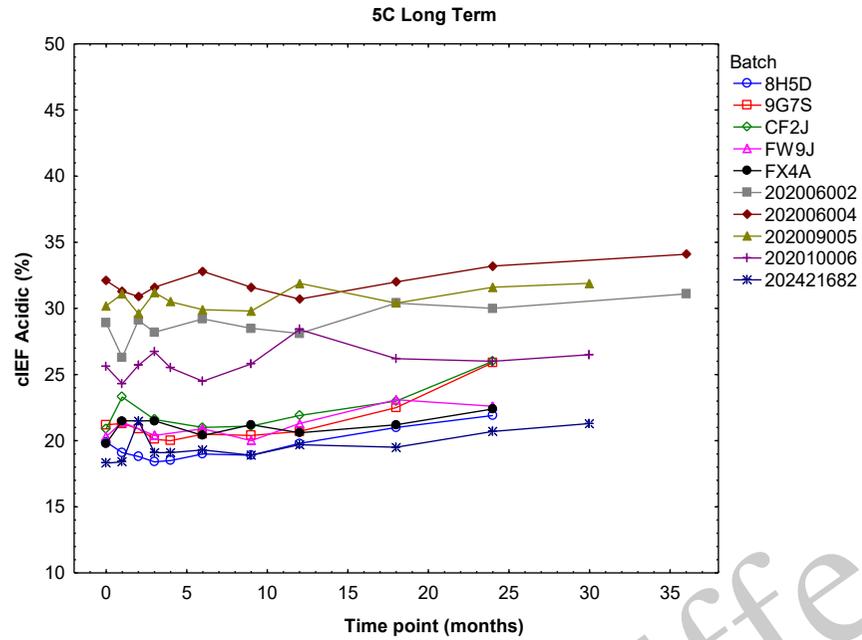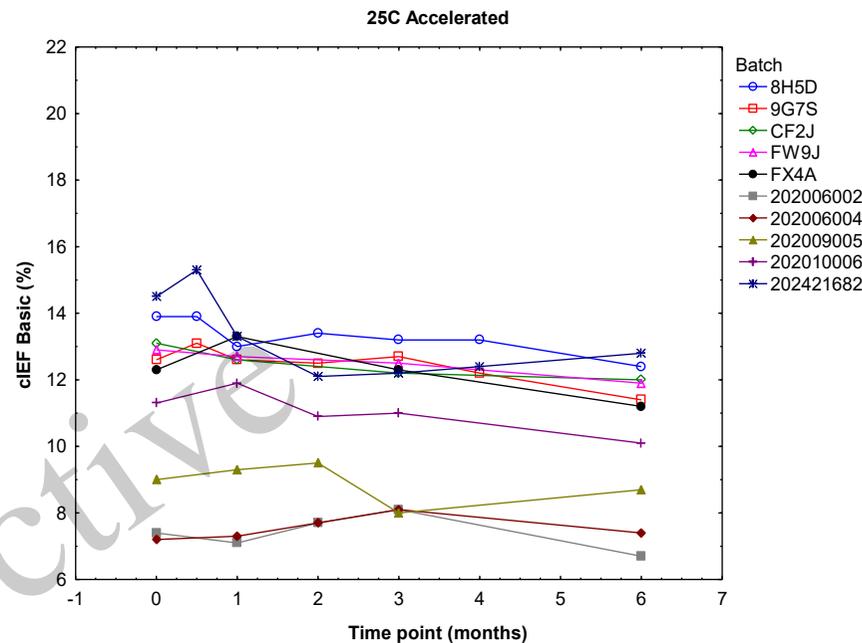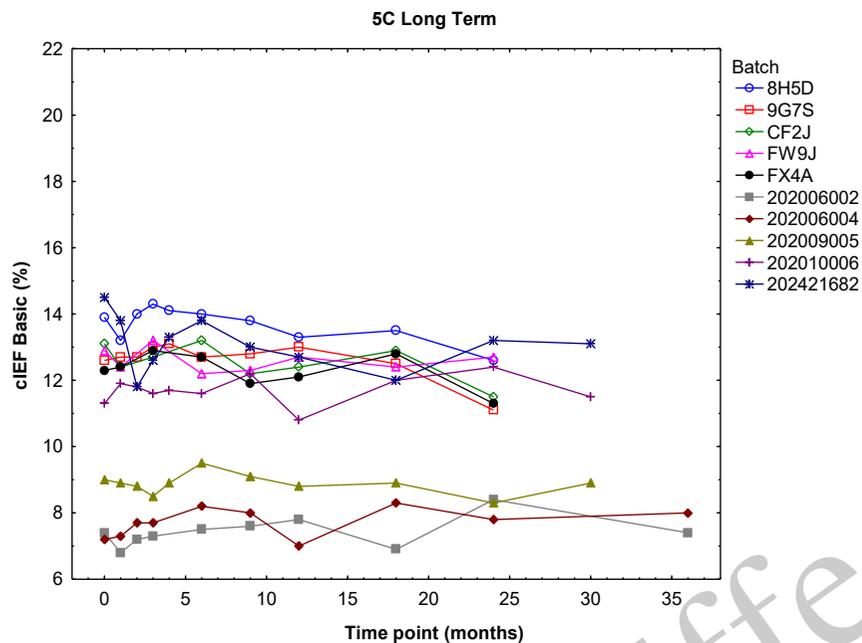
Figure 8: SEC HPLC for VIR-7831 (GSK4182136) DP

# VIR-7831 Drug Product Stability Trend Report

Figure 9: Protein Concentration for VIR-7831 (GSK4182136) DP
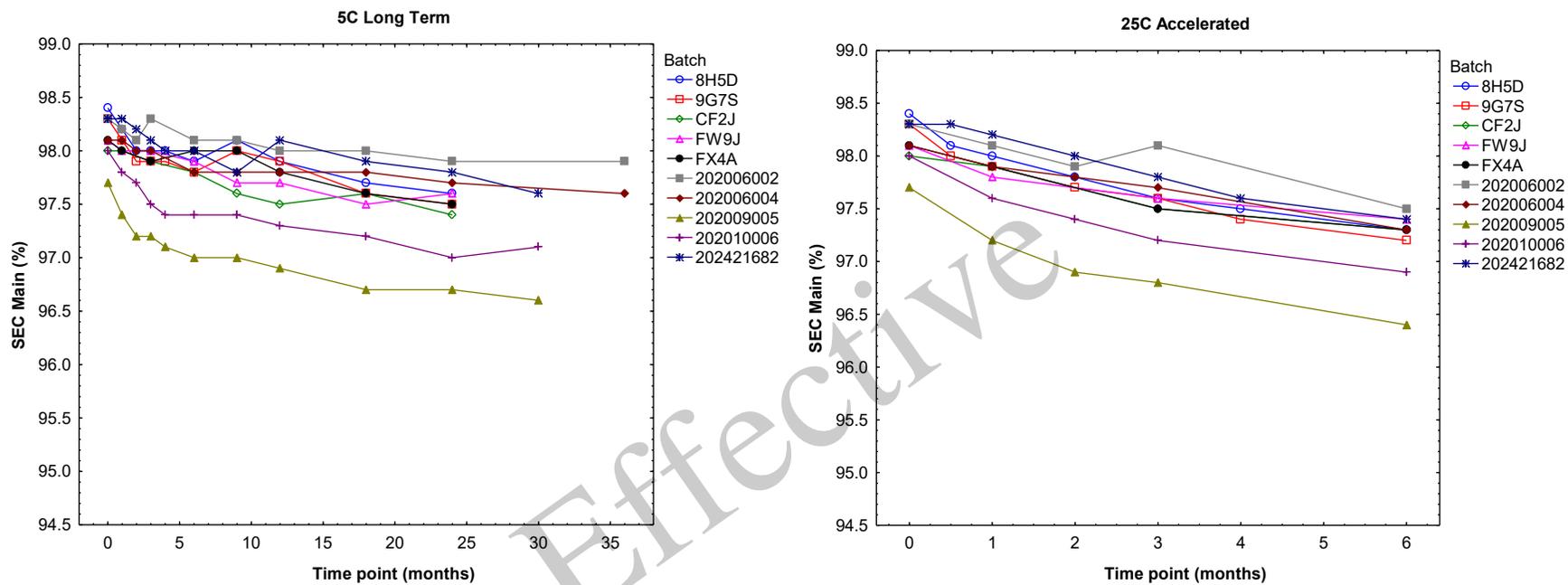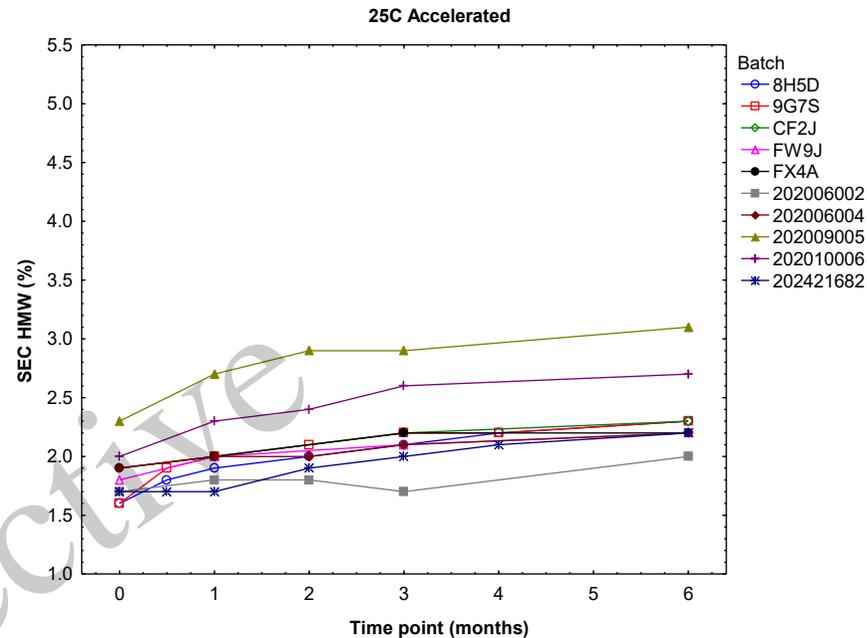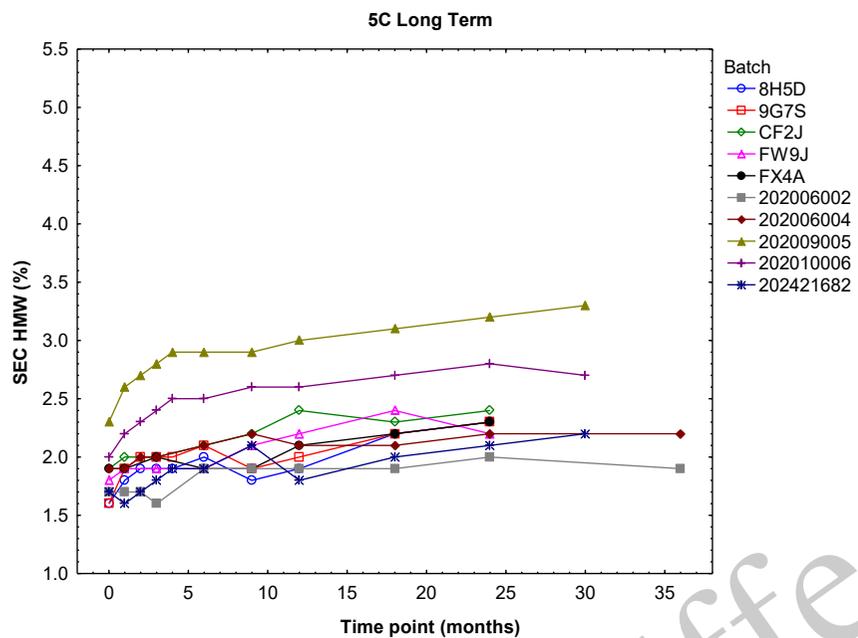
Evaluation of Nominal Storage Condition Stability Test Data for Statistically Significant Change with Time

Statistical analysis of long-term stability data in **Table 1** and **Table 2** was performed using Statistica 13.5.0 to determine if assay results displayed statistically significant trends with storage time. Clinical and commercial batches were included since the data could be pooled. The Statistica stability macro was used to determine whether if a common slope could be used or if separate slopes should be used. Table 6 indicates when a common slope for all batches were used and when the separate slopes are used with the p-values of each batch.   Slopes with a p-value ≤ 0.05 were considered statistically different from zero, while slopes with a p-value > 0.05 were considered not significantly different from zero. For assays with statistically significant trends (slope p-value ≤0.05), the predicted shelf life was taken as the time (in months) when either the upper or lower 95% prediction interval equalled the assay upper or lower specification acceptance criteria. Assays with an insignificant slope (p-value > 0.05) were not used to predict shelf life. The maximum allowable shelf-life was set to 144 months in this analysis. **Table 6** summarizes the slope p-values and predicted shelf life from each assay. Statistica Stability Reports have been uploaded to the Veeva system, reference VQD-RPT-242787.

Table 6:   SHELF-LIFE ANALYSIS SUMMARY

Evaluation of slopes and intercepts per Q1E using degradation modeling

Test	Stability Specification	p-value of slope	Predicted time to specification 95% CI at 5°C	Statistical Assessment per Test
Clarity	≤ 15.0 NTU	Common Slopes 0.029532	>144 months	Shelf-Life not found within maximum allowed extrapolation distance
pH	6.0 ± 0.5	Separate Slopes Lots Below 0.05: 8H5D – 0.000006 9G7S – 0.000057 FW9J – 0.012365 202006002 – 0.017308	46 months[1]	46 months - 8H5D 50 months - 9G7S 68 months - FW9J 100 months - 202006002
Charge Variants by cIEF	Main peak: ≥ 50.0%	Common Slopes 0.000000	>144 months	Shelf-Life not found within maximum allowed extrapolation distance
	Acidic peaks: ≤ 45.0%	Separate Slopes Lots below p 0.05: 8H5D – 0.002595 9G7S – 0.000025 CF2J – 0.000690 FW9J – 0.016953 202006002 – 0.001337 202006004 – 0.012925 202421682 – 0.027579	107 months	107 months - 9G7S 115 months – CF2J 133 months – 202006002 128 months – 202006004 For the remaining lots with p-values below 0.05 the shelf-life not found within maximum allowed extrapolation distance.
	Basic peaks: ≤ 20.0%	Separate Slopes Lots below p 0.05: 8H5D – 0.025100 9G7S – 0.014628	>144 months	Shelf-Life not found within maximum allowed extrapolation distance

Test	Specification	Slopes	Shelf-Life	Comments
Purity by SEC-HPLC	Main Peak (monomer): ≥ 95.0%	Separate Slopes Lots below p 0.05: 8H5D – 0.000000 9G7S – 0.000000 CF2J – 0.000000 FW9J – 0.000000 FX4A – 0.000001 202006002 – 0.000037 202006004 – 0.000001 202009005 – 0.000000 202010006 – 0.000000 202421682 – 0.000000	>144 months	Shelf-Life not found within maximum allowed extrapolation distance
	HMW ≤ 5.0%	Separate Slopes Lots below p 0.05: 8H5D – 0.000019 9G7S – 0.000223 CF2J – 0.000109 FW9J – 0.000070 FX4A – 0.001123 202006002 – 0.015949 202006004 – 0.018740 202009005 – 0.000000 202010006 – 0.000000 202421682 – 0.000022	78 months	112 months – 8H5D 122 months – 9G7S 107 months – CF2J 109 months – FW9J 126 months – FX4A 78 months - 202009005 108 months – 202010006 For the remaining lots with p-values below 0.05 the shelf-life not found within maximum allowed extrapolation distance.
CE-SDS (Non-Reduced)	Main Peak% ≥ 95.0%	Common Slopes 0.000000	<144 months	Shelf-Life not found within maximum allowed extrapolation distance
CE-SDS (Reduced)	(Light Chain + Heavy Chain) ≥ 95.0%	Separate Slopes Lots below p 0.05: 9G7S – 0.036216 202010006 – 0.022063	111 months	111 months – 202010006 For lot 9G7S the shelf-life not found within maximum allowed extrapolation distance.
Potency by ELISA	70%-130% relative potency	Common Slopes 0.001157	>144 months	Shelf-Life not found within maximum allowed extrapolation distance
Subvisible Particulate Matters (≥ 10µm)	≤ 6000 particles/container	Common Slopes 0.062779	N/A	No Trend
Subvisible Particulate Matters (≥ 25µm)	≤ 600 particles/container	Common Slopes 0.726515	N/A	No Trend
Polysorbate 80	0.02 ± 0.06% (w/v)	Separate Slopes Lots below p 0.05: FW9J – 0.000822 FX4A – 0.000001 202006002 – 0.017135 202009005 – 0.007919 202010006 – 0.007919	41 months[1]	55 months - FW9J 41 months – FX4A 94 months - 202006002 51 months – 202009005 51 months – 202010006
Protein Concentration	56.3 – 68.7 mg/mL	Common Slopes 0.353248	N/A	No Trend

[1] See discussion in Stability Analysis section.

Statistical analysis was performed to determine any significant change in the rate of degradation in the stability attributes for VIR-7831 DP batches at the nominal storage condition (5±3°C). The analysis showed P values for the 'Time (months)' effect to be statistically insignificant (P > 0.05) for the following attributes, confirming no significant change over time:

- Subvisible Particles ≥ 10 µm
- Subvisible Particles ≥ 25 µm
- Protein Concentration

Data analysis of the following product quality attributes yielded 'Time (months)' effect P values ≤ 0.05, indicating a statistically significant change in the attribute as function of storage time:

- pH
- Clarity
- Binding Potency
- SEC (Monomer)
- SEC (HMW)
- Non-reduced CE-SDS
- Reduced CE-SDS
- cIEF (Main)
- cIEF (Acidic)
- cIEF (Basic)
- PS80

Data for the following product quality attributes which demonstrate statistically significant change as function of storage time at the nominal condition, were analysed and extrapolated to the 48-month storage interval. The extrapolation is intended to determine continued conformance of the analysed product quality attributes with stability acceptance criteria at the 48-month stability interval. Attributes that had no trend were not analysed and no graphs are presented:

- pH
- Clarity
- Binding Potency
- SEC (Monomer)
- SEC (HMW)
- Non-reduced CE-SDS
- Reduced CE-SDS
- cIEF (Main)
- cIEF (Acidic)
- cIEF (Basic)
- PS80

Assays with Statistically Significant Trends - Pooled Data with 95% Prediction Intervals

Figure 10   Pooled Stability Data for Clarity at 5°C
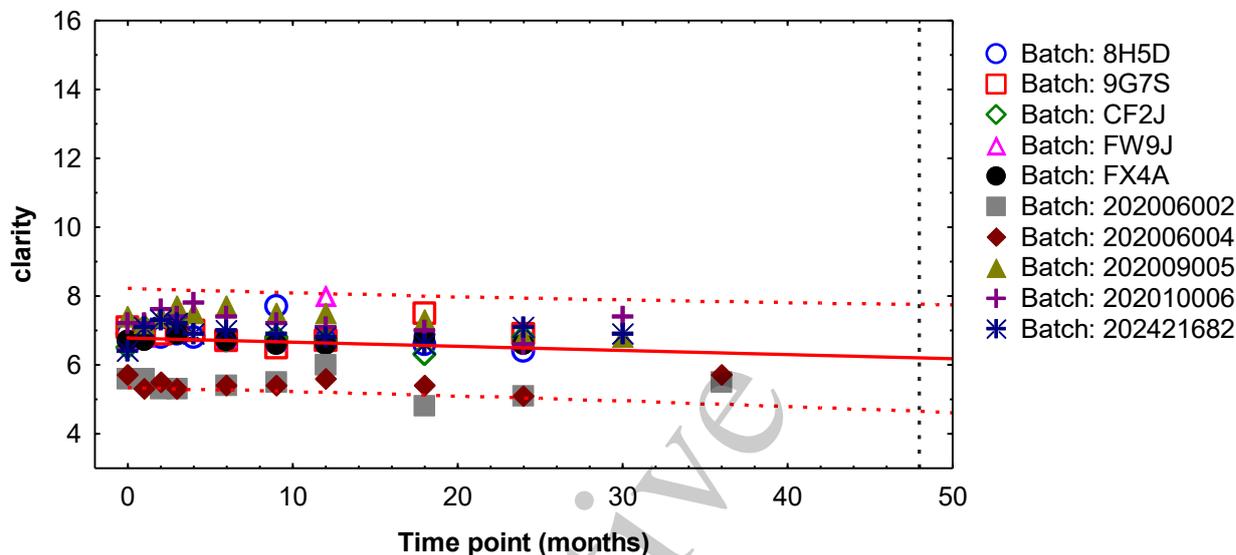
**Figure 11   Pooled Stability Data for pH at 5°C**
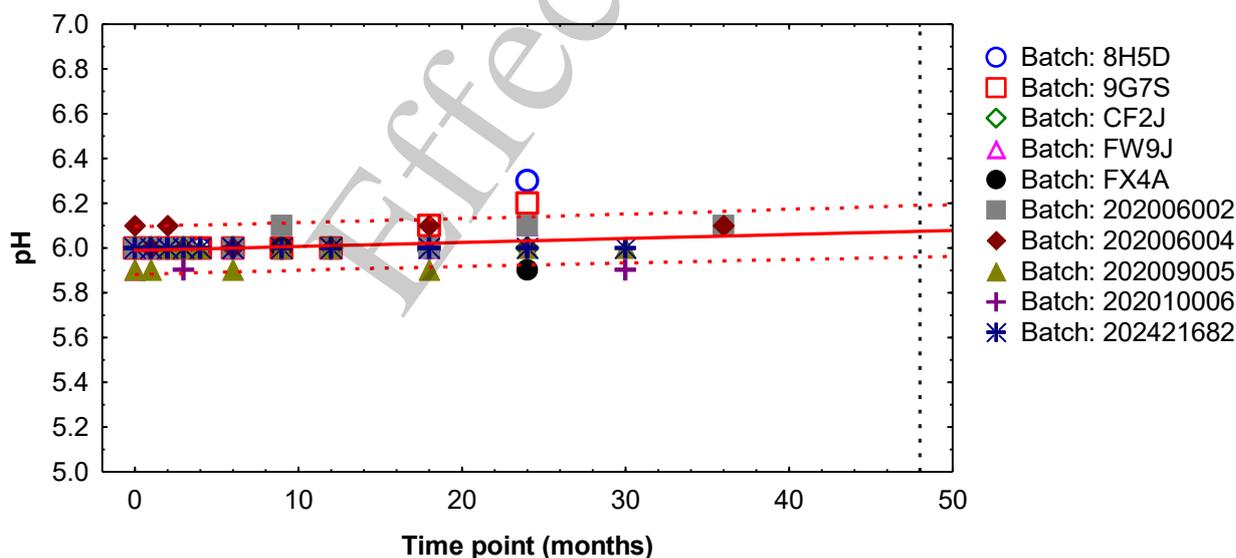
Figure 12   Stability Data for cIEF Main at 5°C
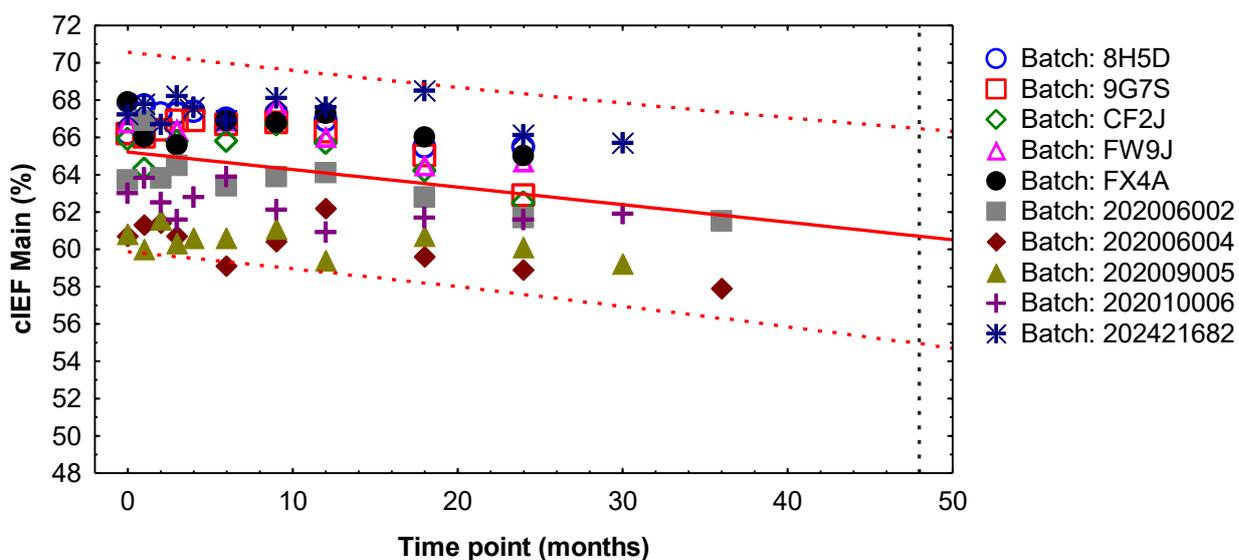
**Figure 13   Stability Data for cIEF Acidic at 5°C**
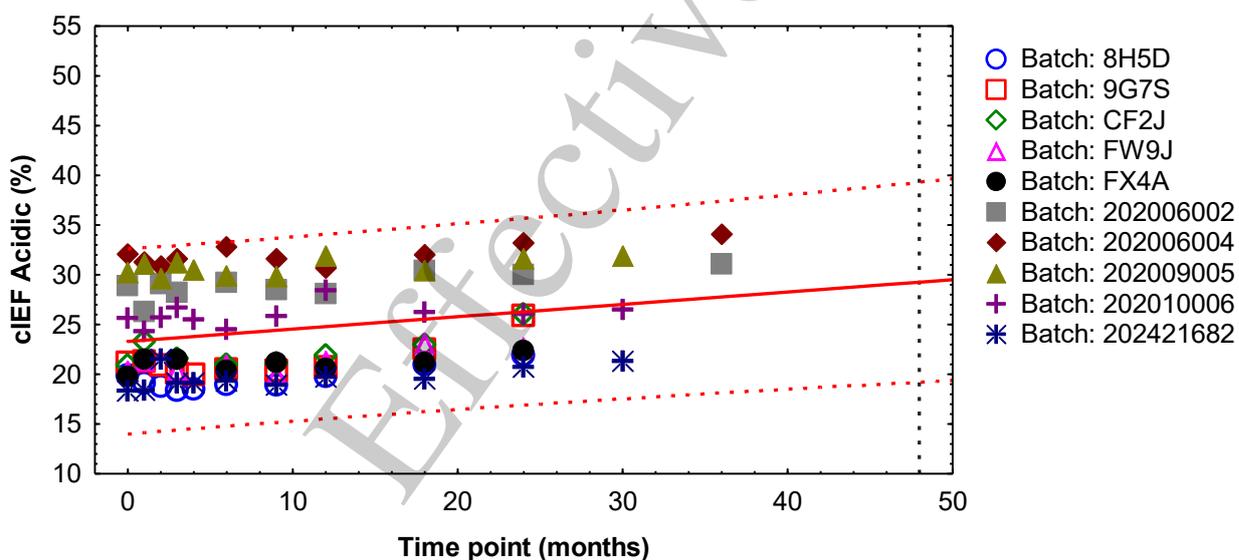
Figure 14   Stability Data for cIEF Basic at 5°C
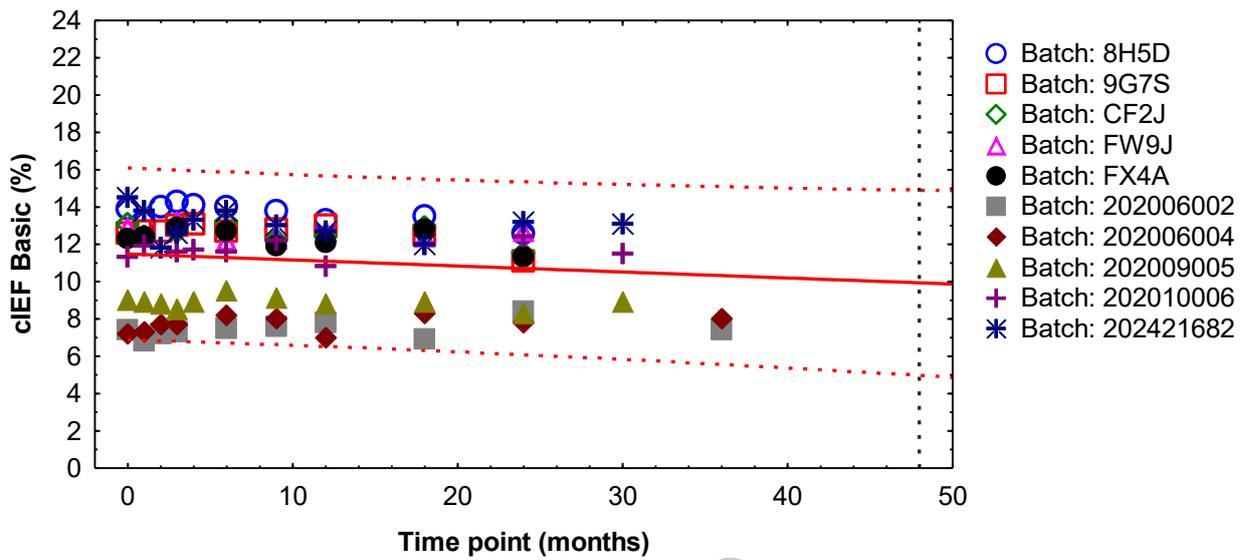
Figure 15   Stability Data for SEC Monomer at 5°C
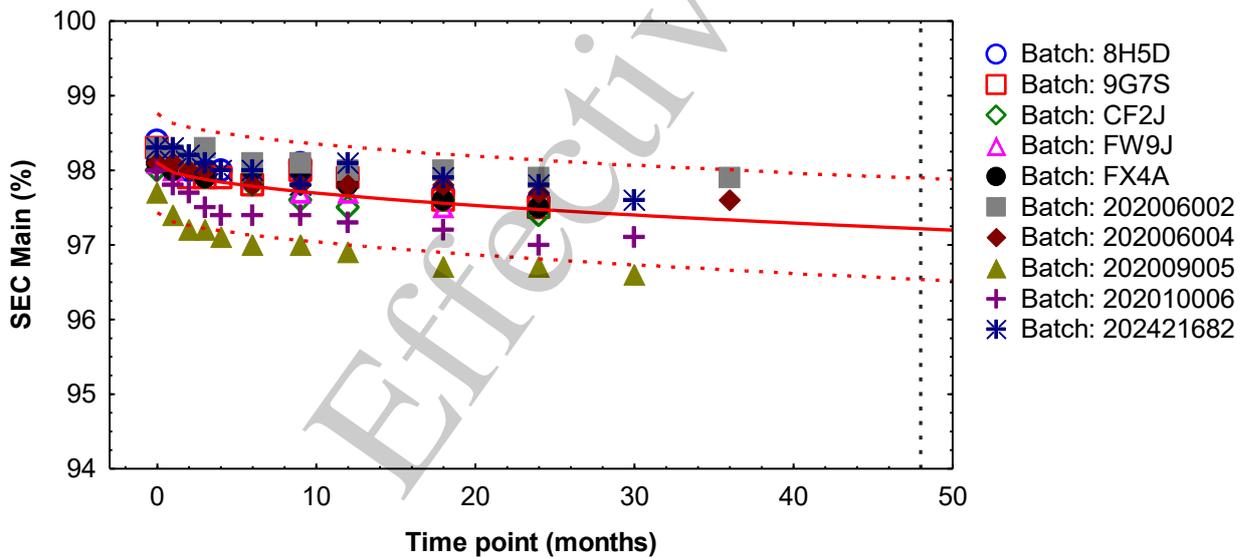
Figure 16   Stability Data for SEC HMW at 5°C
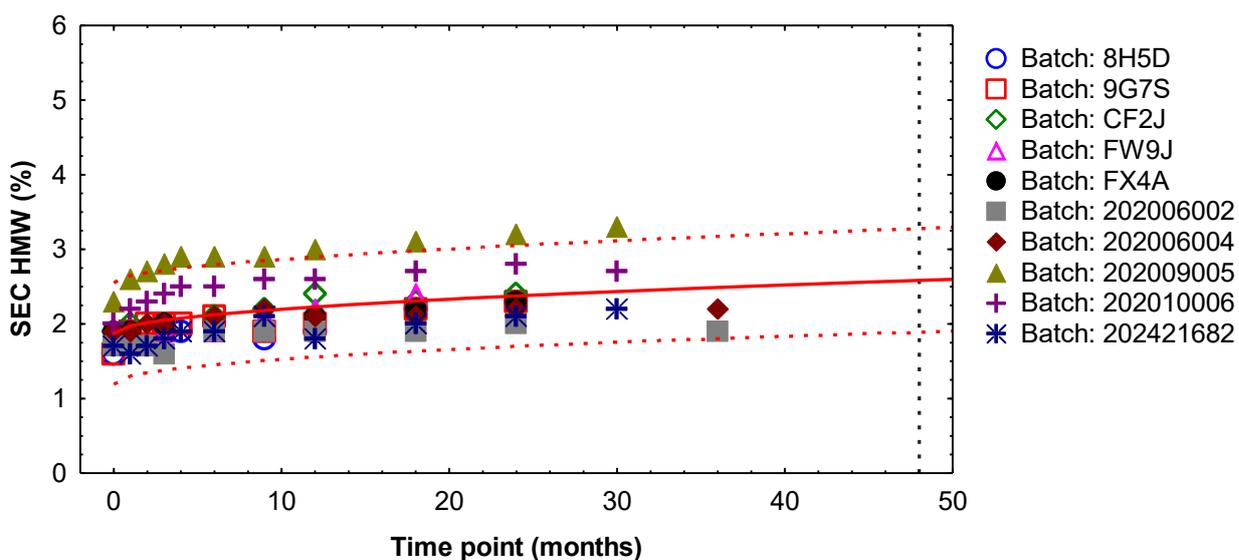
Figure 17   Stability Data for CE-SDS Non-Reduced at 5°C
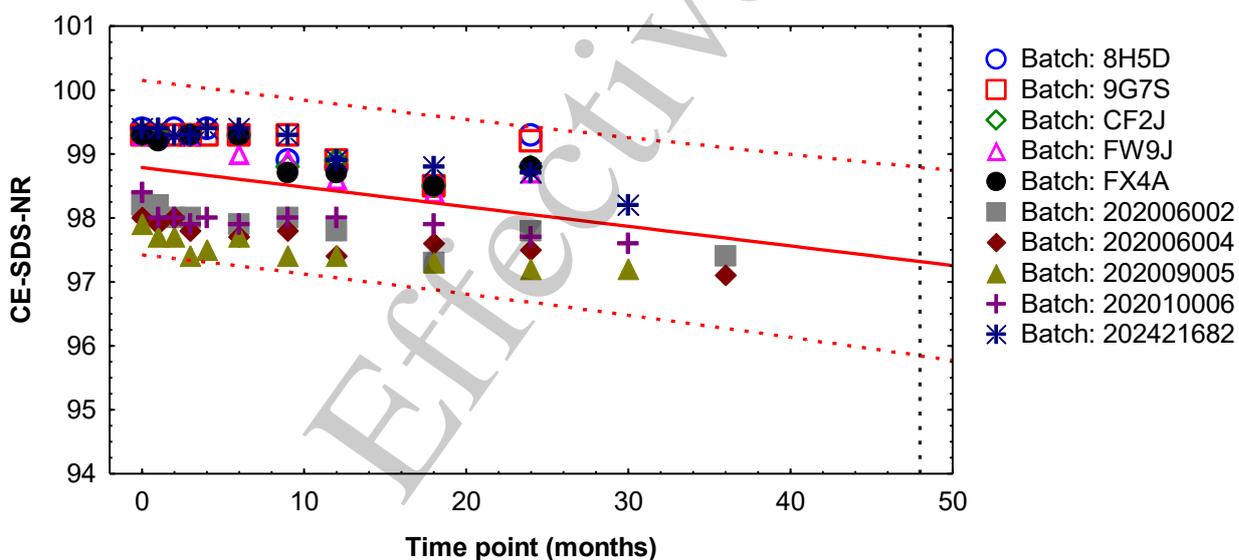
Figure 18   Stability Data for CE-SDS Reduced at 5°C
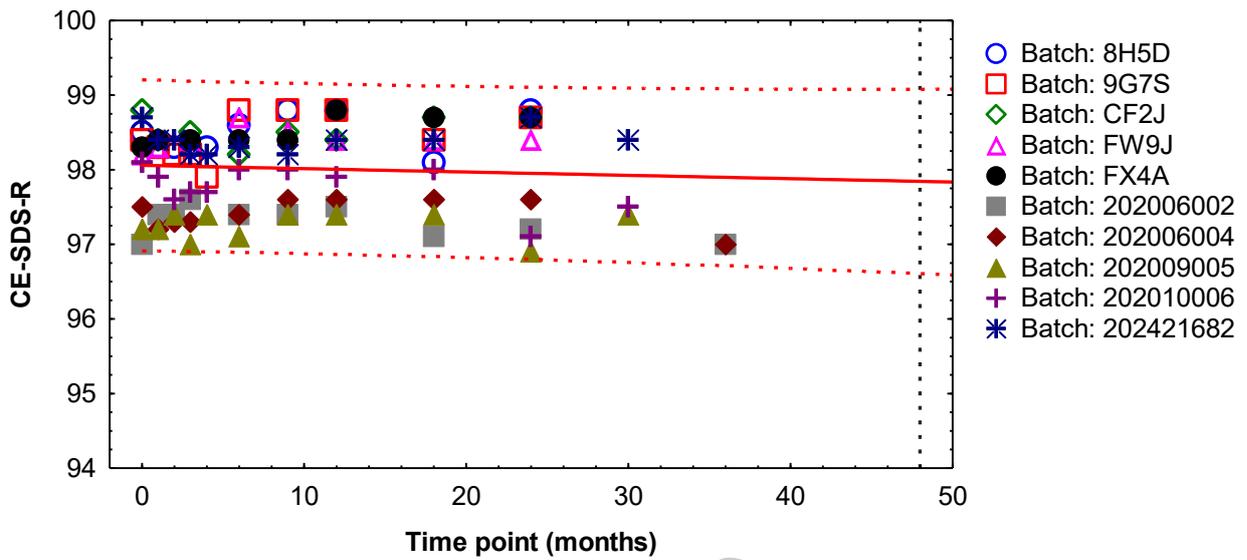
Figure 19   Stability Data for Binding Potency at 5°C
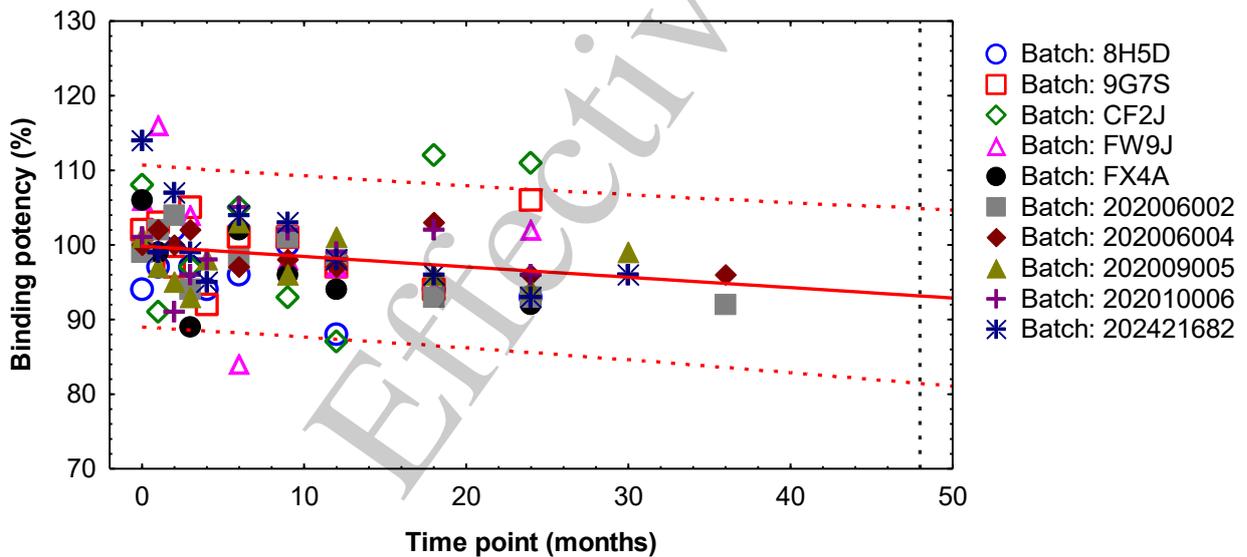
Figure 20   Stability Data for Polysorbate 80 at 5°C
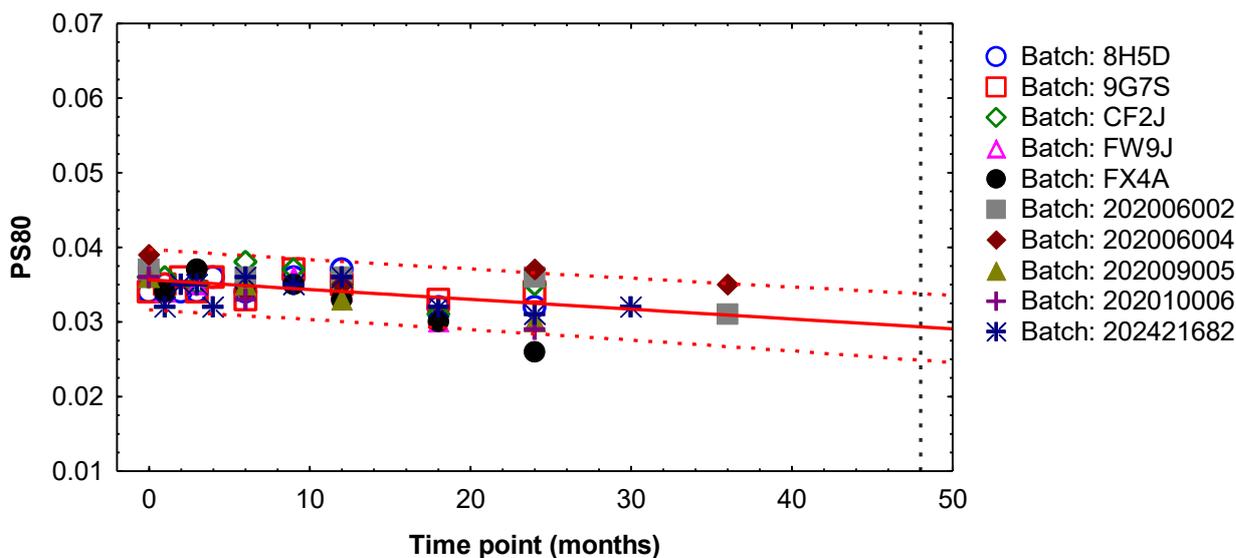
Statistical Analysis using Degradation Analysis for Composite Batches at 5°C Storage Condition

Figure 21: Degradation Modeling for pH

DP Data for SLE 24 months

**Least Favourable Shelf Life Plot with 95% Confidence Limits
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life = 46**

Separate Slopes Model - Least Favourable Batch: 8H5D

Figure 22: Degradation Modeling for Clarity

DP Data for SLE 24 months

Least Favourable Shelf Life Plot with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life > 144

Common Slopes Model - Least Favourable Batch: 202009005

Figure 23   Degradation Modeling for cIEF Main

DP Data for SLE 24 months

Least Favourable Shelf Life Plot with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life = 124

Common Slopes Model - Least Favourable Batch: 202006004
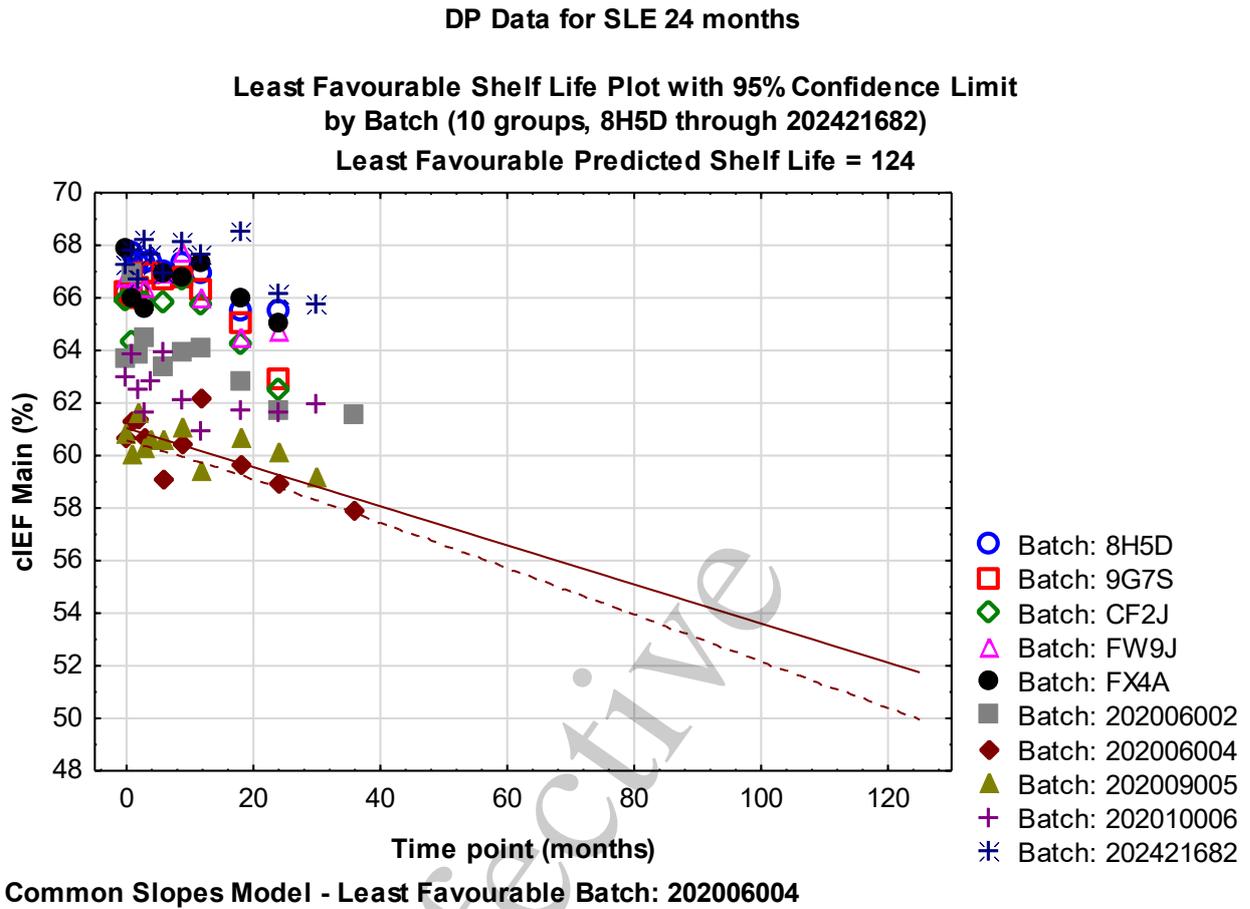
Figure 24: Degradation Modeling for cIEF Acidic

DP Data for SLE 24 months

**Least Favourable Shelf Life Plot with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life = 107**

Separate Slopes Model - Least Favourable Batch: 9G7S
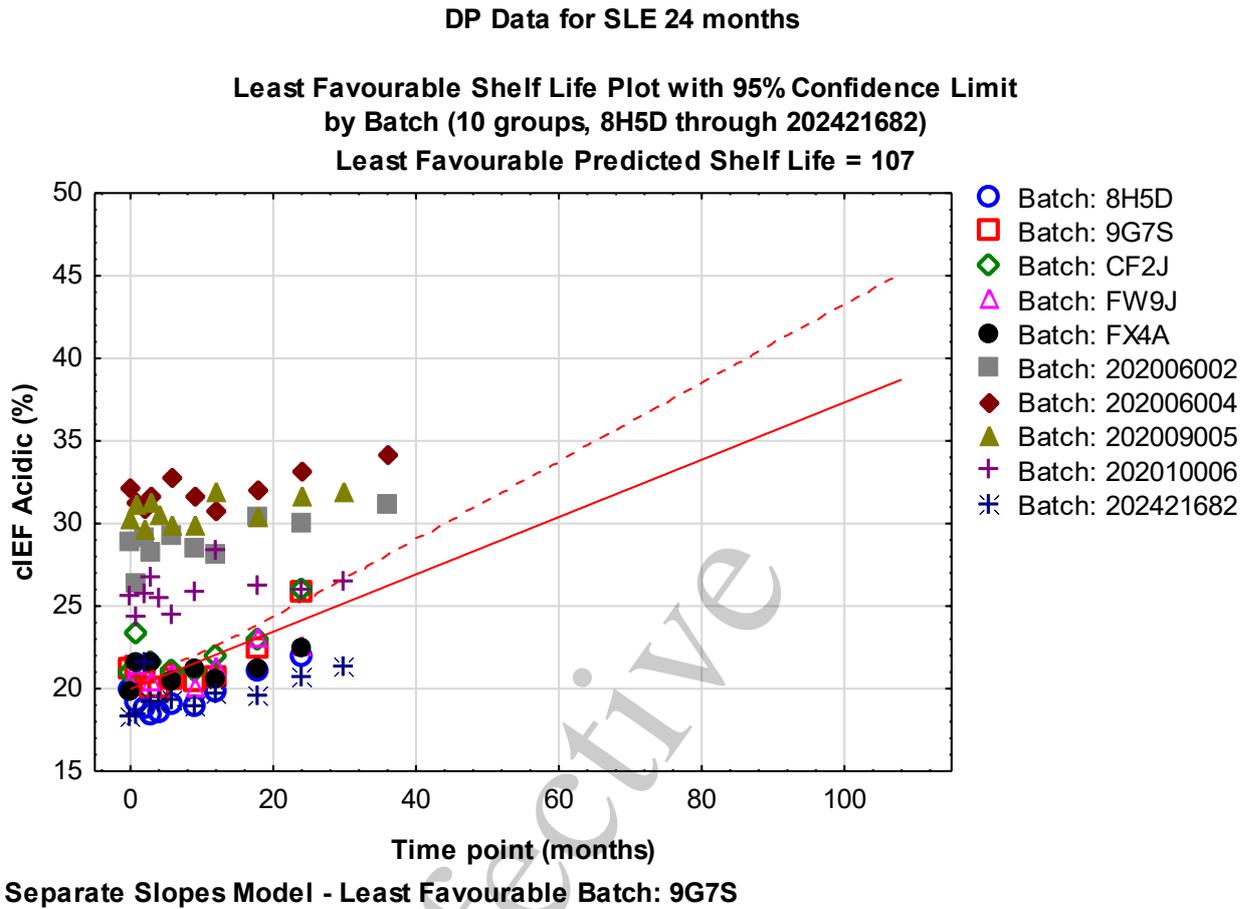
Figure 25 Degradation Modeling for cIEF Basic

DP Data for SLE 24 months

**Least Favourable Shelf Life Plot with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life > 144**

Separate Slopes Model - Least Favourable Batch: FW9J
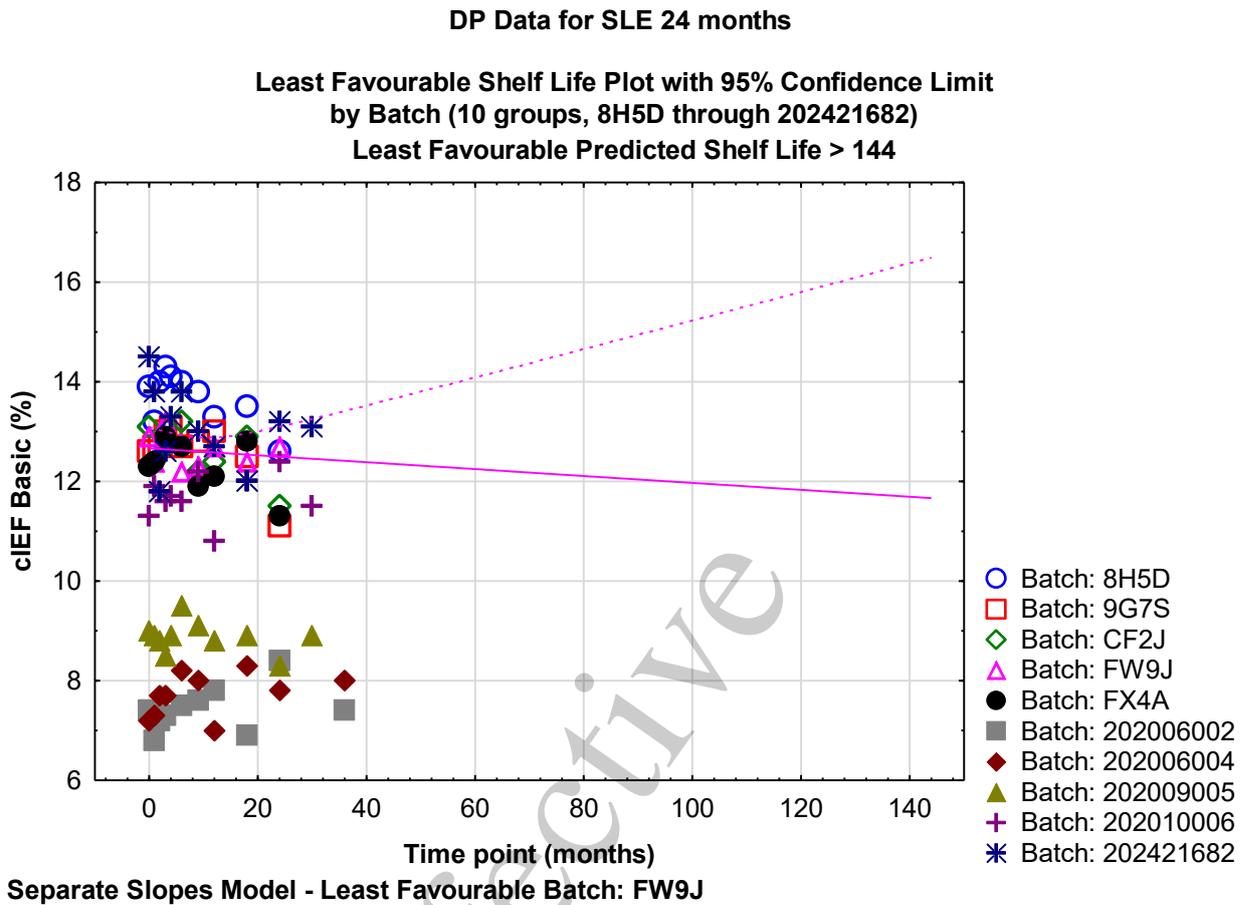
Figure 26: Degradation Modeling for SEC Main

DP Data for SLE 24 months

Least Favourable Shelf Life Plot using Square root X with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life > 144

Separate Slopes Model - Least Favourable Batch: 202009005
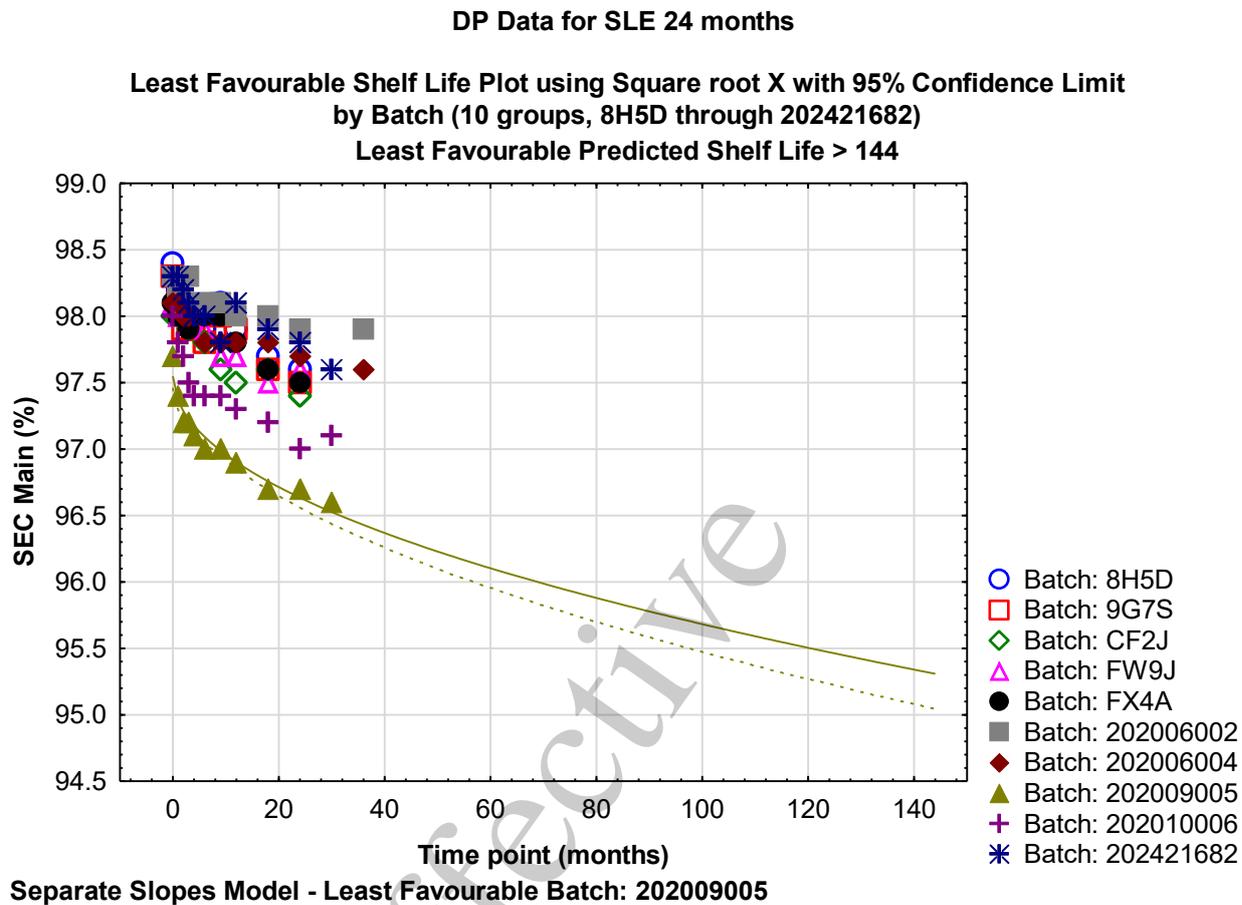
Figure 27: Degradation Modeling for SEC HMW

DP Data for SLE 24 months

**Least Favourable Shelf Life Plot with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life = 78**

Separate Slopes Model - Least Favourable Batch: 202009005
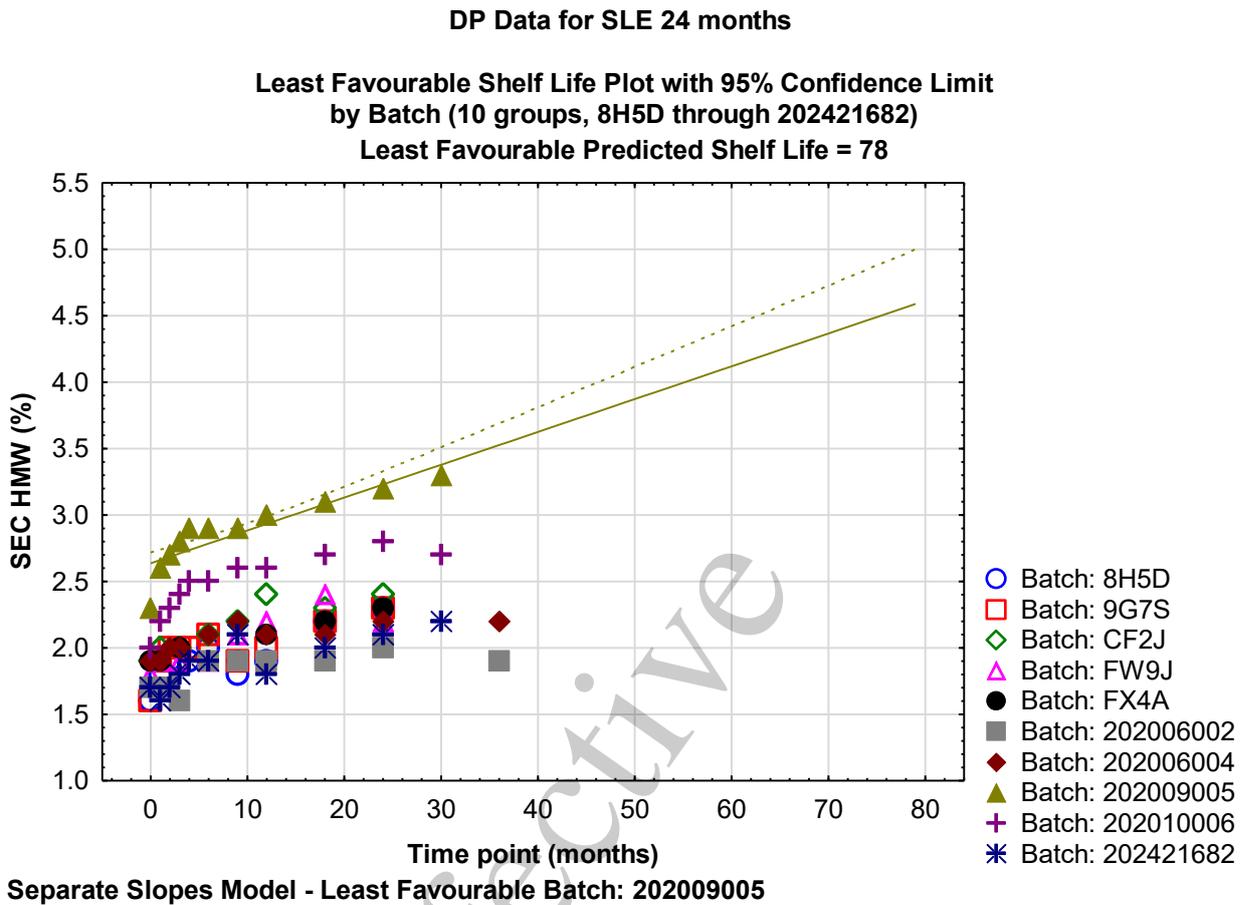
Figure 28: Degradation Modeling for CE-SDS Reduced

DP Data for SLE 24 months

**Least Favourable Shelf Life Plot with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life = 111**

Separate Slopes Model - Least Favourable Batch: 202010006
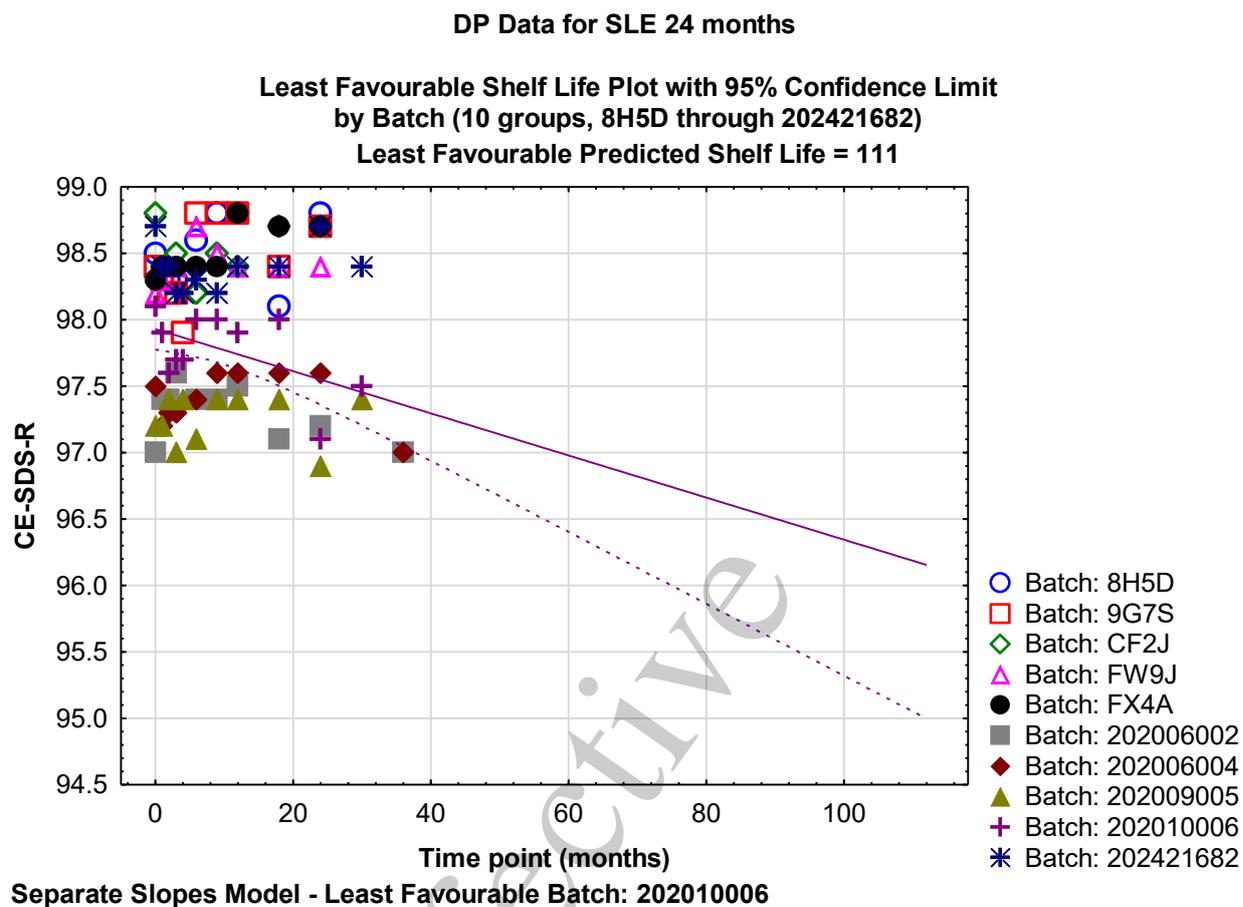
Figure 29: Degradation Modeling for CE-SDS Non-Reduced

DP Data for SLE 24 months

Least Favourable Shelf Life Plot using Square root X with 95% Confidence Limit
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life > 144

Common Slopes Model - Least Favourable Batch: 202009005

Figure 30: Degradation Modeling for Polysorbate 80

DP Data for SLE 24 months

**Least Favourable Shelf Life Plot with 95% Confidence Limits
by Batch (10 groups, 8H5D through 202421682)
Least Favourable Predicted Shelf Life = 41**

Separate Slopes Model - Least Favourable Batch: FX4A

Conclusion:

The shelf-life of VIR 7831 (GSK4182136) Drug Product was assessed using the following stability data available to date: 36-month time point data from analysis of VIR 7831 Gen 1 DP batches, 30-month time point data from analyses of the GMP Gen 2 WuXi DP batches, and 24-month time point data from analyses of the GMP Gen 2 Parma DP batches. The overall stability between VIR-7831 Gen 1 and Gen 2 WuXi and Parma DP batches has been deemed comparable (VQD-RPT-102561).

Data from this shelf-life assessment supports amending the expiry period for the Clinical batches to 48 months and the Gen2 Parma drug product batches currently being used in ongoing studies out to 42 months for EUA batches. The data indicate that all attributes tested on stability are expected to remain within specifications through the 48-month shelf-life. Data from the ongoing stability studies at the long-term recommended storage condition will be monitored.

VERSION HISTORY:

Version	Change	Justification
6.0	Updated Data 202006002 36M @5C 202006004 36M @5C FX4A 24M @ 5C Removed Batches DV4T DY9B DV4U	Updated all scatterplot graphs to reflect the new data and updated the statistical analysis graphs with the new statistical assessment. Added pooled data plots since these are used in some regulatory filings. Removed the batches that are not submitted in all markets.
5.0	Updated Data 202009005 30M @ 5C 202010006 30M @ 5C 202421682 24M @ 5C 8H5D 24M @ 5C 9G7S 24M @ 5C CF2J 24M @ 5C FW9J 24M @ 5C FX4A 18M @ 5C DV4T 12M @ 5C DY9B 12M @ 5C DV4U 12M @ 5C Added batches NK2W up to 6 months	Updated all scatterplot graphs to reflect the new data and updated the statistical analysis graphs with the new statistical assessment. Removed the Stressed Condition data.
4.0	Updated Data 202009005 24M @ 5C 202010006 24M @ 5C 202421682 18M @ 5C 8H5D 18M @ 5C 9G7S 18M @ 5C CF2J 12M @ 5C FW9J 12M @ 5C FX4A 12M @ 5C Added batches DV4T, DY9B, DV4U up to 6 months	Updated all scatterplot graphs to reflect the new data, and updated the statistical analysis graphs with the new statistical assessment. Updated the conclusion for a 36 month expiry.
3.0	202006002 24M @ 5C 202006004 24M @ 5C 202009005 18M @ 5C 202010006 18M @ 5C 202421682 12M @ 5C 8H5D 12M @ 5C 9G7S 12M @ 5C CF2J 12M @ 5C FW9J 12M @ 5C FX4A 12M @ 5C	Align with updated specification document and reflect current stability data time points used in trending.

VIR-7831 Drug Product Stability Trend Report

Document Approvals by Electronic Signature

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