2025 Annual Quality Review

DESCOVY®

(emtricitabine 200 mg/tenofovir alafenamide 10 mg, emtricitabine 200 mg/tenofovir alafenamide 25 mg, and emtricitabine 120 mg/tenofovir alafenamide 15 mg) Tablets

Review Period

04 April 2024 to 03 April 2025

REP-63010 (1.0)

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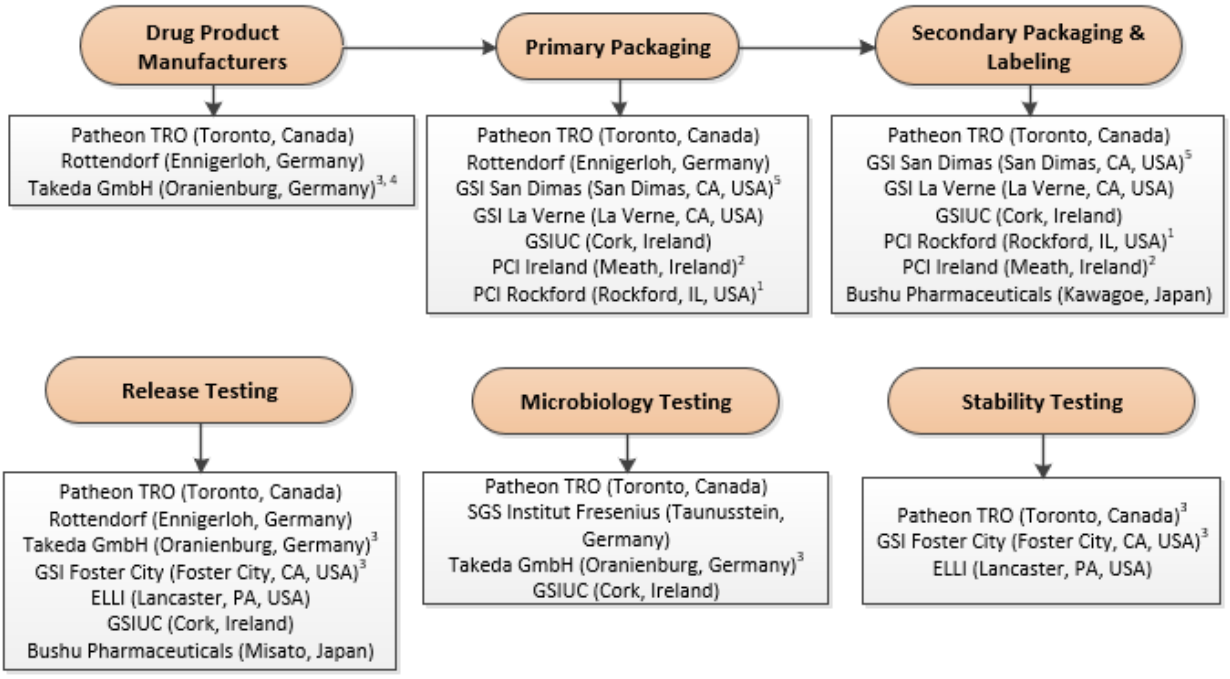
PRODUCT DESCRIPTION

DESCOVY is a two-drug fixed-dose combination of emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV nucleoside analog reverse transcriptase inhibitors (NRTIs), taken as a single tablet once daily orally in combination with other antiretroviral agents for the treatment of HIV-1 infection. The dosage strengths for DESCOVY are 200 mg FTC/25 mg TAF, 200 mg FTC/10 mg TAF, and 120 mg FTC/15 mg TAF. DESCOVY (strength 200 mg FTC/25 mg TAF for adults) was first approved for commercial production in 2016 by the Food and Drug Administration (FDA). DESCOVY (strength 200 mg FTC/10 mg TAF for adults) was first approved for commercial production in 2016 by the European Medicines Agency (EMA). DESCOVY (strength 120 mg FTC/15 mg TAF for low dose (pediatrics)) was first approved for commercial production in 2022 by the FDA.

DESCOVY 200 mg FTC/25 mg TAF tablets are blue, rectangular-shaped, film-coated, and debossed with "GSI" on one side and "225" on the other side. DESCOVY 200 mg FTC/10 mg TAF tablets are gray, rectangular-shaped, film-coated, and debossed with "GSI" on one side and "210" on the other side. DESCOVY 120 mg FTC/15 mg TAF tablets are white, round, film-coated, and debossed with "GSI" on one side and "15" on the other side.

DESCOVY tablets are manufactured, tested, packaged, and labeled at the sites detailed in the flow diagrams below.

DESCOVY 200 mg FTC/25 mg TAF and 200 mg FTC/10 mg TAF



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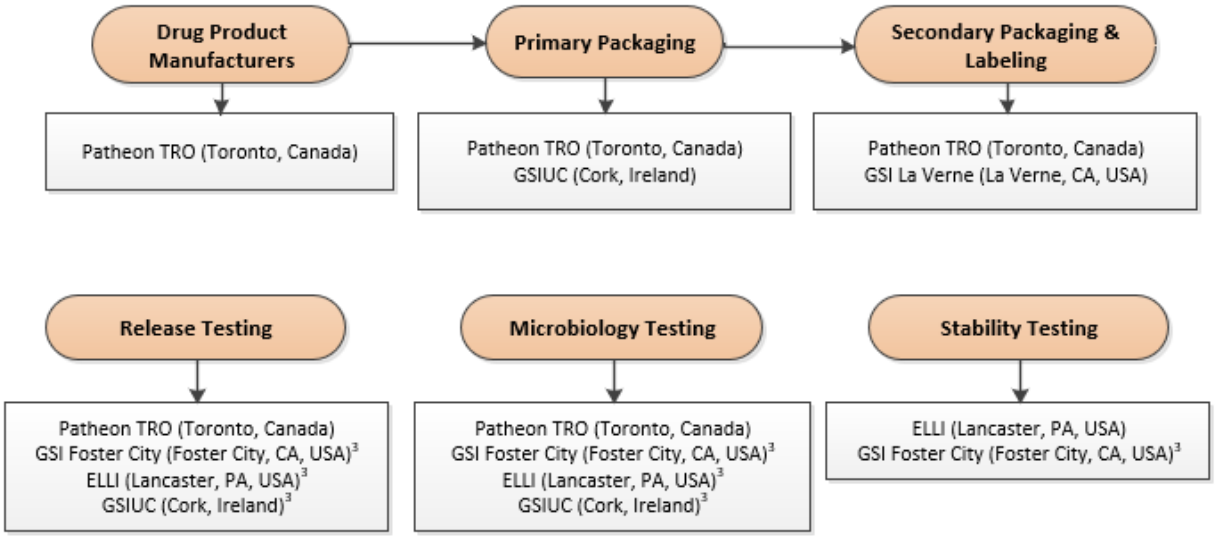
DESCOVY 120 mg FTC/15 mg TAF (Low Dose)



Patheon TRO = Patheon Toronto Region Operations
Rottendorf, RPH = Rottendorf Pharma GmbH
GSI = Gilead Sciences, Inc.
GSIUC = Gilead Sciences Ireland Unlimited Company
PCI = Packaging Coordinators, Inc.
ELLI = Eurofins Lancaster Laboratories, Inc.
[1] Packaging Coordinators, Inc. (USA) is registered with FDA as AndersonBrecon
[2] Packaging Coordinators, Inc. (Ireland) is registered with FDA as Millmount Healthcare Ltd.
[3] Registered sites were not used during the current review period.
[4] Takeda is only used for 200 mg FTC/25 mg TAF manufacturing.
[5] San Dimas site GMP operations were ceased on October 1, 2023; site decommissioning is ongoing per QE-180199 and update of product filing is ongoing per QE-011687.

EXECUTIVE SUMMARY

Review Summary

The annual product quality review for DESCOVY was completed for the review period from 04 April 2024 to 03 April 2025 with results summarized below.

During the review period, there were one hundred and six (106) bulk lots of DESCOVY manufactured, sixty-one (61) britestock lots, and three hundred twenty-seven (327) finished goods lots released. The lots released include lots manufactured prior to the current review period.

There were no DESCOVY lots rejected during the review period. The deviations reported at the manufacturing and packaging sites were distributed across different categories with no trends identified.

There were no confirmed release out-of-specification results for DESCOVY lots tested during the review period.

Review of the in-process control (IPC) and critical quality attribute (CQA) data for lots manufactured at Patheon TRO and Rottendorf for DESCOVY, through the Continued Process Verification (CPV) program, demonstrated that the processes are within established baseline control limits, and no adverse trends were observed.

Results for all current lots on stability continue to remain within the specification limits and continue to support the longest filed shelf-life of up to 48 months for DESCOVY 200mg FTC/25 mg TAF, and 120 mg FTC/15 mg TAF tablets in bottles, up to 36 months for DESCOVY 200mg FTC/25 mg TAF in blisters, and

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200 mg FTC/10 mg TAF tablets in bottles, when stored at the labeled storage condition in the original container/closure system.

The post-market surveillance data of returns, complaints, reserve samples, and recalls were reviewed. There were two (2) Major trend investigations for DESCOVY during the review period regarding Quantity Issue and Secondary Packaging Operations. For Quantity Issue (Lot 7447301A), improper recovery of reject bottles on the packaging line was identified as the root cause of the reported complaint. CAPAs to enhance the recovery process at PCI Rockford were implemented to prevent empty bottles from being released. For Secondary Packaging Operations (Lot 7447203A), manual process was identified as the root cause of the reported complaint. Awareness training was provided to operations personnel at PCI Rockford to ensure each blister wallet contains the correct number of blister cards to prevent missing blisters from the wallet.

There was one (1) trend deviation identified during the current review period for DESCOVY blister packs where the complaint rate upper limit was exceeded in two (2) consecutive months in June and July 2024. The most reported complaint subcategory in the 24-month complaint trend review period was User Experience (Difficulty in Opening Blisters) (87%); all of these complaints were reported from the U.S. market. However, for each of the individual complaint investigations performed, no root cause could be determined. It should be noted that the DESCOVY 30 count blister production was stopped at the end of 2024; no additional designs for DESCOVY blisters will be done. No further actions are required at this time.

There was no evidence of deterioration of packaging components during visual examination of reserve samples, and no recalls for DESCOVY during this review period.

Conclusion

Based on the review of manufactured lots, quality control data, manufacturing processes, and product surveillance data, it can be concluded that the manufacturing process of DESCOVY remains in an acceptable state of control with finished product test results well within the approved specification. There were no CAPAs, process improvements, or changes to the starting material and drug product specifications recommended from this review. The product remains stable for the duration of its shelf-life.

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1 BATCH PRODUCTION AND DISPOSITION

The manufacturing and product dispositions for DESCOVY conducted during the review period are summarized below in Table 1 through Table 3 with details provided in Attachment 1; no lots were manufactured / packaged at Takeda during the review period.

Table 1: Summary of DESCOVY Bulk Lots Manufactured and Rejected

Manufacturing Site	Bulk Lots Manufactured	Bulk Lots Rejected
200 mg FTC/25 mg TAF		
Patheon TRO	10	0
Rottendorf	92	0
Takeda	0	0
200 mg FTC/10 mg TAF		
Patheon TRO	3	0
Rottendorf	0	0
120 mg FTC/15 mg TAF		
Patheon TRO	1	0
Total	**106**	**0**

Table 2: Summary of DESCOVY Britestock Lots Released and Rejected

Manufacturing Site	Britestock Lots Released[1]	Britestock Lots Rejected[1]
200 mg FTC/25 mg TAF		
Patheon TRO	13	0
Rottendorf	39	0
Takeda	0	0
200 mg FTC/10 mg TAF		
Patheon TRO	7	0
Rottendorf	0	0
120 mg FTC/15 mg TAF		
Patheon TRO	2	0
Total	**61**	**0**

[1] Includes lots manufactured prior to the current review period.

Table 3: Summary of DESCOVY Finished Goods Lots Released and Rejected

Manufacturing Site	Finished Good Lots Released[1]	Finished Good Lots Rejected[1]
200 mg FTC/25 mg TAF		
Patheon TRO	83	0[2]
Rottendorf	173	0
Takeda	0	0
200 mg FTC/10 mg TAF		
Patheon TRO	70	0[3]
Rottendorf	0	0

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Manufacturing Site	Finished Good Lots Released[1]	Finished Good Lots Rejected[1]
120 mg FTC/15 mg TAF		
Patheon TRO	1	0
Total	**327**	**0**

[1] Includes lots manufactured prior to the current review period.
[2] One (1) lot was partially rejected.
[3] Four (4) lots were partially rejected.

A comparison of the lots manufactured and dispositioned from the previous review period and current review period is presented in Table 4.

Table 4: Summary of DESCOVY Lots Manufactured and Dispositioned from Current and Previous Review Period

Review Period	Previous Review Period (2024)	Current Review Period (2025)
200 mg FTC/25 mg TAF		
Bulk Lots Manufactured	119	102
Bulk Lots Rejected	0	0
Britestock Lots Released[1]	38	52
Britestock Lots Rejected[1]	0	0
Finished Goods Lots Released[1]	255	256
Finished Goods Lots Rejected[1]	0	0[2]
200 mg FTC/10 mg TAF		
Bulk Lots Manufactured	5	3
Bulk Lots Rejected	0	0
Britestock Lots Released[1]	5	7
Britestock Lots Rejected[1]	0	0
Finished Goods Lots Released[1]	70	70
Finished Goods Lots Rejected[1]	0	0[3]
120 mg FTC/15 mg TAF		
Bulk Lots Manufactured	0	1
Bulk Lots Rejected	0	0
Britestock Lots Released[1]	1	2
Britestock Lots Rejected[1]	0	0
Finished Goods Lots Released[1]	1	1
Finished Goods Lots Rejected[1]	0	0

[1] Includes lots manufactured prior to the current review period.
[2] One (1) lot was partially rejected
[3] Four (4) lots were partially rejected.

2 IN-PROCESS CONTROL AND FINISHED PRODUCT RELEASE TEST RESULTS

The manufacturing processes at Patheon TRO and Rottendorf for DESCOVY manufactured during the review period was assessed through trend analysis and the Continued Process Verification (CPV) program. Consistent with the outcomes of the CPV review of DESCOVY, conducted per protocol PRO-13413, it can be concluded that the process was in a state of control at Patheon TRO and Rottendorf; there were no CAPAs identified. There was no manufacturing at Takeda during the review period.

Results for IPCs and CQAs for all DESCOVY lots released during the review period were within the acceptance limits as summarized from Table 5 to Table 10 below. Control charts were created using statistical control limits and centerlines defined in REP-55950.

In-process results and quantitative lot release values for water content, assay, total degradation products, dissolution, and content uniformity are also presented graphically in Attachment 2. The qualitative tests of appearance and identity consistently met their respective specifications (GSPEC-M248 (200 mg FTC/10 mg TAF) and GSPEC-M249 (200 mg FTC/25 mg TAF)).

Since only three (3) lots of DESCOVY 200 mg FTC/10 mg TAF and one (1) lot of DESCOVY 120 mg FTC/15 mg TAF were manufactured at Patheon TRO within the review period, no charts were generated. Instead, the data is presented in tabular form; the in-process and release test results were within specification as summarized in Table 6, Table 7, Table 9, and Table 10.

No statistical trends have been identified by review of the quantitative lot release data presented graphically in the charts. The release data support the conclusion that the manufacturing process for DESCOVY at the manufacturing sites remains in an acceptable level of control.

Attachment 8 summarizes the quantitative test results for DESCOVY bulk lots manufactured prior to the current review period that were not charted in the previous APQR's.

Import Testing

The sampling plan for import products has been assessed and is deemed adequate, where applicable.

Vendor qualification (lab, method, contract manufacturing site qualification) has been completed. Import testing results, when performed, and CMO results are confirmed to be within the product specification. Any major and critical deviations or investigations are captured in Section 6. Refer to Attachment 9 for list of imported lots for Colombia and Mexico.

Table 5: In-Process Data for DESCOVY 200 mg FTC/25 mg TAF

Mfg. Site	Test	Limits	Mean	Minimum	Maximum	Chart Reference
Patheon TRO	Tablet Weight during Compression (mg)	340 – 360	350	349	350	Chart 1
	Tablet Hardness during Compression (N)	98 - 147	120	117	124	Chart 2
Rottendorf	Tablet Weight during Compression (mg)	340 – 360	350	349	352	Chart 3
	Tablet Hardness during Compression (N)	98 - 147	116	104	126	Chart 4

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Table 6: In-Process Data for DESCOVY 200 mg FTC/10 mg TAF Lots from Patheon TRO

Lot Number	Tablet Weight during Compression (mg)	Tablet Hardness during Compression (N)
	340 – 360	98 - 147
CTNKV	350	126

Table 7: In-Process Data for DESCOVY 120 mg FTC/15 mg TAF Lots from Patheon TRO

Lot Number	Individual Tablet Weight during Compression (mg)	Average Tablet Weight during Compression (mg)	Tablet Hardness during Compression (kp)
	200 – 220	204 – 216	4 - 10
CTWVC	202 – 218	209	7

Table 8: Release Data Summary for DESCOVY 200 mg FTC/25 mg TAF

Mfg. Site	Test	Limits	Mean	Minimum	Maximum	Chart Reference
Patheon TRO	Assay – FTC (%)	95.0 – 105.0	100.2	99.4	100.9	Chart 5
	Assay – TAF (%)	95.0 – 105.0	98.7	97.8	99.4	Chart 6
	Total FTC Degradation (%)	NMT 0.5	0.0	0.0	0.0	Chart 7
	Total TAF Degradation (%)	NMT 3.5	0.3	0.2	0.6	Chart 8
	Dissolution (%) – FTC (30 minutes)	Q = 80	100	97	102	Chart 9
	Dissolution (%) – TAF (30 minutes)	Q = 80	99	95	101	Chart 10
	Content Uniformity – FTC	NMT 15.0	2.1	1.2	2.9	Chart 11
	Content Uniformity – TAF	NMT 15.0	2.7	1.8	3.5	Chart 12
	Water Content (%)	NMT 4.5	1.5	1.1	1.9	Chart 13
Rottendorf	Assay – FTC (%)	95.0 – 105.0	100.1	99.1	101.5	Chart 14
	Assay – TAF (%)	95.0 – 105.0	99.1	97.0	100.5	Chart 15
	Total FTC Degradation (%)	NMT 0.5	0.0	0.0	0.0	Chart 16
	Total TAF Degradation (%)	NMT 3.5	0.4	0.2	0.5	Chart 17
	Dissolution (%) – FTC (30 minutes)	Q = 80	100	97	103	Chart 18
	Dissolution (%) – TAF (30 minutes)	Q = 80	100	97	103	Chart 19
	Content Uniformity – FTC	NMT 15.0	2.4	1.1	3.5	Chart 20
	Content Uniformity – TAF	NMT 15.0	3.1	1.6	4.9	Chart 21
	Water Content (%)	NMT 4.5	1.4	1.1	1.7	Chart 22

NMT = Not More Than

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Table 9: Release Data for DESCOVY 200 mg FTC/10 mg TAF Lots from Patheon TRO

Lot Number	Assay (%)		Total Degradation (%)		Dissolution (%) (30 minutes)		Content Uniformity		Water Content (%)
	FTC	TAF	FTC	TAF	FTC	TAF	FTC	TAF	
	95.0 – 105.0		NMT 0.5	NMT 3.5	Q = 80		NMT 15.0		NMT 4.5
CTNKV	99.2	97.9	0.0	0.5	100	99	2.7	3.3	1.8

NMT = Not More Than

Table 10: Release Data for DESCOVY 120 mg FTC/15 mg TAF Lots from Patheon TRO

Lot Number	Assay (%)		Total Degradation (%)		Dissolution (%) (30 minutes)		Content Uniformity		Water Content (%)
	FTC	TAF	FTC	TAF	FTC	TAF	FTC	TAF	
	95.0 – 105.0		NMT 0.5	NMT 3.5	Q = 80		NMT 15.0		NMT 4.5
CTWVC	100.1	97.6	0	0.4	102	100	2.1	2.6	1.4

NMT = Not More Than

3 MICROBIOLOGY TEST RESULTS

Microbial testing for USP <61>, Ph. Eur 2.6.12, and JP <4.05 Part I> for DESCOVY is performed per GSPEC-M249 (200 mg FTC/25 mg TAF), GSPEC-M248 (200 mg FTC/10 mg TAF), and GSPEC-M395 (120 mg FTC/15 mg TAF). A summary of the microbial results is presented in Table 11. A detailed list of lots and results are presented in Attachment 3.

Table 11: Microbial Testing Results for DESCOVY

Number of Lots	TAMC	TYMC	Comment
	% Lots with counts % Lots in specification	% Lots with counts % Lots in specification	
Patheon TRO (200 mg FTC/10 mg TAF)			
3	0% Lots with counts 100% in specification	0% Lots with counts 100% in specification	None
Patheon TRO (200 mg FTC/25 mg TAF)			
7	0% Lots with counts 100% in specification	0% Lots with counts 100% in specification	None
Rottendorf (200 mg FTC/25 mg TAF)			
101	0.0% Lots with counts 100% in specification	2.0% Lots with counts 100% in specification	TYMC Growth for Lots 7749402 and 7839401
Rottendorf (120 mg FTC/15 mg TAF)			
2	0% Lots with counts 100% in specification	0% Lots with counts 100% in specification	None

3.1 Summary of Results

Counts were observed for the following:

- Rottendorf for DESCOVY 200 mg FTC/25 mg TAF lot 7749402 with TYMC 10 colony forming units per gram (cfu/g). The count is within the specification of NMT 10^2 cfu/g and no counts were observed for TAMC. The growth identified the species to be *Purpureocillium Lilacinum*

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which, after evaluation, was deemed acceptable risk per WRK-03940. No trend in growth is seen at Rottendorf.

- Rottendorf for DESCOVY 200 mg FTC/25 mg TAF lot 7839401 with TYMC 10 colony forming units per gram (cfu/g). The count is within the specification of NMT 10^2 cfu/g and no counts were observed for TAMC. The growth identified the species to be *Cladosporium Spp* which, after evaluation, was deemed acceptable risk per WRK-03940. No trend in growth is seen at Rottendorf.

3.2 Review of Microbial Results Against Previous Review Period

There was a decrease in the percentage of growth of TAMC and an increase in growth of TYMC between the previous and current review period. Total growth and the number of lots with growth is low and numbers remain consistent between the years (two (2) lots in 2024 vs. two (2) lots in 2025). As the total number of lots with growth is low and results are within the release specification, there is no impact to product quality. Refer to Table 12.

Table 12: Comparison of Microbial Results Between Review Periods for Rottendorf

APQR Review Year	Number of Lots Tested	TAMC Growth	TYMC Growth	Recovered Microbes	Comments
2024	90	1.1%	0%	*Bacillus Pumilus* (Lot 7363102)	PR 277599
				Bacillus pumilus/Bacillus safenis (Lot 7647003)	QE-217090
2025	101	0%	2.0%	*Purpureocillium Lilacinum* (Lot 7749402)	QE-221469
				Cladosporium Spp (Lot 7839401)	QE-226277

4 RELEASE TESTING OUT-OF-SPECIFICATION/OUT-OF-TREND/OUT OF ACTION INVESTIGATIONS

During the review period, there were no OOS, OOT, or OOA investigations at Patheon TRO and Takeda for DESCOVY.

During the review period, there was one (1) OOS investigation at GSIUC, and two (2) OOT investigations at Rottendorf for DESCOVY. The investigations at the test sites for DESCOVY are shown in Table 13. No adverse trends were identified within or across laboratories.

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Table 13: Distribution of Investigations

OOS / OOT/OOA	Record Number (Lot Number)	Description of Issue	Root Cause	Resolution
GSIUC				
OOS	QE-236638 (Lots CVDWB, 7929901P and CVDWH)	Identification by Retention Time results of 4.405 min, 4.323 min, and 4.378 min for FTC for DESCOVY Lots CVDWB, 7929901P and CVDWH respectively were outside specification of 2.0% range of 4.42862-4.60938 min.	Pending Investigation	Pending Investigation
Rottendorf				
OOT	QE-234185 (Lot 7975102)	OOT (alert limit) observed for TAF Assay at 97.0% Control limits per REP-29464 are: 97.2%-101.8% for TAF	Probable root cause: Material / Product > Material Characteristic > Chemical Property The probable root cause can be due to lower tablet weight, indicative of a lower drug substance content may have been charged resulting in 97.0% TAF assay.	Gilead and Rottendorf investigation determined that the original result of 97.0% for TAF is the correct assay result and will be reported as the final. All AQL passed and lower tablet weights are still within the acceptance criteria.
Invalidated OOT	QE-234564 (Lot 7975103 and 7975104)	OOT observed for Content Uniformity (CU) tests acceptance value (AV): Lot 7975103: AV 5.5% FTC AV 6.6% TAF Lot 7975104: AV 4.5% FTC AV 6.5% TAF Alert Limits: Results exceeds 5.1% for FTC 5.9% for TAF	Machinery / Equipment > Equipment / System Reliability > Equipment / System Issue During the investigational testing a laboratory error regarding an injection failure of CU sample 10 of Lot 7975103 and CU sample 2 of Lot 7975104 was confirmed.	The initial results of the content uniformity analysis were invalidated. A reinjection sequence on the HPLC system was performed with new prepared standard solutions. All results of all lots in the reinjection sequence comply with the specification and trend limits. Lots 7975103, and 7975104 are suitable for QC release. CMO OOS-00463 was closed as not confirmed OOT.

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4.1 Assessment of Invalidated OOS

There were no invalidated OOS investigations reported during the review period.

4.2 Comparison of Invalidated OOS vs. Previous APQR

There were no invalidated OOS investigations during the current and previous review period.

4.3 Comparison of Confirmed OOS vs. Previous APQR

There were no confirmed OOS for the current and previous review periods at GSIUC, Patheon TRO, Takeda and Rottendorf.

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5 STARTING MATERIALS AND PACKAGING MATERIALS

The approved suppliers of the starting materials and packaging materials used in DESCOVY were reviewed and listed in Attachment 4. Refer to FTC AQR (Attachment 3 in REP-62368) and TAF AQR (Attachment 3 in REP-56593) for details on the supply chain diagram of the drug substance used in the manufacture of DESCOVY. Starting and packaging material are evaluated against defined criteria as per incoming material release procedures prior to use in Drug Product manufacturing. Deviations and changes related to the starting and packaging materials in the current review period are evaluated and listed below.

5.1 Deviations Associated with the Starting Materials and Packaging Materials

5.1.1 Starting and Packaging Materials Deviations

There were no major or critical deviations associated with starting or packaging materials for DESCOVY at Bushu, GSI La Verne, GSI San Dimas, PCI Ireland, PCI Rockford, Patheon TRO, Rottendorf, and Takeda, during the review period.

The major and critical starting and packaging material deviations are summarized in Table 14.

Table 14: Starting and Packaging Material Deviations

Record Number (Lot Number(s) Classification)	GSIUC	
QE-180645 (Lot 7182303P, 7182303PD, 7182307PD, 7182307P, Major)	**Description**	During Secondary Packaging, on set up of the BL400 Bottle Labeler for DESCOVY Lot 7182303PD, a technician noticed that some of the labels applied to the britestock bottles were skewed. Engineering was called to the line and on further investigation it was noticed that when the bottles were measured that the radius of the top of bottle differed to the radius of the bottom of the bottle, i.e. the bottle was tapered. The britestock was supplied to GSIUC by Rottendorf. The same issue was noted on set up of the BL400 Bottle Labeler for DESCOVY Portugal Lot 7182307PD.
	Failure Mode	Equipment/System Design
	Impacted Process	Secondary Packaging
	Root Cause	Machinery/Equipment There was no failure in Rottendorf Pharma that could have caused the defect. Nolato Jaycare Limited (Bottle Suppliers) found the root cause to be an excessive flame heat from the burners (surging) which caused an increased surface treatment, which softened the bottle resulting in the indentation.

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Record Number (Lot Number(s) Classification)	GSIUC	
	CAPA	CMO CAPA-04647: Further control strategies were reviewed in consultation with the supplier Nolato to avoid reoccurrence of the error pattern. CMO CAPA-04659: Incoming goods inspection process was reviewed and improved to increase the detection probability. CMO CAPA-04659: Tracking of external complaints from Nolato. **CAPAs completed at Nolato Jaycare Limited (Britestock bottle suppliers):** -Review flamer control systems: 1) Gauge indicators added to monitor process, 2) Lock box installed over flamer controls. - Updated the internal product quality inspection (PQI) sheet to check for any changes to surface finish and any visible distortion.
	Resolution	Risk Assessment REP-49599, assessed the risk of a patient receiving DESCOVY with illegible preprint/overprint patient information due to skewed labels as a result of the tapered britestock bottles. The Risk Priority Number was 45 (low), failure effects do not constitute a viable risk to product, process or GMP compliance. A protocol was executed to 100 % inspect Lots 7182303P and 7182307P (4 Lots; 7182307P DESCOVY Netherlands, 7182303P DESCOVY Germany, 7182303P DESCOVY Australia and 7182303P DESCOVY Italy Hospital). The purpose of the protocol was to inspect for skewed labels and reject any defects. In total there were 377 defects found within 16490 bottles of britestock. No britestock was rejected, as the defects found during the inspection were reworked. All britestock for 7182303P and 7182307P were consumed into finished good (FG) Lots ready for release (FG Lots 7182303PD and 7182307PD). No impact to product or safety, efficacy or quality as a result of this issue.

5.1.2 Review of Starting and Packaging Material Deviations Against Previous APQRs

The comparison of starting and packaging material deviations at the manufacturing sites between the current and previous APQR review periods is presented in Table 15.

There were no starting and packaging material deviations reported for Bushu, GSI La Verne, GSI San Dimas, PCI Ireland, PCI Rockford, Patheon TRO, and Takeda during the current and previous review period.

There were no trends observed within the manufacturing sites.

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Table 15: Comparison of Starting Material Deviations between Current and Previous Review Periods

APQR Review Year	Site	Failure Mode	Impacted Process	Root Cause	Number of Deviations	Rejection of Starting/Packaging Material
2024	GSIUC	Facility Design	Supply Chain	Mother nature/ Environment	1	No
	Rottendorf	External Controls	Packaging	Material / Product	1	No
2025	GSIUC	Equipment/System Design	Secondary Packaging	Machinery/Equipment	1	No
	Rottendorf	None	None	None	None	None

5.2 Changes Associated with the Starting Materials and Packaging Materials

5.2.1 Drug Substance Changes

During the review period, there were no relevant drug substance changes for DESCOVY at Patheon TRO, Rottendorf, and Takeda.

5.2.2 Excipient Changes

During the review period, there were no changes to excipient materials at Patheon TRO, Rottendorf and Takeda.

5.2.3 Packaging Material Changes

During the review period, there were no changes to the packaging material at Bushu, GSIUC, GSI La Verne, GSI San Dimas, Rottendorf, PCI Rockford and PCI Ireland.

Changes to packaging materials were made for DESCOVY during the review period at Patheon TRO. Refer to Table 16 below for additional information.

Table 16: Changes to Packaging Materials

Change Reference	Material Type	Description	Assessment
Patheon TRO			
QE-179356	Serialization	Canada market serialization, no change to packaging materials but the bottle label layout has been changed to accommodate serialization print.	No impact to packaging operations, new labels were qualified during line trials and artwork updates are being applied post RAAN receipt.

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6 MAJOR/CRITICAL DEVIATIONS, RELATED INVESTIGATIONS, AND CAPAS

There were no major or critical deviations, post-shipment non-conformances, and no ineffective CAPAs reported for Bushu, GSI La Verne, GSI San Dimas, PCI Ireland, and Takeda during the current and previous review period.

6.1 GSIUC Deviations

6.1.1 Major/Critical Deviations Reported

There were no major or critical deviations reported within the review period and no lots were rejected. There was one (1) pending deviation from the previous review period that was downgraded to a minor. Refer to Table 17.

Table 17: Major/Critical Deviations – GSIUC

Record Number (Lot Number(s) Classification)	GSIUC	
QE-181801 (7182307PD, 7182201D, CMTGPD2, Minor) ***Pending from Last Review Period***	**Description**	A QA Specialist was completing the Rejectable Quality Level (RQL) inspection for GENVOYA Lot 23GV0002D and noted that the print on the bottle label had an illegible expiry date. All lots packaged on line 6 between 12 Dec 2023 to 20 Dec 2023 were within the scope of this deviation; this included DESCOVY Lots 7182307PD, 7182201D, CMTGPD2. Previous lots packaged were put on hold as part of this event.
	Failure Mode	Equipment / System Reliability
	Impacted Process	Secondary Packaging
	Root Cause	Machinery / Equipment - Machine is the root cause; the defect was the result of two contributing factors. 1. The domino printer was producing poor print quality for the digit “6” 2. The Antares vision system was accepting the illegible digit “6” printed on the label
	CAPA	None
	Resolution	Reclassified to a minor as final severity is low, lots with the failed RQLs were 100% inspected and all defects were removed from the lots under protocols.

6.1.2 Post Shipment Nonconformances

There were no post shipment nonconformances reported during the review period.

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6.1.3 CAPA Effectiveness

The effectiveness check at GSIUC is performed by evaluating CAPAs according to their internal procedure. There were no ineffective CAPAs reported by GSIUC during the review period.

6.1.4 Review of Deviation Trends Against Previous APQR

The comparison of the deviations at the manufacturing site between the current and previous APQR review periods is presented in Table 18. There were no trends observed within GSIUC.

Table 18: Comparison of Deviations between Current and Previous Review Periods

APQR Review Year	Site	Failure Mode	Impacted Process	Root Cause/ Reason	Number of Deviations	Rejection
2024	GSIUC	Process	Primary Packaging	Method/Process	1	No
		Procedure	Distribution	Method/Process	1	No
		Execution	Secondary Packaging	Man/Personnel	1	No
2025	GSIUC	None	None	None	None	None

6.2 Patheon TRO Deviations

6.2.1 Major/Critical Deviations Reported

The major and critical deviations reported within the review period are summarized in Table 19 and there were no lots rejected.

Table 19: Major/Critical Deviations – Patheon TRO

Record Number (Lot Number(s) Classification)	Patheon TRO	
QE-234322 (Lot CVMVK, Major)	**Description**	Patheon TRO discovered that the pan differential pressure (PDP) was out of specification (OOS) for approximately 31 minutes during the coating of DESCOVY Lot CVMVK. The required PDP per the effective MBR is -0.1 to -0.3 W.C. During the time that the PDP was OOS, the highest PDP value reached +0.14 W.C and the lowest PDP value reached +0.02 W.C. (CMO QR 979109)
	Failure Mode	Execution
	Impacted Process	Coating

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Record Number (Lot Number(s) Classification)	Patheon TRO	
	Root Cause	Man / Personnel, Execution, Oversight Although the effective MBR specifically requires the coating technician to monitor and maintain the PDP during coating, the coating technician tasked with monitoring the PDP during coating of DESCOVY Lot CVMVK confirmed that they failed to identify the OOS immediately due to attending to separate tasks.
	CAPA	Patheon TRO initiated a Quality Broadcast for all necessary Patheon TRO technicians regarding the nature of this event.
	Resolution	Patheon TRO resumed coating DESCOVY Lot CVMVK to completion. The lot passed AQL inspection criteria, confirming there were no defects due to the excursion. No evidence of coating adhesion issues or tablet agglomeration were detected in real-time in-process checks during coating. The bulk product testing results met acceptance criteria, indicating no adverse impact on drug release or dosage uniformity. There was no product impact.

6.2.2 Post Shipment Nonconformances

The post shipment nonconformances reported in the review period are summarized in Table 20.

There were five (5) lots with partial rejections due to TE seal issues observed during incoming inspection at Patheon TRO:

- Lot CSGMV: two (2) cartons missing TE seals (QE-219065).
- Lot CSXVD: two (2) cartons missing TE seals (QE-221836).
- Lot CSXVC: one (1) carton missing TE seal (QE-222387).
- Lot CTTVX: one (1) carton damaged TE seal, two cartons (2) stained TE seals (QE-229094).
- Lot CTXHC: one (1) carton missing TE seal (QE-233828).

Table 20: Post Shipment Nonconformance – Patheon TRO

Record Number (Lot Number(s) Classification)	Patheon TRO	
QE-219065	**Description**	Gilead Mexico detected two (2) cartons with missing tamper evident (TE) seals during the incoming inspection of DESCOVY Lot CSGMV. (CMO QR 806313)

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Record Number (Lot Number(s) Classification)	Patheon TRO	
(Lot CSGMV, Major)	**Failure Mode**	Execution External Controls
	Impacted Process	Packaging
	Root Cause	Material/Product Essentra Packaging had previously performed an investigation which determined that excess adhesive was likely contributing to damaged, missing, or double seals when the seal were applied during packaging at Patheon TRO manually by the packaging technicians. Man/Personnel Patheon TRO also confirmed that a 100% manual visual inspection was performed after the seals were applied to the cartons.
	CAPA	While no CAPAs were initiated at Patheon TRO for this event, Patheon TRO previously performed a trend investigation (CMO QR 583055) which resulted in the previously mentioned Essentra Packaging investigation. A second trend investigation (CMO QR 805214) was initiated at Patheon TRO and a CAPA will be opened to enhance the Patheon TRO packaging MBRs instructions to make the inspection process more robust and identify all seal defects.
	Resolution	Gilead Mexico performed a 100% inspection to remove all cartons with missing TE seals. Since all defective units were rejected, DESCOVY Lot CSGMV was released.
QE-221836 (Lot CSXVD, Major)	**Description**	Gilead Colombia detected two (2) cartons with missing tamper evident (TE) seals during the incoming inspection of DESCOVY Lot CSXVD. (CMO QR 834890)
	Failure Mode	Execution External Controls
	Impacted Process	Packaging
	Root Cause	Material/Product Man/Personnel Essentra Packaging had previously performed an investigation which determined that excess adhesive was likely contributing to damaged, missing, or double seals when the seal were applied during packaging at Patheon TRO manually by the packaging technicians. Patheon TRO also confirmed that a 100% manual visual inspection was performed after the seals were applied to the cartons.

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Record Number (Lot Number(s) Classification)	Patheon TRO	
	CAPA	Trend investigation CMO QR 805214 was initiated to monitor CMO CAPA 850973 and the Essentra CAPAs. Patheon TRO CAPA 850973 was initiated for the Patheon TRO packaging team to update Gilead MBRs with enhanced inspection requirements regarding TE seals. Essentra initiated two (2) CAPAs which include training the operator involved in the event and adding Essentra QA verification regarding the specific instructions involved in the TE seal manufacturing.
	Resolution	Gilead Colombia performed a 100% inspection to remove all cartons with missing TE seals. Since all defective units were rejected, DESCOVY Lot CSXVD was released.
QE-222387 (Lot CSXVC, Major)	**Description**	Gilead Colombia detected one (1) carton with a missing tamper evident (TE) seal during the incoming inspection of DESCOVY Lot CSXVC. (CMO QR 841221)
	Failure Mode	External Controls Execution
	Impacted Process	Packaging
	Root Cause	Material/Product Man/Personnel Essentra Packaging had previously performed an investigation which determined that excess adhesive was likely contributing to damaged, missing, or double seals when the seal were applied during packaging at Patheon TRO manually by the packaging technicians. Patheon TRO also confirmed that a 100% manual visual inspection was performed after the seals were applied to the cartons.
	CAPA	Trend investigation CMO QR 805214 was initiated to monitor CMO CAPA 850973 and the Essentra CAPAs. CMO CAPA 850973 was initiated for the Patheon TRO packaging team to update Gilead MBRs with enhanced inspection requirements regarding TE seals. Essentra initiated two (2) CAPAs which include training the operator involved in the event and adding QA verification regarding the specific instructions involved in the TE seal manufacturing.
	Resolution	Gilead Colombia performed a 100% inspection to remove the carton with missing TE seal. Since the defective units were rejected, DESCOVY Lot CSXVC was released.
QE-229094 (Lot CTTVX, Major)	**Description**	Gilead Colombia detected one (1) carton with a damaged tamper evident (TE) seal and two (2) cartons with stained TE seals during the incoming inspection of DESCOVY Lot CTTVX. (CMO QR 913788).
	Failure Mode	Execution

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Record Number (Lot Number(s) Classification)	Patheon TRO	
	Impacted Process	Packaging
	Root Cause	Man/Personnel Essentra Packaging had previously performed an investigation which determined that excess adhesive was likely contributing to damaged, missing, or double seals when the seal were applied during packaging at Patheon TRO manually by the packaging technicians. Patheon TRO also confirmed that a 100% manual visual inspection was performed after the seals were applied to the cartons.
	CAPA	Trend investigation CMO QR 805214 was initiated to monitor CMO CAPA 850973 and the Essentra CAPAs CMO CAPA 850973 was initiated for the Patheon TRO packaging team to update Gilead MBRs with enhanced inspection requirements regarding TE seals. Target completion for CAPA 850973 was 24Feb2025. Essentra initiated two (2) CAPAs which include the training of the operator involved in this event and the addition of Essentra QA verification regarding the specific instructions involved in the TE seal manufacturing.
	Resolution	Gilead Colombia performed a 100% inspection to remove the cartons with damaged or stained TE seals. Since the defective units were rejected, DESCOVY Lot CTTVX was released.
QE-233828 (Lot CTXHC, Major)	**Description**	Gilead Colombia detected one (1) missing tamper evident (TE) seal during the incoming inspection of DESCOVY Lot CTXHC. (CMO QR 974117)
	Failure Mode	Execution
	Impacted Process	Packaging
	Root Cause	Man/Personnel Patheon TRO technician failed to identify the missing TE seal during the TE seal 100% inspection (a 100% manual visual inspection was performed after the seals were applied to the cartons). Quality Awareness Broadcasts specific to this particular TE seal issue at Patheon TRO had been performed so the root cause category is limited to Man/Personnel moving forward.

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Record Number (Lot Number(s) Classification)	Patheon TRO	
	CAPA	Trend investigation CMO QR 805214 was initiated to monitor CMO CAPA 850973 and the Essentra CAPAs Patheon TRO CAPA 850973 was initiated for the Patheon TRO packaging team to update Gilead MBRs with enhanced inspection requirements regarding TE seals. CMO CAPA 850973 was completed on 08 Feb 2025 and DESCOVY Lot CTXHC was packaged prior to the completion of CMO CAPA 850973.
	Resolution	Gilead Colombia performed a 100% inspection to remove the carton with the missing TE seal. Since the defective unit was rejected, DESCOVY Lot CTXHC was released.

6.2.3 CAPA Effectiveness

The effectiveness check at Patheon TRO is performed by evaluating CAPAs according to their internal procedure. There were no ineffective CAPAs reported by Patheon TRO during the review period.

6.2.4 Review of Deviation Trends Against Previous APQR

The comparison of the deviations at the manufacturing sites between the current and previous APQR review periods are presented in Table 21. A trend was observed at Patheon TRO involving tamper evident (TE) seals across the previous and current review period. A total of six (6) events related to damaged and/or missing TE seals were identified (one (1) from 2024 and five (5) from 2025). CAPAs and trend investigations were implemented at both Patheon TRO and Essentra, the TE seal manufacturer. The Essentra investigation determined that excess adhesive likely contributed to damaged, missing, or double seals. CAPAs were implemented to strip the matrix from the turn bar and issue a quality alert to their technicians. The Patheon TRO CAPAs were initiated to monitor TE seal complaint trends, issue Quality Broadcast alerts to their technicians, and update the master batch records to provide detailed instructions regarding the TE seal inspections after the TE seals are applied to the cartons.

Table 21: Comparison of Deviations between Current and Previous Review Periods

APQR Review Year	Site	Failure Mode	Impacted Process	Root Cause/ Reason	Number of Deviations	Rejection
2024	Patheon TRO	Execution	Packaging	Man/Personnel	1	No
2025	Patheon TRO	Execution	Coating	Man/Personnel	1	No
		External Controls Execution	Packaging	Material/Product Man/Personnel	3	No[1]
		Execution	Packaging	Man/Personnel	2	No[1]

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[1]Partial rejection

6.3 Rottendorf Deviations

6.3.1 Major/Critical Deviations Reported

The major and critical deviations reported within the review period are summarized in Table 22 and there were no lots rejected.

Table 22: Major/Critical Deviations – Rottendorf

Record Number (Lot Number(s) Classification)	Rottendorf	
QE-236386 (Lot 8010901P, Major)	**Description**	Rottendorf detected a leak test failure during primary packaging of DESCOVY Lot 8010901P. (CMO DEV-06147).
	Failure Mode	Pending Investigation
	Impacted Process	Pending Investigation
	Root Cause	Pending Investigation
	CAPA	Pending Investigation
	Resolution	Pending Investigation

6.3.2 Post Shipment Nonconformances

There were no post shipment nonconformances reported in the review period associated with DESCOVY manufactured and/or packaged at Rottendorf.

6.3.3 CAPA Effectiveness

The effectiveness check at Rottendorf is performed by evaluating CAPAs according to their internal procedure. There were no ineffective CAPAs reported by Rottendorf during the review period.

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6.3.4 Review of Deviation Trends Against Previous APQR

The comparison of the deviations at the manufacturing site between the current and previous APQR review periods is presented in Table 23. There were no trends observed within Rottendorf.

Table 23: Comparison of Deviations between Current and Previous Review Periods

APQR Review Year	Site	Failure Mode	Impacted Process	Root Cause/ Reason	Number of Deviations	Rejection
2024	Rottendorf	Execution	Batch Release	Man/Personnel	1	No
		External Controls Procedure	Labeling	Material/Product Method/Process	1	No
2025	Rottendorf	None	None	None	None	None

6.4 PCI Rockford Deviations

6.4.1 Major/Critical Deviations Reported

There were no major or critical deviations reported within the review period and no lots were rejected.

6.4.2 Post Shipment Nonconformances

There were no post shipment nonconformances reported in the review period associated with DESCOVY manufactured and/or packaged at PCI Rockford.

6.4.3 CAPA Effectiveness

The effectiveness check at PCI Rockford is performed by evaluating CAPAs according to their internal procedure. There were no ineffective CAPAs reported by PCI Rockford during the review period.

6.4.4 Review of Deviation Trends Against Previous APQR

The comparison of the deviations at the manufacturing site between the current and previous APQR review periods is presented in Table 24. There were no trends observed within PCI Rockford.

Table 24: Comparison of Deviations between Current and Previous Review Periods

APQR Review Year	Site	Failure Mode	Impacted Process	Root Cause/ Reason	Number of Deviations	Rejection
2024	PCI Rockford	Equipment/System Reliability	Packaging	Machinery/Equipment	1	No
2025	PCI Rockford	None	None	None	None	None

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6.5 Overall Assessment – Cross Site Analysis

There were no major or critical deviations reported for Bushu, GSI La Verne, GSI San Dimas, PCI Ireland, and Takeda during the current and previous review periods.

The comparison of all the deviations at all the manufacturing sites between the current and previous review periods is presented in Table 25. No new trends were identified.

Table 25: Comparison of Deviations between Current and Previous Review Periods

APQR Review Year	Site	Failure Mode	Impacted Process	Root Cause/ Reason	Number of Deviations	Rejection
2024	GSIUC	Process	Primary Packaging	Method/Process	1	No
		Procedure	Distribution	Method/Process	1	No
		Execution	Secondary Packaging	Man/Personnel	1	No
	Patheon TRO	Execution	Packaging	Man/Personnel	1	No
	Rottendorf	Execution	Batch Release	Man/Personnel	1	No
		External Controls Procedure	Labeling	Material/Product Method/Process	1	No
	PCI Rockford	Equipment/System Reliability	Packaging	Machinery/Equipment	1	No
2025	GSIUC	None	None	None	None	None
	Patheon TRO	Execution	Coating	Man/Personnel	1	No
		External Controls Execution	Packaging	Material/Product Man/Personnel	3	No[1]
		Execution	Packaging	Man/Personnel	2	No[1]
	Rottendorf	None	None	None	None	None
	PCI Rockford	None	None	None	None	None

[1]Partial rejection

7 CHANGE CONTROL SUMMARY

7.1 Manufacturing Process/Equipment Changes

There were no manufacturing process or equipment changes implemented at Takeda, Patheon TRO, and Rottendorf during the review period.

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7.2 Packaging Process/Equipment Changes

There were no packaging process or equipment changes implemented at Bushu, GSI La Verne, GSI San Dimas, Patheon TRO, Rottendorf, PCI Rockford, PCI Ireland during the review period.

The packaging process or equipment changes implemented during the review period at the packaging sites are detailed in Table 26 below.

Table 26: Packaging Process/Equipment Changes

Change Reference	Description	Assessment
Primary Packaging		
GSIUC		
QE-178662	Change control for the introduction of Intermediate Bulk Containers (IBCs) of purified water from pre-approved supplier Micro - Bio Limited and update in address of Micro Bio.	Implemented. All change action were completed. Introduction of the service provider was successful. All lots of Purified water (PW) from Micro bio were tested. All containers that used the PW underwent cleaning validation as per REP-47988. An audit was completed on the service provider, and they received an approved audit rating. Use of these Intermediate Bulk Containers of PW took place from Nov 2023 to Mar 2024 after which normal PW was restored. As PW supply is now restored, it has been deemed that Micro Bio is no longer required to be detailed in the Approved Supplier List and can be removed.
Secondary Packaging		
GSIUC		
QE-178379	Installation of temporary Compressed Air system MC21 to support resumption of Secondary Packaging and warehouse sampling.	Implemented. All change actions are completed per the original implementation plan. Temporary Compressed Air System MC21 is classified as Indirect impact, a risk assessment was not required for an Indirect system.
QE-004499	End of line Serialized Camera for Manual Line 3 and 4	Change was executed to plan. All actions were completed. During installation of the equipment in Manual line 4 prior to IQ execution, it was observed that the Antares supplied camera jobfile was not operational. The project was stopped, and a memo was created documenting the roll back measures. The project recommenced after a new camera set was provided. There was no GMP impact as a result of this and the installation and qualification of the camera was performed successfully on Manual lines 3 and 4.

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7.3 Analytical Changes

There were no analytical changes during the review period for DESCOVY.

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8 FACILITY, EQUIPMENT, AND PROCESS QUALIFICATION/VALIDATION REVIEW

8.1 External Sites

The facilities, including utilities and major equipment, at external sites where DESCOVY is manufactured, packaged, labeled, tested and stored are maintained in a validated/qualified state according to site specific procedures. Per the quality agreements with these sites, Gilead is notified of any facility, utility, equipment and process related deviations and changes that have the potential to impact Gilead product quality. These deviations and changes have been assessed for the current review period and are captured in Section 6 and 7 of this AQR.

8.2 Internal Sites

For GSIUC and GSI La Verne, where DESCOVY is packaged, labeled and stored, validation/qualification is conducted in accordance with Gilead validation policies and Standard Operating Procedures (SOPs). Requalification activities at GSI La Verne and GSIUC were verified to be completed at the specified intervals per the relevant SOPs. Validation and qualification activities were reviewed, and the equipment, processes, utilities and facilities were determined to be in the validated/qualified state and acceptable for use in the production of DESCOVY. These deviations and changes have been assessed for the current review period and are captured in Section 6 and 7 of this AQR. Refer to Attachment 5 for a summary of qualification activities performed during the review period.

9 STABILITY PROGRAM

9.1 Stability Program Overview

Gilead maintains a stability program for DESCOVY 200 mg FTC/10 mg TAF tablets in bottles, 200 mg FTC/25 mg TAF tablets in bottles, 200 mg FTC/25 mg TAF tablets in blister packs, and 120 mg FTC/15 mg TAF tablets in bottles to ensure that the commercial product continues to support the labeled shelf-life when stored in the commercial primary packaging configuration. Table 27 is an overview of the DESCOVY stability program and Table 28 lists the details of the lots placed on stability during the review period.

The packaging configuration DESCOVY 200 mg FTC/10 mg TAF and 200 mg FTC/25 mg TAF tablets in bottles is 30-count HDPE bottle. The packaging configuration DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs is 30-count blister wallets. The packaging configuration for DESCOVY 120 mg FTC/15 mg TAF tablets in bottles is 30 count HDPE bottle.

There were no changes to the DESCOVY stability testing during the review period.

Table 27: DESCOVY Stability Program Overview

Test Site	Eurofins Lancaster Laboratories, Inc.			
Dosage Strength	200 mg FTC/10 mg TAF	200 mg FTC/25 mg TAF	200 mg FTC/25 mg TAF	120 mg FTC/15 mg TAF
Packaging Configuration	Bottles	Bottles	Blister Pack	Bottles
Stability Specification	GSPEC-248-99	GSPEC-249-99	GSPEC-249-99	GSPEC-395-99
Long-Term Stability Protocol	PRO-02683	PRO-02683	PRO-20710	PRO-28589
Accelerated Stability Protocol	PRO-13255	PRO-13255	PRO-20711	PRO-28591
Active Studies	7	17	9	5

Table 28: DESCOVY Lots Placed on Stability during the Review Period

Dosage Strength	Bulk Lot Number	Packaged Lot Number	Manufacturing Site	Packaging Configuration	Purpose
200 mg FTC/ 10 mg TAF	CSVVN	CSVVS	Patheon TRO	30 tablets/bottle	2024 Annual Commitment Lot
200 mg FTC/ 25 mg TAF	CSVVY	CSVWB	Patheon TRO	30 tablets/bottle	2024 Annual Commitment Lot
200 mg FTC/ 25 mg TAF	7630401	7630401P	Rottendorf	30 tablets/bottle	2024 Annual Commitment Lot
200 mg FTC/ 25 mg TAF	7682201	7682201A	Rottendorf	30 tablets/ blister pack	2024 Annual Commitment Lot
120 mg FTC/ 15 mg TAF	CSVVX	CSVWD	Patheon TRO	30 tablets/bottle	2024 Annual Commitment Lot

9.2 Stability Data Assessment

As per the stability protocols, samples are tested for appearance, assay, degradation products, water content, and dissolution at each scheduled time point while microbiological examination is performed at initial and end of product shelf-life. A summary of the current lot on stability is provided in Attachment 6.

The key stability indicators monitored during stability testing remained within the specified acceptance criteria listed in GSPEC-248-99 Version 6.0, GSPEC-249-99 Version 8.0, and GSPEC-395-99 Version 1.0 for all samples tested of DESCOVY 200 mg FTC/10 mg TAF tablets in bottles, 200 mg FTC/25 mg TAF tablets in bottles and blister packs, and 120 mg FTC/15 mg TAF tablets in bottles, respectively. No change in product appearance was observed upon the labeled long-term storage condition. The assay, degradation products, water content, dissolution, and microbial examination results were all within the acceptance criteria.

As key stability indicators, the impact of assay, degradation products, and water content on product stability were assessed by Discoverant analysis. There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC degradation products is therefore not provided. Dissolution is assessed using the GLIMS Dissolution Range Chart.

The longest filed shelf-life for DESCOVY 200 mg FTC/10 mg TAF tablets in bottles is 36 months. The longest filed shelf-life for DESCOVY 200 mg FTC/25 mg TAF tablets in bottles is 48 months. The longest filed shelf-life for DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs is 36 months. The longest filed shelf-life for DESCOVY 120 mg FTC/15 mg TAF tablets in bottles is 48 months. For ongoing studies that have not yet reached the shelf-life time point, a predicted value at 12 months beyond the most recent time point available is determined by linear regression analyses for each testing attribute. The results for the worst-case prediction of the one-sided or two-sided 95% confidence interval and the specification limits are summarized in Table 8 of Attachment 7 for DESCOVY 200 mg FTC/25 mg TAF tablets in bottles at 30 °C/75%RH and Table 9 of Attachment 7 for DESCOVY 120 mg FTC/15 mg TAF tablets in bottles at 25 °C/60%RH. As discussed in Attachment 7, there are no lots with greater than 5 data points that have not reached the shelf-life time point for DESCOVY 200 mg FTC/10 mg TAF in bottles and DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs, so statistical analysis with extrapolation of 12 months for predictions is not performed

For all DESCOVY 200 mg FTC/10 mg TAF tablets in bottles stability indicators, the results at the shelf-life time point were well within the specification limits supporting the current shelf-life of 36 months. For all DESCOVY 200 mg FTC/25 mg TAF tablets in bottles stability indicators, the results

at the shelf-life time point and the worst-case assessments were well within the specification limits supporting the current shelf-life of 48 months. For all DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs stability indicators, the results at the shelf-life time point were well within the specification limits supporting the current shelf-life of 36 months. For all DESCOVY 120 mg FTC/15 mg TAF tablets in bottles stability indicators, the results at the shelf-life time point and the worst-case assessments were well within the specification limits supporting the current shelf-life of 48 months. For additional details regarding statistical analysis, see Attachment 7.

9.3 Stability Deviation Investigations

No out of specification investigations, out of trend investigations, or deviations were generated during the stability testing of DESCOVY 200 mg FTC/10 mg TAF tablets in bottles, 200 mg FTC/25 mg TAF tablets in bottles, and 200 mg FTC/25 mg TAF tablets in blister packs through the respective shelf-life for each product during this review period. There was one (1) deviation for 120 mg FTC/15 mg TAF tablets in bottles as described in Table 29 below.

Table 29: DESCOVY 200 mg FTC/25 mg TAF in Bottles Deviations/Investigations Summary

Record Type	Record Number (Lot Number)	Description of Issue	Laboratory Root Cause	Resolution/Comment
ELLI Lancaster				
Deviation	QE-231013 (Lot CHZBB)	Deviation observed for dissolution testing of DESCOVY 120/15 mg tablets Lot CHZBB at 36 months, 25°C/60%RH. Dissolution results did not meet stage 1 criteria of each individual vessel value needs to be 85% or higher – Vessel 5 TAF % dissolved = 83%.	Man/Personnel Execution Oversight Manual evaluation of the data against the specification is required as eLIMS does not automatically evaluate the data.	Original sample bottles were still available, so no reserves were pulled. Stage 2 testing was performed, and results met acceptance criteria. A new COA was issued to report both stage 1 and stage 2 dissolution results.

9.4 Conclusion

All lots tested continue to support the 36 months shelf-life for DESCOVY 200 mg FTC/10 mg TAF tablets in bottles when stored at the labeled storage condition in the original container/closure system.

All lots tested continue to support the 48 months shelf-life for DESCOVY 200 mg FTC/25 mg TAF tablets in bottles when stored at the labeled storage condition in the original container/closure system.

All lots tested continue to support the 36 months shelf-life for DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs when stored at the labeled storage condition in the original container/closure system.

All lots tested continue to support the 48 months shelf-life for DESCOVY 120 mg FTC/15 mg TAF tablets in bottles when stored at the labeled storage condition in the original container/closure system.

The DESCOVY stability program is in a state of control.

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10 POST MARKETING SURVEILLANCES

10.1 Returned Goods

No quality related returns occurred during the review period except for the returns related to complaint cases (see Section 10.3).

10.2 Retains/Reserve Sample Inspection

Retain/reserve samples for all DESCOVY finished product lots manufactured and packaged by Gilead were stored and inspected at GSI La Verne and GSIUC during the review period.

Retain/reserve samples for all DESCOVY finished product lots manufactured and packaged by Patheon TRO for the Canadian market were stored and inspected at Canadian Third-Party Logistics (3PL) during the review period.

At each of the sites where retain/reserve samples were inspected, there was no evidence of deterioration of packaging components observed.

10.3 Product Complaints

Complaint Rate

The complaint rate and the total number of complaints decreased in the current review period when compared to the previous review period (see Table 30 and Table 31 below). The complaint data for DESCOVY bottle packaging configuration and DESCOVY blister packaging configuration was separated.

Table 30: Comparison of Total Complaints and Complaints Rate between Current and Previous Review Periods for DESCOVY in Bottles

Review Period	Previous Review Period (2024)	Current Review Period (2025)
Total Number of Complaints	57	32
Complaint Rate (ppm[1])	26	13

[1]Complaint rate (ppm) is the number of complaints received per million units sold.

Table 31: Comparison of Total Complaints and Complaints Rate between Current and Previous Review Periods for DESCOVY Blister Packs

Review Period	Previous Review Period (2024)	Current Review Period (2025)
Total Number of Complaints	27	22
Complaint Rate (ppm[1])	172	116

Distribution of Complaints

During the current review period, there were a total of fifty-four (54) commercial product complaints for DESCOVY. The majority of complaints were received for Broken/Chipped Tablet(s) (31%) and User Experience (31%) (refer to Table 32), similar to the previous review period. For the seventeen (17) Broken/Chipped Tablet(s), the majority were reported for fully coated partial tablets, followed by bottles that contained tablets with multiple breakage types. The majority of the Broken/Chipped Tablet(s) complaints were reported from Japan (8 complaints) followed by the United States (6 complaints). No patterns or trends were noted for Broken/Chipped Tablet(s) complaints. All seventeen (17) User Experience complaints were reported from the United States market and were for Difficulty in Opening Blisters. There are no automated systems in place to check for dispensability defects. No trends were noted for these complaints.

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Table 32: Distribution of Complaints by Complaint Subcategory

Complaint Subcategory	Number of Complaints (2024)	Percent of Total Complaints (2024)	Number of Complaints (2025)	Percent of Total Complaints (2025)
User Experience – Difficulty in Opening Blister	26	31%	17	31%
Broken/Chipped Tablet(s)	25	30%	17	31%
Quantity Issue	10	12%	9	17%
Secondary Packaging Operations	1	1%	4	7%
Tamper Evident Seal Issue	5	6%	0	0%
Carton Issue	3	4%	0	0%
Cosmetic	3	4%	0	0%
Labelling Issue	3	4%	1	2%
Other	8*	10%	6**	11%

*Other includes complaint types for which <3 complaints were reported per complaint type in 2024. These include; Missing Components (2), Product Appearance (2), Product Characteristics (2), Defective/Damaged Components (1), and Induction Seal Issue (1).
**Other includes complaint types for which <3 complaints were reported per complaint type in 2025. These include; Defective/Damaged Components (2), Product Appearance (2), Missing Components (1), and Product Characteristics (1).

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Major/Critical Complaints

There were zero (0) Critical complaints, and two (2) Major complaints reported during the current review period. Refer to Table 33 for details.

Table 33: Major Complaints

Complaint Details		
Complaint ID: QE-226783 **Date Reported:** 18-Sep-2024 **Country:** United States	**Description**	Gilead QA received a complaint regarding an empty sealed bottle of DESCOVY Lot 7447301A.
	Investigation Outcome	PCI Rockford determined a root cause of Man and Method as improper recovery would have contributed to the empty bottle being packed out with the finished goods.
	Action	Previously, PCI Rockford initiated CAPA-2022-0712 (due 25 Apr 2025) to capture an action plan and sustainment to enhance the recovery process due to various complaints and investigations that were impacted by improper recovery through manual intervention. External Request Task (ERT-000542) was created to track the implementation and closure of the PCI Rockford action items. PCI Rockford implemented actions items to coach all three (3) shifts at PCI Rockford to mark all set up bottles with an "X" to prevent empty bottles from being released. Gilead CAPA QE-230067 was created to track the closure of PCI Rockford CAPA-2022-0712.
Complaint ID: QE-232072 **Date Reported:** 16-Dec-2024 **Country:** United States	**Description**	One (1) blister card was missing from one (1) blister wallet of DESCOVY Lot 7447203A.
	Investigation Outcome	The secondary packaging line at PCI Rockford does not include automated inspection systems to defect for missing blister; the blisters are manually inserted into the wallets. During IPC and finished goods hourly inspections, production is required to verify two (2) of each blister counts are present in the blister wallets. Since there was no placement of the seven (7)-count blisters in the complaint sample and this was not identified before packout; man was determined to be the root cause.
	Action	PCI Rockford previously launched three (3) CAPAs (AI-2024-25103, AI-2024-25105, and AI-2024-25107) for awareness training to be provided to the operations personnel to ensure each wallet contains two (2) seven (7)-count cards and two (2) eight (8)-count cards. Gilead opened an External Request Task (ERT-000799) in QE-229997 to track the PCI Rockford CAPAs.

Evaluation of previous trends and CAPAS:

There were two (2) lot specific trends identified during the previous review period for Broken/Chipped tablets and Difficulty in Opening Blister for DESCOVY. Both lot trends had a root cause of Indeterminate. There were no issues identified that would have contributed to the reported complaints.

There was one (1) trend complaint deviation investigation performed in the previous review period where an increase in the number of Broken/Chipped Tablet(s) and Tamper Evident Seal (TES) Issue complaints directly contributed to DESCOVY exceeding its established upper limits in two (2) consecutive months (May and June 2023). The Broken/Chipped Tablets complaints were distributed among various manufacturing and packaging sites, and no process deviations were noted that would have accounted for the reported complaints. There were no corrective actions identified. For the TES Issue complaints, Patheon TRO indicated that a root cause was identified by the TES vendor. CAPAs were implemented at the vendor (refer to the 2024 DESCOVY APQR for details). In the current review period, there were zero (0) TES Issue complaints reported.

Trend Investigations

There were no lot specific trend investigations during the current review period; however, there were two (2) trends identified for complaints classified as Major during the current review period. The Major complaint trend investigations initiated during the current review period are listed in Table 34. In addition, there was one (1) trend complaint deviation initiated during the review period; see Table 35.

Table 34: Major Complaint Trends

Record ID	Lot Number	Subcategory	Impacted Site	Root cause	CAPA
QE-226783	7447301A	Quantity Issue	PCI Rockford	Man and Method due to improper recovery (see Table 33 above for summary).	Enhance the recovery process and coach all three (3) shifts at PCI to mark all set up bottles with an “X” to prevent empty bottles from being released.
QE-232072	7447203A	Secondary Packaging Operations	PCI Rockford	Man due to manual process (see Table 33 above for summary).	Awareness training to be provided to the operations personnel to ensure each wallet contains two (2) seven (7)-count cards and two (2) eight (8)-count cards to prevent missing blisters from wallet.

Table 35: Trend Complaint Deviations

Record ID	Investigation Details	
QE-173672	**Analysis Details**	The complaint rate for DESCOVY Blister Pack (BP) exceeded the established upper limit (UL) of 222 ppm for two (2) consecutive months in June 2024 (326 ppm) and July 2024 (325 ppm).

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Record ID	Investigation Details	
	Root Cause	Overall, an increase in the number of reported complaints was noted in June and July 2024 when the UL was exceeded with five (5) complaints reported in each month. The UL was only exceeded during these months in the review period. During the rest of the review period, complaints ranged from zero (0) to three (3) reported complaints per month, except for December 2023, when a spike was observed as seven (7) complaints were reported (429 ppm). However, the complaint rate did not exceed the UL as it was not established in 2023. The most reported complaint subcategory in the 24-month review period was User Experience (45, 87%). All the complaints reported were for Difficulty in Opening Blister from the U.S. market. The number of User Experience complaints remained stable throughout the review period with zero (0) to three (3) complaints reported per month, except for the month of December 2023 (six (6) complaints; no UL available) and July 2024 (four (4) complaints). This contributed to the complaint rate exceeding the UL of 222 ppm in July 2024. However, based on each of the complaint investigations performed, no root cause could be determined.
	CAPA	DESCOVY BP product complaints were determined to be in a state of control. It should be noted that the DESCOVY blister production was stopped at the end of 2024; no additional designs for DESCOVY blisters will be done. No further actions are required at this time.

Summary

There was decrease in the complaint rate when compared to the previous period. There were zero (0) complaints classified as Critical and two (2) complaints classified as Major during the current review period; the Major complaints were also marked as trends. For the Major complaint where an empty DESCOVY bottle was observed, a root cause was identified as Man and Method due to improper recovery. Corrective actions included enhancing the recovery process and coaching all three (3) shifts at PCI to mark all set up bottles with an “X” to prevent empty bottles from being released. For the Major complaint where the seven (7)-count blister cards were missing from a DESCOVY wallet, a root cause of Man was identified since the cards are manually added and IPCs are performed. As such, the missing blister cards were missed by the packaging personnel. Awareness training was performed as a corrective action to ensure that the appropriate number of blister cards are added to each wallet.

There was one (1) trend deviation identified during the current review period for DESCOVY blister packs where the complaint rate upper limit was exceeded in two (2) consecutive months in June and July 2024. The most reported complaint subcategory in the 24-month complaint trend review period was User Experience (Difficulty in Opening Blisters) (87%); all of these complaints were reported from the U.S. market. However, for each of the individual complaint investigations performed, no root cause could be determined. It should be noted that the DESCOVY 30 count blister production was stopped at the end of 2024; no additional designs for DESCOVY 30 count blisters will be done. No further actions are required at this time.

The overall state of complaints for DESCOVY was determined to be in a state of control.

10.4 Market Actions

No quality related returns occurred during the review period except for returns related to complaint cases (see section 10.3).

There were no market recalls, withdrawals, or field corrective actions for DESCOVY during the review period.

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11 CORRECTIVE AND PREVENTIVE ACTIONS IDENTIFIED IN APQRS

There were no follow up actions from the previous APQR for DESCOVY. There are no recommended actions identified from the APQR in this review period.

12 REGULATORY SUBMISSION STATUS

12.1 Submissions

The regulatory submissions filed and approved during the review period are listed in Table 36 below.

Submission dates in **bold** indicate that the submission occurred prior to the current review period.

Table 36: Listing of Regulatory Submissions in Current Review Period

Submission/ Reference No.	Country	Agency	Description	Submission Date	Approval Date
FTAF-15-039	Benin	MoH	Original application for MAA	**01-Jun-2017**	Pending
HB003	Brazil	Agência Nacional de Vigilância Sanitária (Brazil)	Artwork notification due to updates required in RDC 768/202	12-Sep-2024	12-Sep-2024
BP010	Canada	Health Canada	Updates to package label (bottle label) to add GS1 datamatrix barcode for serialization	12-Sep-2024	12-Sep-2024
FP027	China	NMPA	PI update per NMPA request, NMPA issued the formal notification on Revision to the Package Insert of TAF-containing products on July 16, 2024.	28-Aug-2024	29-Aug-2024
89124	Costa Rica	MoH	Drug product Shelf-life extension to 36 months for 200/10 mg	**19-Mar-2024**	Pending
8A052	Costa Rica	MoH	Drug product Shelf-life extension to 36 months for 200/25 mg	**19-Mar-2024**	Pending
DW041	Dominican Republic	Ministry of Public Health and Social Assisstance	Addition of Secondary packaging site (Saval) to the PI and taken the opportunity to align with the latest EU texts	10-Jul-2024	22-Nov-2024
87103	EU	EMA	TAF DS- Add tosylate reagent suppliers Chengda and Huangshi Fuertai	**22-Mar-2024**	04-Apr-2024
BV001	Great Britain	MHRA	Addition of alternative 120kg lot size for 200/10 mg tablets	**26-Mar-2024**	05-Apr-2024

Submission/ Reference No.	Country	Agency	Description	Submission Date	Approval Date
BJ017	Great Britain	MHRA	Addition of Chengda Pharmaceuticals Co., Ltd., (Jiaxing, Zhejjang, China) and Huangshi Fuertai Pharmaceutical Technology Co,, Ltd., (Huangshi, Hubei Province, China) for tosylate reagent for TAF DS	22-Apr-2024	15-May-2024
CL014	Israel	MoH	Addition of Chengda Pharmaceuticals Co., Ltd., (Jiaxing, Zhejjang, China) and Huangshi Fuertai Pharmaceutical Technology Co, Ltd., (Huangshi, Hubei Province, China) for tosylate reagent for TAF DS	18-Apr-2024	09-May-2024
HV024	Korea	Ministry of Food and Drug Safety	Correction of Opadry specification in Korea approved matter (200/10 mg)	06-Feb-2025	Pending
HS030	Korea	Ministry of Food and Drug Safety	Correction of Opadry specification in Korea approved matter (200/25 mg)	06-Feb-2025	Pending
80124	Kuwait	Ministry of Health (Kuwait)	Addition of F/TAF 200/25 PrEP	24-Apr-2024	16-Oct-2024
C7049	Kuwait	Ministry of Health (Kuwait)	Update F/TAF 200/10 mg tablets to align labeling with EU	24-Apr-2024	16-Oct-2024
FTAF-15-055	Mauritania	MoH	Original application for MAA	**17-Apr-2017**	Pending
GY021	Mexico	COFEPRIS	Esteve Quimica address update, PV email address update & Legal Representative address change	06-Nov-2024	Pending
FTAF-15-058	Niger	MoH	Original application for MAA	**09-May-2017**	Pending
DVY-23-22228	Nigeria	NAFDAC	200/10 mg renewal with CMC variations	**10-Jul-2023**	27-Mar-2024
DVY-23-23075	Nigeria	NAFDAC	200/25 mg renewal with CMC variations	**10-Jul-2023**	30-April-2024
81127	Saudi Arabia	SFDA	Indication extension to include F/TAF 200/25 PrEP and label update to	24-Apr-2024	30-Jul-2024

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Submission/ Reference No.	Country	Agency	Description	Submission Date	Approval Date
			align with the latest EU label		
81127	Saudi Arabia	SFDA	Update to algin F/TAF 200/10 mg tablets with the latest EU label	24-Apr-2024	30-May-2024
8K035	Singapore	HSA	Addition of alternative 120kg lot size for 200/10 mg tablets plus Opadry changes	**22-Feb-2024**	01-May-2024
CM018	Switzerland	Swissmedic	Addition of Chengda Pharmaceuticals Co., Ltd., (Jiaxing, Zhejjang, China) and Huangshi Fuertai Pharmaceutical Technology Co, Ltd., (Huangshi, Hubei Province, China) for tosylate reagent for TAF DS	02-May-2024	15-May-2024
81133	Switzerland	Swissmedic	Update of PI/PIL on HIV transmission and breastfeeding and admin changes	25-Mar-2024	25-Jul-2024
EL017	Taiwan	TFDA	PI update of Desovy 200/10 mg tablets	25-Oct-2024	08-Apr-2025
EM017	Taiwan	TFDA	PI update of Desovy 200/25 mg tablets	25-Oct-2024	08-Apr-2025
7Z113	UAE	UAE Ministry of Health and Prevention	Indication extension to include F/TAF 200/25 PrEP	25-Apr-2024	29-Apr-2024
C8025	UAE	UAE Ministry of Health and Prevention	Update to align F/TAF 200/10 mg tablets with the latest EU label	25-Apr-2024	30-Apr-2024
GX014	United States	USFDA	Addition of Cambrex Charles City, Inc. as a new FTC manufacturing and release test site.	20-Sep-2024	07-Mar-2025
DVY-19-4426	Zambia	ZAMRA	200/10 mg renewal	**07-Mar-2024**	Pending
26381	Zambia	ZAMRA	200/25 mg renewal	**07-Mar-2024**	Pending
3H141	United States	USFDA	Update USPI to include pediatric patients weighing at least 14 kg on a HIV-1 protease inhibitor that is administered with either ritonavir or cobicistat	27-Sep-2024	Pending

12.2 Submissions Withdrawn, Rejected, or Refused (not approved)

There were two (2) submission withdrawals for DESCOVY during the review period. Refer to Table 37.

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Table 37: Submissions Withdrawn, Rejected, or Refused (not approval)

Country	Agency	Date
Panama	National Directorate of Pharmacy and Drugs (Panama)	21-Jan-2025 – Gilead withdrew the 200 mg/10 mg license renewal submission since the request to withdraw the low strength license was about to be submitted. 17-Mar-2025 (Approval Date of Withdrawal) – Gilead withdrew the 200 mg/10 mg license in Panama (Treatment of HIV-1 Infection 200/10 mg)
United States	Food and Drug Administration (FDA)	03-Feb- 2025 – FDA shared a refusal to file letter regarding Gilead's proposal to remove restrictions for DESCOVY PrEP in women.

12.3 New Marketing Authorizations

There were three (3) new Market Authorizations for DESCOVY during the review period. Refer to Table 38.

Table 38: New Marketing Authorizations

Country	Agency	Approval Date
Kuwait	Kuwait Ministry of Health, Pharmaceutical & Herbal Medicines Registration and Control Administration	16-Oct-2024 (PrEP 200/25 mg bottle)
Saudi Arabia	Saudi Food and Drug Authority (SFDA)	30-Jul-2024 (PrEP 200/25 mg bottle)
UAE	Ministry of Health and Prevention, UAE	29-Apr-2024 (PrEP 200/25 mg bottle)

12.4 Post-Market Commitments

There were nine (9) post marketing commitments for DESCOVY during the review period. Refer to Table 39.

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Table 39: Post-Marketing Commitments

Country	Agency	Description
China	NMPA	Develop the post-marketing clinical study protocol to evaluate safety and effectiveness after NDA approval in China, in order to validate DESCOVY PrEP's safety and effectiveness in Chinese population and collect the virological surveillance data.
Canada	HC	Submit final reports of the survey studies for PrEP Prescribers and PrEP Users in Canada to evaluate the levels of knowledge, attitudes, and behaviors regarding the use and risks with oral HIV-1 PrEP (GS-US-412-6209 and GS-US-412-6213, respectively)
EU	EMA	Post marketing commitment for Article 46 submission GS-US-311-1269
EU	EMA	Post marketing commitment for Article 46 submission GS-US-412-5624
US	FDA	PMC 3723-1: Conduct a randomized, comparative trial to evaluate the safety and efficacy of DESCOVY for pre-exposure prophylaxis (PrEP) in cisgender women and adolescent girls weighing at least 35 kg, who are at risk of sexually acquired HIV-1 infection. The trial should include a Truvada arm. The trial should employ two distinct methods to estimate the background HIV-1 incidence rate as external controls. HIV-1 incidence estimates should be based on current estimates from sites involved in recent clinical trials, cross-sectional HIV surveillance surveys, and from high quality local epidemiology data.
US	FDA	PMR 3531-1: Conduct a study to evaluate the pharmacokinetics (PK), safety and antiviral activity of DESCOVY (emtricitabine and tenofovir alafenamide) administered in combination with atazanavir and TYBOST (cobicistat), and in combination with darunavir and TYBOST in HIV-1 infected pediatric subjects weighing less than 25 kg. The safety and activity of the treatment regimen must be assessed for a minimum of 24 weeks. The minimum age criteria for the treatment regimen being evaluated are specified below. • DESCOVY administered in combination with atazanavir co-administered with TYBOST must be evaluated in pediatric patients 3 months of age and older • DESCOVY administered in combination with darunavir co-administered with TYBOST must be evaluated in pediatric patients 3 years of age and older
US	FDA	PMR 3531-2: Conduct a study to evaluate the PK, safety, and antiviral activity of DESCOVY administered in combination with atazanavir and TYBOST, and in combination with darunavir and TYBOST in HIV-1 infected pediatric subjects 6 to less than 12 years of age (weighing 25 kg to less than 35 kg). The safety and activity of the treatment regimen must be assessed for a minimum of 24 weeks.
US	FDA	PMR 3531-3: Conduct a study to evaluate the pharmacokinetics (PK), safety and antiviral activity of DESCOVY administered in combination with regimens that do not contain cobicistat or other PI/CYP3A inhibitor in HIV-1 infected pediatric subjects 4 weeks of age and older and weighing less than 25 kg. The safety and activity of DESCOVY must be assessed for a minimum of 24 weeks. Clinical trials evaluating DESCOVY administered in combination with regimens that do not contain cobicistat or a PI/CYP3A inhibitor are not required if data from other ongoing or completed pediatric studies can be leveraged to provide the requested PK, safety, and antiviral activity data for DESCOVY.
US	FDA	PMR 3531-4: Conduct a study to evaluate the PK, safety and antiviral activity of DESCOVY administered in combination with lopinavir/ritonavir in HIV-1 infected pediatric subjects 4 weeks to less than 3 months of age. The safety and activity of DESCOVY must be assessed for a minimum of 24 weeks.

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13 REVIEW OF QUALITY AGREEMENTS

The quality agreements for the manufacturing, packaging, testing, and supply of DESCOVY are reviewed and verified to be current. Quality agreements that were revised during the review period are indicated in **bold**. Refer to Table 40.

Table 40: Quality Agreements

Document Number and Version	Executed Date	Contract Service Provider
Drug Substance Suppliers		
AGR-01048 v18.0	08-May-2023	Gilead Alberta ULC (TAF/FTC)
AGR-01597 v7.0	**09-Sep-2024**	Esteve Quimica, S.A.(TAF)
AGR-00388 v3.0	11-Jul-2018	Evonik Operations GmbH (FTC)
AGR-00395 v.3.0	10-Nov-2022	Union Quimico Farmaceutica Uquifa SAU (FTC)
AGR-00546 v6.0	12-Oct-2023	Yuhan Corporation (FTC)
Primary Packaging Component Suppliers		
AGR-01406 v4.0	**18-Oct-2024**	Drug Plastics and Glass Company, Inc.
AGR-00956 v7.0	**18-Apr-2024**	Nolato Jaycare, Ltd
AGR-00534 v4.0	13-Sep-2021	Van Blarcom Closures, Inc.
AGR-01443 v4.0	**10-Feb-2025**	Colorcon Inc.
AGR-00700 v5.0	29-Sep-2021	Carolina Absorbent Cotton
Secondary Packaging Component Suppliers		
AGR-00349 v10.0	31-May-2023	WestRock Healthcare Packaging Ireland Limited
AGR-00454 v4.0	13-Sep-2021	Nosco Inc.
AGR-00648 v9.0	04-Sep-2023	MM Fiber Packaging Ireland Limited
AGR-00132 v6.0	24-Jun-2022	Label Craft
AGR-00182 v6.0	17-Nov-2022	Multi Color Corporation
AGR-00888 v6.0	**14-Feb-2025**	Apex Graphics
AGR-01400 v9.0	**14-Jan-2025**	Pharmaceutic Litho and Label Co. and Gilead Sciences, Inc.
Manufacturing and Packaging Sites		
AGR-01077 v7.0	**15-Aug-2024**	Takeda GmbH, Plant Oranienburg
AGR-08177 v1.0 (Amendment 1)	02-Jun-2023	
AGR-00415 v11.0	20-Jun-2022	Patheon Inc. (Toronto Region Operations)
AGR-07868 v1.0 (Amendment 1)	12-Apr-2023	
AGR-08797 v1.0 (Amendment 2)	08-Aug-2023	
AGR-11554 v1.0 (Amendment 3)	02-Feb-2024	

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AGR-12759 v1.0 (Amendment 4)	**05-Sep-2024**	
AGR-00421 v9.0	28-Feb-2022	Rottendorf Pharma Inc. (Ostenfelder, Germany and Am Fleigendahl, Germany)
AGR-05496 v1.0 (Amendment 1)	12-Aug-2022	
AGR-06779 v1.0 (Amendment 2)	05-Dec-2022	
AGR-00894 v8.0	24-Jun-2021	AndersonBrecon Inc. (an Illinois Corporation doing business as "PCI Pharma Services")
AGR-06631 v1.0 (Amendment 1)	14-Nov-2022	
AGR-10716 v1.0 (Amendment 2)	05-Feb-2024	
AGR-17425 v1.0 (Amendment 3)	18-Sep-2024	
AGR-00949 v8.0	**21-Mar-2025**	Millmount Healthcare Ltd. Trading as PCI Pharma Services
AGR-01048 v18.0	08-May-2023	Gilead Sciences Inc. (Foster City and San Dimas/La Verne) and Gilead Sciences Ireland UC
AGR-00603 v15.0	**05-Mar-2025**	Bushu Pharmaceuticals Ltd.
Laboratory Services		
AGR-00347 v10.0	**11-Feb-2025**	Almac Sciences (Ireland) Limited (Previously BioClin Research Laboratories)
AGR-01082 V5.0	06-Aug-2021	Reading Scientific Services Limited (RSSL)
AGR-00754 v9.0	28-Sep-2022	Eurofins Lancaster Laboratories Inc.
AGR-01485 v6.0	22-Dec-2020	Patheon Inc. (Toronto Region Operations)
AGR-04072 v1.0 (Amendment 1)	24-Sep-2021	

14 ATTACHMENTS

Attachment 1: Lots Manufactured and Dispositioned

Attachment 2: Finished Product Test Results

Attachment 3: Microbiology Testing Results for DESCOVY

Attachment 4: List of Approved Suppliers/Vendors for DESCOVY

Attachment 5: Facility and Equipment Qualification

Attachment 6: Summary of Current Lots on Stability

Attachment 7: Statistical Analysis of Stability Data

Attachment 8: Release and In Process Data from Previous Review Period

Attachment 9: Imported Lots

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Attachment 1: Lots Manufactured and Dispositioned

Note: In the tables below, dates noted in **bold** indicate that they are outside the review period.

The GMP releasing site is denoted by color where Orange is GSIUC, Blue is GSI Foster City, Green is GSI La Verne, Purple is Japan.

Any notable items are documented in the comments column.

TBD = To Be Determined

Table 1: Manufactured and Dispositioned Lots – Patheon TRO (200 mg/25 mg)

Patheon TRO (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
CKSKF*	**13-Dec-21**	CKSKG	**09-Feb-22**	6195894171	CMPMH	TBD	TBD	None
CNPBP*	**12-Dec-22**	CNPBT	**23-Feb-23**	101839	CNPBTD	29-May-24	Spain	None
				102043	CNPBTD	29-May-24	Australia, New Zealand	None
				102374	CNPBTD	05-Jul-24	Italy	None
				101614	10005730	21-Aug-24	Cyprus, Greece	None
CNTYM*	**11-Jan-23**	CNTYM	**10-Mar-23**	102043	10007270	19-Nov-24	Australia, New Zealand	None
				102059	10005890	02-Sep-24	Denmark, Iceland, Norway	None
				102369	10006983	22-Oct-24	Bulgaria, Romania	None
				102554	10008855	06-Feb-25	Austria	None
				103287	10005851	30-Aug-24	United Kingdom	None
CNZXZ*	**19-Mar-23**	CNZYB	**01-Jun-23**	6195890831	CSZKD	30-May-24	Canada	None
				6195890831	CVDWD	12-Dec-24	Canada	None
				101788	CNZYBD	18-Jul-24	Belgium, Luxembourg	None

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Patheon TRO (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
CPDSX*	**28-Mar-23**	CPDTC	**01-Jun-23**	6195890831	CTDVW	28-Jun-24	Canada	None
				6195890831	CVDWF	02-Jan-25	Canada	None
				101620	CPDTCD	31-May-24	Korea	None
				102372	CPDTCD	04-Apr-24	Hong Kong	None
				101722	CPDTCM	20-Sep-24	Germany	None
				101614	10007106	31-Oct-24	Cyprus, Greece	None
				101620	10006033	04-Oct-24	Korea	None
CPNCZ*	**05-Jun-23**	CPNDB	**15-Aug-23**	6195894351	CSXVD	11-Apr-24	Colombia	Refer to QE-221836 in Section 6.2.2
				6195890831	CTHXZ	27-Jun-24	Canada	None
				TBD	TBD	TBD	TBD	None
				101616	CPNDBAD	15-May-24	Israel	None
				102380	CPNDBD	07-May-24	Singapore	None
				6195893001	CPNDBD1	22-Apr-24	Thailand, GAP	None
		CPNDBA	**24-Nov-23**	101613	10006066	13-Sep-24	Germany	None
				102442	10009850	21-Mar-25	Italy	None
CPVTB*	**15-Aug-23**	CPVTC	**24-Oct-23**	6195890831	CTWTG	10-Oct-24	Canada	None
				102372	CPVTCD	29-Jul-24	Hong Kong	None
				103697	CPVTCD	08-May-24	Ireland, Malta	None
				103704	CPVTCD	12-Jul-24	Germany	None
				6195893001	CPVTCD	01-Jul-24	Thailand, GAP	None
				102372	CPVTCD	01-Aug-24	Hong Kong	None

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Patheon TRO (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				102372	10006703	10-Oct-24	Hong Kong	None
				102380	10007016	24-Oct-24	Singapore	None
CSCMF*	**20-Oct-23**	CSCMF	22-May-24	101722	CSCMFM	27-Jan-25	Germany	None
				102159	CSCMFD	03-Jul-24	Saudi Arabia	None
				101613	10007947	11-Dec-24	Germany	None
				101617	10007866	12-Dec-24	Netherlands	None
				101619	10007525	29-Nov-24	Portugal	None
				101619	10009419	24-Feb-25	Portugal	None
				101621	10007874	18-Dec-24	Finland, Sweden	None
				101839	10006587	29-Oct-24	Spain	None
				101839	10007928	16-Dec-24	Spain	None
				101909	10007358	19-Nov-24	Switzerland	None
				102369	10007526	25-Nov-24	Bulgaria, Romania	None
				103697	10007129	04-Nov-24	Ireland, Malta	None
CSGMW*	**10-Nov-23**	CSGMX	**19-Jan-24**	6195894171	CTDWK	15-May-24	Mexico	None
				6195890831	CVDVY	02-Jan-25	Canada	None
				102159	CSGMXD	19-Jun-24	Saudi Arabia	None
				102159	10006097	11-Sep-24	Saudi Arabia	None
CSTBY*	**29-Jan-24**	CSTCB	08-May-24	6195892421	NA1171	19-Jun-24	Japan	None
				6195892421	NA1172	19-Jun-24	Japan	None
				6195892421	NA1173	19-Jun-24	Japan	None
CSVVY*	**20-Feb-24**	CSVWB	08-May-24	6195894171	CVCYC	24-Sep-24	Mexico	None

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Patheon TRO (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				6195894171	CVCYD	04-Dec-24	Mexico	None
				6195890831	CVGTW	11-Feb-25	Canada	None
				6195894171	CVHZF	13-Feb-25	Mexico	None
				6195892751	CSVWBD	26-Jul-24	Uganda, GAP	None
				6195892751	CSVWBD	01-Aug-24	Uganda, GAP	None
				102159	10006619	22-Oct-24	Saudi Arabia	None
				102164	10007071	16-Dec-24	United Arab Emirates	None
				102370	10007200	07-Jan-25	Bahrain	None
				102372	10006724	10-Oct-24	Hong Kong	None
				102372	10007417	20-Nov-24	Hong Kong	None
				102376	10007201	05-Nov-24	Kuwait	None
				102376	10007861	10-Dec-24	Kuwait	None
		CSVWBA	22-Aug-24	102159	10006991	22-Oct-24	Saudi Arabia	None
				102159	10008202	06-Jan-25	Saudi Arabia	None
				102372	10007987	17-Dec-24	Hong Kong	None
				102380	10008125	23-Jan-25	Singapore	None
CTTTC	23-Jul-24	10007114	28-Nov-24	6195891881	10007894	16-Dec-24	China	None
				6195891881	10009685	06-Mar-25	China	None
CTWVB**	30-Aug-24	CVGSZ	29-Jan-25	TBD	TBD	TBD	TBD	None
CTWVF	31-Aug-24	CTWVG	13-Nov-24	6195894351	CVVYX	05-Mar-25	Colombia	None
		CVGTG	07-Jan-25	TBD	TBD	TBD	TBD	None
CTWYK**	01-Sep-24	CVGTP	25-Feb-25	TBD	TBD	TBD	TBD	None

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Patheon TRO (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
		CTWYM	03-Dec-24	6195892421	NA1181	10-Feb-25	Japan	None
				6195892421	NA1182	10-Feb-25	Japan	None
CVCZF	27-Sep-24	CVCZG	22-Nov-24	6195890831	CVMZS	20-Mar-25	Canada	None
				101620	10008587	23-Jan-25	Korea	None
				102159	10008468	23-Jan-25	Saudi Arabia	None
				102159	10008885	12-Feb-25	Saudi Arabia	None
				102164	10009973	26-Mar-25	United Arab Emirates	None
				102370	10009425	03-Mar-25	Bahrain	None
				102376	10009718	12-Mar-25	Kuwait	None
				6195892751	10009716	12-Mar-25	Uganda, GAP	None
CVDWG**	29-Sep-24	CVDWH	25-Nov-24	TBD	TBD	TBD	TBD	None
CVVYV**	23-Jan-25	CVVYW	25-Mar-25	TBD	TBD	TBD	TBD	None
CVXPH	17-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
CVXPN	18-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
CVXPS	18-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None

* Lot was trended in previous APQR.
** Data not available and will be trended when available.

Table 2: Manufactured and Dispositioned Lots – Patheon TRO (200 mg/10 mg)

Patheon TRO (200 mg/10 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
CMWVN*	**22-Jun-22**	CMGXY	**05-Aug-22**	101685	CMGXYD	29-Apr-24	Greece, Cyprus	None
				101719	CMGXYD	30-Apr-24	Switzerland	None

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Patheon TRO (200 mg/10 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				102042	CMGXYD	29-Apr-24	Australia, New Zealand	None
				102553	CMGXYD	30-May-24	Austria	None
				101666	CMGXYM1	16-Apr-24	Germany	None
CNMVH*	**05-Nov-22**	CNMVK	**24-Feb-23**	101644	CNMVKD	08-May-24	Czech Republic, Slovakia	None
				6195890821	CSZKC	23-Apr-24	Canada	None
CPPGC*	**26-Jul-23**	CPPGG	**14-Dec-23**	6195894341	CSXVC	12-Apr-24	Colombia	Refer to QE-222387 in Section 6.2.2
				6195894341	CTDWD	15-May-24	Colombia	None
CPPGD*	**26-Jul-23**	CPPGH	**11-Dec-23**	101696	CPPGHD	08-Apr-24	Italy	None
				101706	CPPGHD	07-May-24	Netherlands	None
				101718	CPPGHD	08-Apr-24	Spain	None
				103285	CPPGHD	07-May-24	United Kingdom	None
CPPGF*	**27-Jul-23**	CPPGK	**14-Dec-23**	101637	CPPGKD	17-May-24	Germany	None
				101640	CPPGKD	17-May-24	Belgium, Luxembourg	None
				101651	CPPGKD	30-May-24	Sweden, Finland	None
				101696	CPPGKD	19-Jul-24	Italy	None
				101711	CPPGKD	08-Jul-24	Poland	None
				101715	CPPGKD	17-May-24	Bulgaria, Romania	None
				101718	CPPGKD	19-Jul-24	Spain	None

Patheon TRO (200 mg/10 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				101719	CPPGKD	20-May-24	Switzerland	None
				102013	CPPGKD	17-May-24	Portugal	None
				103285	CPPGKD	19-Jul-24	United Kingdom	None
				103286	CPPGKD	17-May-24	Ireland, Malta	None
				101637	10005598	19-Aug-24	Germany	None
				101711	10005825	28-Aug-24	Poland	None
				101715	10006062	12-Sep-24	Bulgaria, Romania	None
				103703	10005599	16-Aug-24	Germany	None
CSMNT*	**07-Jan-24**	CSMNZ	**22-Feb-24**	6195894161	CTDWG	04-Jun-24	Mexico	None
				6195890821	CTHXT	26-Jul-24	Canada	None
				6195890821	CTWYH	16-Oct-24	Canada	None
				6195890821	CVMVH	04-Feb-25	Canada	None
CPZFF*	**08-Jan-24**	CPZFG	**15-Feb-24**	6195894341	CTTVX	28-Aug-24	Colombia	Refer to QE-229094 in Section 6.2.2
				102042	CPZFGD	05-Jun-24	Australia, New Zealand	None
				102365	CPZFGD	30-May-24	Saudi Arabia	None
				102417	CPZFGD	30-May-24	Hong Kong	None
				102683	CPZFGD	11-Jun-24	Singapore	None
				101666	CPZFGM	20-Sep-24	Germany	None
				101666	CPZFGM1	20-Sep-24	Germany	None

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Patheon TRO (200 mg/10 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				101640	10006065	16-Sep-24	Belgium, Luxembourg	None
				101644	10005945	11-Sep-24	Czech Republic, Slovakia	None
				101685	10006127	17-Sep-24	Greece, Cyprus	None
				101696	10006100	13-Sep-24	Italy	None
				101706	10005800	29-Aug-24	Netherlands	None
				101715	10007948	17-Dec-24	Bulgaria, Romania	None
				101718	10006122	13-Sep-24	Spain	None
				102058	10006120	13-Sep-24	Denmark, Iceland, Norway	None
				102417	10005734	23-Aug-24	Hong Kong	None
				102482	10005950	02-Sep-24	Korea	None
				102553	10006063	13-Sep-24	Austria	None
CSVVN*	**18-Feb-24**	CSVVS	09-May-24	6195894341	CTXHC	01-Oct-24	Colombia	Refer to QE-233828 in Section 6.2.2
				101651	10006128	16-Sep-24	Finland, Sweden	None
				102042	10006782	30-Oct-24	Australia, New Zealand	None
				102441	10010043	27-Mar-25	Italy	None
				103285	10006329	02-Oct-24	United Kingdom	None
CSZHZ*	**22-Mar-24**	CSZKB	21-May-24	6195894161	CVMZV	14-Feb-25	Mexico	None

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Patheon TRO (200 mg/10 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				101666	CSZKBM	14-Jan-25	Germany	None
				101685	10007490	28-Nov-24	Greece, Cyprus	None
				101696	10008141	03-Jan-25	Italy	None
				101719	10007717	09-Dec-24	Switzerland	None
				102553	10008133	14-Jan-25	Austria	None
				102683	10006763	23-Oct-24	Singapore	None
				103285	10008033	17-Dec-24	United Kingdom	None
CTNKV	12-Jun-24	CTNKW	03-Sep-24	6195892431	MA1051	07-Nov-24	Japan	None
		CTNKX	13-Sep-24	101651	10009720	14-Mar-25	Finland, Sweden	None
				101711	10010188	31-Mar-25	Poland	None
				102013	10009689	05-Mar-25	Portugal	None
				102365	10009417	26-Feb-25	Saudi Arabia	None
				102482	10009561	03-Mar-25	Korea	None
				103285	10009821	14-Mar-25	United Kingdom	None
CVDVZ**	29-Sep-24	CVDWB	18-Dec-24	TBD	TBD	TBD	TBD	None
CVMVK**	11-Jan-25	CVMVM	13-Mar-25	TBD	TBD	TBD	TBD	Refer to QE-234322 in Section 6.2.1
		CVMVN	18-Mar-25	TBD	TBD	TBD	TBD	

* Lot was trended in previous APQR.
**Data not available and will be trended when available.

Table 3: Manufactured and Dispositioned Lots – Patheon TRO (120 mg/15 mg)

Patheon TRO (120 mg/15 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
CHSCG*	**15-Jul-21**	CHZBB	**10-Jan-22**	TBD	TBD	TBD	TBD	None
CHSCK*	**17-Jul-21**	CHZBF	**10-Jan-22**	TBD	TBD	TBD	TBD	None
CSVVX**	**20-Feb-24**	CSVWD	26-Apr-24	TBD	TBD	TBD	TBD	None
CTWVC	30-Aug-24	CTWVD	26-Nov-24	61958-2005-1	1000013	22-Jan-25	United States	None

* Lot was trended in previous APQR.
**Data is reported in Attachment 8.

Table 4: Manufactured and Dispositioned Lots – Rottendorf (200 mg/25 mg)

Rottendorf (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
6899002*	**02-Sep-21**	6899002BP	**08-Dec-21**	N/A	N/A	N/A	N/A	Britestock lot reallocated for clinical batch 412-2055/71 in July 2022
7008807*	**22-Mar-22**	7008807P	**18-May-22**	102554	10006061	09-Sep-24	Austria	None
7182303*	**19-Oct-22**	7182303P	**10-Jan-23**	101613	7182303PD	02-Sep-24	Germany	Refer to QE-180645 in Section 5.1.1
				102043	7182303PD	02-Sep-24	Australia, New Zealand	
				102374	7182303PD1	30-Aug-24	Italy	
7182307*	**04-Nov-22**	7182307P	**23-Jan-23**	101617	7182307PD	02-Sep-24	Netherlands	Refer to QE-180645 in Section 5.1.1 and QE-181801 in Section 6.1.1

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Rottendorf (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
7190302*	**19-Nov-22**	7190302P	**06-Feb-23**	102371	7190302PD	09-Apr-24	Croatia	None
7226501*	**04-Dec-22**	7226501P	**27-Feb-23**	101614	7226501PD3	31-May-24	Greece, Cyprus	None
				101614	7226501PD2	30-Apr-24	Greece, Cyprus	None
				101621	7226501PD	03-May-24	Sweden, Finland	None
				102369	7226501PD1	18-Apr-24	Bulgaria, Romania	None
				102369	7226501PD2	27-May-24	Bulgaria, Romania	None
				101722	7226501PM	16-Apr-24	Germany	None
7226502*	**05-Dec-22**	7226502P	**28-Feb-23**	101617	7226502PD	27-May-24	Netherlands	None
				101908	7226502PD	24-Jun-24	Czech Republic, Slovakia	None
				102374	7226502PD	07-Jun-24	Italy	None
				103287	7226502PD	15-Jul-24	United Kingdom	None
				101908	10007518	26-Nov-24	Czech Republic, Slovakia	None
				102554	10007132	04-Nov-24	Austria	None
7226503*	**05-Dec-22**	7226503P	**01-Mar-23**	101613	7226503PD	11-Jun-24	Germany	None
				102059	7226503PD	04-Jun-24	Denmark, Iceland, Norway	None
				102554	7226503PD	10-Apr-24	Austria	None
				103287	7226503PD	05-Jun-24	United Kingdom	None
				103704	7226503PD	16-Apr-24	Germany	None
7226504*	**05-Dec-22**	7226504P	**08-Mar-23**	101908	7226504PD1	03-May-24	Czech Republic, Slovakia	None
				101909	7226504PD	07-Jun-24	Switzerland	None

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Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
				101909	7226504PD1	16-Jul-24	Switzerland	None
				102374	7226504PD	09-Apr-24	Italy	None
				103697	7226504PD	05-Jun-24	Ireland, Malta	None
				103697	7226504PD1	19-Jun-24	Ireland, Malta	None
				101909	7226504PD1	01-Aug-24	Switzerland	None
7363101*	**30-Apr-23**	7363101P	**11-Jul-23**	101619	7363101PD	16-May-24	Portugal	None
				101895	7363101PD	27-May-24	Poland	None
				101722	7363101PM	21-Oct-24	Germany	None
				101617	10006328	20-Sep-24	Netherlands	None
				101621	10006625	07-Nov-24	Finland, Sweden	None
				101839	10005818	02-Sep-24	Spain	None
				101895	10006985	24-Oct-24	Poland	None
				102059	10007510	25-Nov-24	Denmark, Iceland, Norway	None
				102162	10007687	02-Dec-24	Slovenia	None
				102371	10008132	10-Jan-25	Croatia	None
				102374	10006469	25-Sep-24	Italy	None
				103697	10006034	11-Sep-24	Ireland, Malta	None
7503101*	**19-Sep-23**	N/A	N/A	61958-2002-1	7503101B	19-Apr-24	United States	None
7503103*	**20-Sep-23**	N/A	N/A	61958-2002-1	7503103B	05-Apr-24	United States	None
7503104*	**21-Sep-23**	N/A	N/A	61958-2002-2	7503104A	29-May-24	United States	None
7536001*	**11-Oct-23**	7536001P	**12-Jan-24**	101895	10005741	05-Sep-24	Poland	None
				103287	10006817	17-Oct-24	United Kingdom	None

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Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
7560101*	**25-Oct-23**	N/A	N/A	61958-2002-1	7560101A	09-Apr-24	United States	None
7560102*	**25-Oct-23**	N/A	N/A	61958-2002-1	7560102A	05-Apr-24	United States	None
7560103*	**26-Oct-23**	N/A	N/A	61958-2002-1	7560103A	11-Apr-24	United States	None
7560104*	**26-Oct-23**	N/A	N/A	61958-2002-1	7560104A	05-Apr-24	United States	None
7560301*	**06-Nov-23**	7560301P	19-Apr-24	TBD	TBD	TBD	TBD	None
7560302*	**06-Nov-23**	7560302P	**27-Feb-24**	101614	10007535	10-Dec-24	Greece, Cyprus	None
				101614	10008320	10-Jan-25	Greece, Cyprus	None
				101614	10008399	21-Jan-25	Greece, Cyprus	None
				101619	10009684	05-Mar-25	Portugal	None
				101909	10008721	30-Jan-25	Switzerland	None
				102374	10008585	04-Feb-25	Italy	None
				103287	10008195	15-Jan-25	United Kingdom	None
7560303*	**07-Nov-23**	7560303P	**27-Feb-24**	101614	10009888	13-Mar-25	Greece, Cyprus	None
				101839	10009693	06-Mar-25	Spain	None
				101908	10009686	04-Mar-25	Czech Republic, Slovakia	None
				101909	10009984	19-Mar-25	Switzerland	None
				102374	10009404	25-Feb-25	Italy	None
7560107*	**07-Nov-23**	N/A	N/A	61958-2002-1	7560107A	09-Apr-24	United States	None
7560108*	**14-Nov-23**	N/A	N/A	61958-2002-1	7560108A	09-Apr-24	United States	None
7560109*	**14-Nov-23**	N/A	N/A	61958-2002-1	7560109A	13-May-24	United States	None
7560304***	**15-Nov-23**	7560304P	N/A	N/A	N/A	N/A	N/A	Repackaged. Refer to QE-184928

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Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
7560305*	**15-Nov-23**	7560305P	**07-Mar-24**	103287	10010094	26-Mar-25	United Kingdom	None
				103697	10008867	06-Feb-25	Ireland, Malta	None
				103697	10009687	10-Mar-25	Ireland, Malta	None
7560110*	**15-Nov-23**	N/A	N/A	61958-2002-2	7560110A	29-May-24	United States	None
				61958-2002-2	7560110B	19-Jul-24	United States	None
7591301*	**23-Nov-23**	7591301	30-Jul-24	6195892671	10009005	11-Feb-25	Nigeria, GAP	None
7591501*	**23-Nov-23**	7591501P	**28-Feb-24**	TBD	TBD	TBD	TBD	None
7591502*	**23-Nov-23**	7591502P	**08-Mar-24**	TBD	TBD	TBD	TBD	None
7591503*	**23-Nov-23**	7591503P	**07-Mar-24**	TBD	TBD	TBD	TBD	None
7591302*	**04-Dec-23**	N/A	N/A	61958-2002-1	7591302A	16-May-24	United States	None
7591303*	**04-Dec-23**	N/A	N/A	61958-2002-1	7591303A	13-May-24	United States	None
7591304*	**04-Dec-23**	N/A	N/A	61958-2002-1	7591304A	21-May-24	United States	None
7591504*	**05-Dec-23**	7591504P	**06-Mar-24**	TBD	TBD	TBD	TBD	None
7591305*	**05-Dec-23**	N/A	N/A	61958-2002-1	7591305A	24-May-24	United States	None
7591505***	**05-Dec-23**	7591505P	N/A	N/A	N/A	N/A	N/A	Repackaged. Refer to QE-184928
7630401*	**15-Jan-24**	7630401P	**02-Apr-24**	61958-2002-1	045253	22-May-24	United States	None
7630402*	**16-Jan-24**	7630402P	04-Oct-24	61958-2002-1	045255	21-May-24	United States	None
7630403*	**16-Jan-24**	7630403P	**27-Mar-24**	101614	10007669	02-Dec-24	Greece, Cyprus	None
				101788	10007855	11-Dec-24	Belgium, Luxembourg	None
				101895	10007374	19-Nov-24	Poland	None
				101895	10007870	12-Dec-24	Poland	None

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				102059	10008414	21-Jan-25	Denmark, Iceland, Norway	None
				102369	10009426	27-Feb-25	Bulgaria, Romania	None
				102374	10007356	19-Nov-24	Italy	None
				103287	10007120	08-Nov-24	United Kingdom	None
				103697	10006060	09-Sep-24	Ireland, Malta	None
				103697	10007130	05-Nov-24	Ireland, Malta	None
				103704	10008300	16-Jan-25	Germany	None
7630404*	**16-Jan-24**	7630404P	04-Nov-24	61958-2002-1	045256	06-Dec-24	United States	None
7630405*	**16-Jan-24**	7630405P	**27-Mar-24**	61958-2002-1	045254	21-May-24	United States	None
7630301*	**23-Jan-24**	N/A	N/A	61958-2002-1	7630301A	06-Jun-24	United States	None
7630302*	**23-Jan-24**	N/A	N/A	61958-2002-1	7630302A	07-Jun-24	United States	None
7630303*	**23-Jan-24**	N/A	N/A	61958-2002-1	7630303A	18-Jun-24	United States	None
7630304*	**23-Jan-24**	N/A	N/A	61958-2002-1	7630304A	25-Jul-24	United States	None
7630305*	**24-Jan-24**	N/A	N/A	61958-2002-1	7630305A	29-Jul-24	United States	None
7646901*	**29-Jan-24**	7646901P	05-Aug-24	61958-2002-1	045430	27-Jun-24	United States	None
7646902*	**29-Jan-24**	7646902P	**05-Jan-24**	61958-2002-1	045431	07-Sep-24	United States	None
7646903*	**29-Jan-24**	7646903P	**05-Jan-24**	61958-2002-1	045432	24-Jul-24	United States	None
7646904*	**06-Feb-24**	7646904P	30-Apr-24	61958-2002-1	045433	07-Nov-24	United States	None
7646905*	**06-Feb-24**	7646905P	16-May-24	61958-2002-1	045434	07-Nov-24	United States	None
7646906*	**07-Feb-24**	7646906P	28-May-24	61958-2002-1	046209	07-Dec-24	United States	None
7647001*	**07-Feb-24**	N/A	N/A	61958-2002-1	7647001A	01-Aug-24	United States	None
7647002*	**14-Feb-24**	N/A	N/A	61958-2002-1	7647002A	09-Aug-24	United States	None

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7647003*	**15-Feb-24**	N/A	N/A	61958-2002-1	7647003A	12-Aug-24	United States	None
7647004*	**15-Feb-24**	N/A	N/A	61958-2002-1	7647004A	13-Sep-24	United States	None
7647005***	**15-Feb-24**	N/A	N/A	61958-2002-1	7647005A	13-Aug-24	United States	None
7682301***	**27-Feb-24**	7682301P	31-May-24	61958-2002-1	046214	25-Jul-24	United States	None
7682302***	**27-Feb-24**	7682302P	28-May-24	61958-2002-1	046210	07-Dec-24	United States	None
7682303***	**28-Feb-24**	7682303P	23-May-24	61958-2002-1	046211	23-Jul-24	United States	None
7682304***	**28-Feb-24**	7682304P	20-May-24	61958-2002-1	046212	23-Jul-24	United States	None
7682305***	**04-Mar-24**	7682305P	20-May-24	61958-2002-1	046213	24-Jul-24	United States	None
7682306***	**04-Mar-24**	7682306P	17-Jun-24	61958-2002-1	10006021	23-Sep-24	United States	None
7682201***	**04-Mar-24**	N/A	N/A	61958-2002-2	7682201A	31-Oct-24	United States	None
7682202***	**12-Mar-24**	N/A	N/A	61958-2002-3	7682202A	01-Oct-24	United States	None
				61958-2002-1	7682202B	16-Sep-24	United States	None
7682203***	**12-Mar-24**	N/A	N/A	61958-2002-1	7682203A	12-Sep-24	United States	None
7682204***	**12-Mar-24**	N/A	N/A	61958-2002-1	7682204A	04-Sep-24	United States	None
7682205***	**25-Mar-24**	N/A	N/A	61958-2002-2	7682205A	21-Nov-24	United States	None
7682206***	**25-Mar-24**	N/A	N/A	61958-2002-1	7682206A	03-Oct-24	United States	None
7682207***	**25-Mar-24**	N/A	N/A	61958-2002-1	7682207A	04-Oct-24	United States	None
7682208***	**25-Mar-24**	N/A	N/A	61958-2002-1	7682208A	08-Oct-24	United States	None
7717001***	**02-Apr-24**	7717001P	25-Jun-24	61958-2002-1	10006017	23-Sep-24	United States	None
7717002***	**02-Apr-24**	7717002P	21-Jun-24	61958-2002-1	10006019	23-Sep-24	United States	None
7717003***	**02-Apr-24**	7717003P	11-Jul-24	61958-2002-1	10006020	23-Sep-24	United States	None
7716901***	**02-Apr-24**	N/A	N/A	61958-2002-1	7716901A	08-Nov-24	United States	None
7716902	09-Apr-24	N/A	N/A	61958-2002-1	7716902A	07-Nov-24	United States	None

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Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
7716903	10-Apr-24	N/A	N/A	61958-2002-1	7716903A	14-Nov-24	United States	None
7716904	10-Apr-24	N/A	N/A	61958-2002-1	7716904A	06-Dec-24	United States	None
7749401	01-May-24	7749401P	17-Jul-24	61958-2002-1	10006055	09-Oct-24	United States	None
7749402	01-May-24	7749402P	08-Aug-24	61958-2002-1	10006057	02-Oct-24	United States	Refer to QE-221469 in Section 3.2
7749403	01-May-24	7749403P	17-Jul-24	61958-2002-1	10006058	03-Oct-24	United States	None
7717004	02-May-24	7717004P	13-Sep-24	61958-2002-1	10006056	01-Oct-24	United States	None
7749301	27-May-24	N/A	N/A	61958-2002-1	7749301A	03-Dec-24	United States	None
7749302	27-May-24	N/A	N/A	61958-2002-1	7749302A	20-Dec-24	United States	None
7749303	27-May-24	N/A	N/A	61958-2002-1	7749303A	05-Dec-24	United States	None
7776001	06-Jun-24	7776001P	15-Aug-24	61958-2002-1	10006267	04-Oct-24	United States	None
7776701	06-Jun-24	N/A	N/A	61958-2002-1	7776701A	02-Dec-24	United States	None
7776702	06-Jun-24	N/A	N/A	61958-2002-1	7776702A	25-Nov-24	United States	None
7776703	06-Jun-24	N/A	N/A	61958-2002-1	7776703A	05-Dec-24	United States	None
7776002	13-Jun-24	7776002P	19-Aug-24	61958-2002-1	10006268	05-Oct-24	United States	None
7776003	14-Jun-24	7776003P	19-Aug-24	61958-2002-1	10006269	09-Oct-24	United States	None
7800501	26-Jun-24	7800501P	07-Oct-24	61958-2002-1	10007061	13-Nov-24	United States	None
7800401	26-Jun-24	N/A	N/A	61958-2002-1	7800401A	11-Dec-24	United States	None
7800402	26-Jun-24	N/A	N/A	61958-2002-3	7800402A	06-Mar-25	United States	None
				61958-2002-1	7800402B	10-Jan-25	United States	None
7800403	26-Jun-24	N/A	N/A	61958-2002-1	7800403A	11-Dec-24	United States	None
7800502	01-Jul-24	7800502P	30-Sep-24	61958-2002-1	10007062	21-Nov-24	United States	None

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7800503	01-Jul-24	7800503P	30-Sep-24	61958-2002-1	10007063	19-Nov-24	United States	None
7800504	02-Jul-24	7800504P	25-Sep-24	61958-2002-1	10007064	22-Nov-24	United States	None
7800505	02-Jul-24	7800505P	14-Oct-24	61958-2002-1	10007065	22-Nov-24	United States	None
7839401	02-Aug-24	7839401P	13-Dec-24	61958-2002-1	10008184	26-Feb-25	United States	Refer to QE-226277 in Section 3.2
7839301	02-Aug-24	N/A	N/A	61958-2002-1	7839301A	18-Feb-25	United States	None
7839302	02-Aug-24	N/A	N/A	61958-2002-1	7839302A	12-Feb-25	United States	None
7839303	02-Aug-24	N/A	N/A	61958-2002-1	7839303A	12-Feb-25	United States	None
7839402	07-Aug-24	7839402P	12-Dec-24	61958-2002-1	10008185	26-Feb-25	United States	None
7839403	07-Aug-24	7839403P	18-Dec-24	61958-2002-1	10008528	28-Feb-25	United States	None
7843001	30-Aug-24	7843001P	21-Nov-24	61958-2002-1	10008181	23-Jan-25	United States	None
7843002	30-Aug-24	7843002P	25-Nov-24	61958-2002-1	10008182	23-Jan-25	United States	None
7843003	30-Aug-24	7843003P	26-Nov-24	61958-2002-1	10008183	25-Jan-25	United States	None
7843004	30-Aug-24	7843004P	17-Dec-24	61958-2002-1	10008529	04-Mar-25	United States	None
7842901	06-Sep-24	N/A	N/A	61958-2002-1	7842901A	28-Feb-25	United States	None
7842902	06-Sep-24	N/A	N/A	61958-2002-1	7842902A	10-Feb-25	United States	None
7842903	08-Sep-24	N/A	N/A	61958-2002-1	7842903A	25-Feb-25	United States	None
7842904	09-Sep-24	N/A	N/A	61958-2002-1	7842904A	20-Feb-25	United States	None
7906501	25-Sep-24	N/A	N/A	61958-2002-1	7906501A	19-Feb-25	United States	None
7906502	25-Sep-24	N/A	N/A	61958-2002-1	7906502A	06-Mar-25	United States	None
7906503	25-Sep-24	N/A	N/A	61958-2002-1	7906503A	20-Mar-25	United States	None
7906504	26-Sep-24	N/A	N/A	61958-2002-1	7906504A	26-Feb-25	United States	None

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7906505	08-Oct-24	N/A	N/A	61958-2002-1	7906505A	11-Mar-25	United States	None
7906506	08-Oct-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7906507	08-Oct-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7929901	10-Oct-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7929902	11-Oct-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7937501	31-Oct-24	7937501P	22-Jan-25	61958-2002-1	10008531	04-Mar-25	United States	None
7937502	01-Nov-24	7937502P	15-Jan-25	61958-2002-1	10008530	04-Mar-25	United States	None
7938501	04-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7938502	05-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7938503	05-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7938504	05-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7937503	12-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7937504	12-Nov-24	7937504P	30-Jan-25	61958-2002-1	10009520	06-Mar-25	United States	None
7938505	13-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7938506	13-Nov-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975101	02-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975102	02-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975103	02-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975104	04-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975105	04-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975106	05-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975001	11-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975002	11-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None

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7975003	11-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
7975004	11-Dec-24	TBD	TBD	TBD	TBD	TBD	TBD	None
8010801	12-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8010901**	13-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	Refer to QE-236386 in Section 6.3.1
8010902	13-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8010802	13-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8010803	13-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8010903	14-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8010904	14-Jan-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028001	11-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028002	11-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028003	12-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028801	12-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028802	12-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028005	14-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028004	14-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8028006	16-Feb-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8062501	05-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8062502	05-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8062503**	05-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8062601**	05-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None

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Rottendorf (200 mg/25 mg)								
Bulk Lot Number	**Manufacture Date**	**BTSK Lot Number**	**BTSK Release Date**	**FG Part Number**	**FG Lot Number**	**FG Release Date**	**Destination/ Market**	**Comment**
8062504**	10-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8062602**	11-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8062603**	11-Mar-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8088801**	01-Apr-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8088802**	01-Apr-25	TBD	TBD	TBD	TBD	TBD	TBD	None
8088803**	01-Apr-25	TBD	TBD	TBD	TBD	TBD	TBD	None

* Lot was trended in previous APQR.
**Data not available and will be trended when available.
***Data is reported in Attachment 8.

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Attachment 2: Finished Product Test Results

Chart 1: Tablet Weight during Compression – Patheon TRO (200 mg FTC/25 mg TAF)

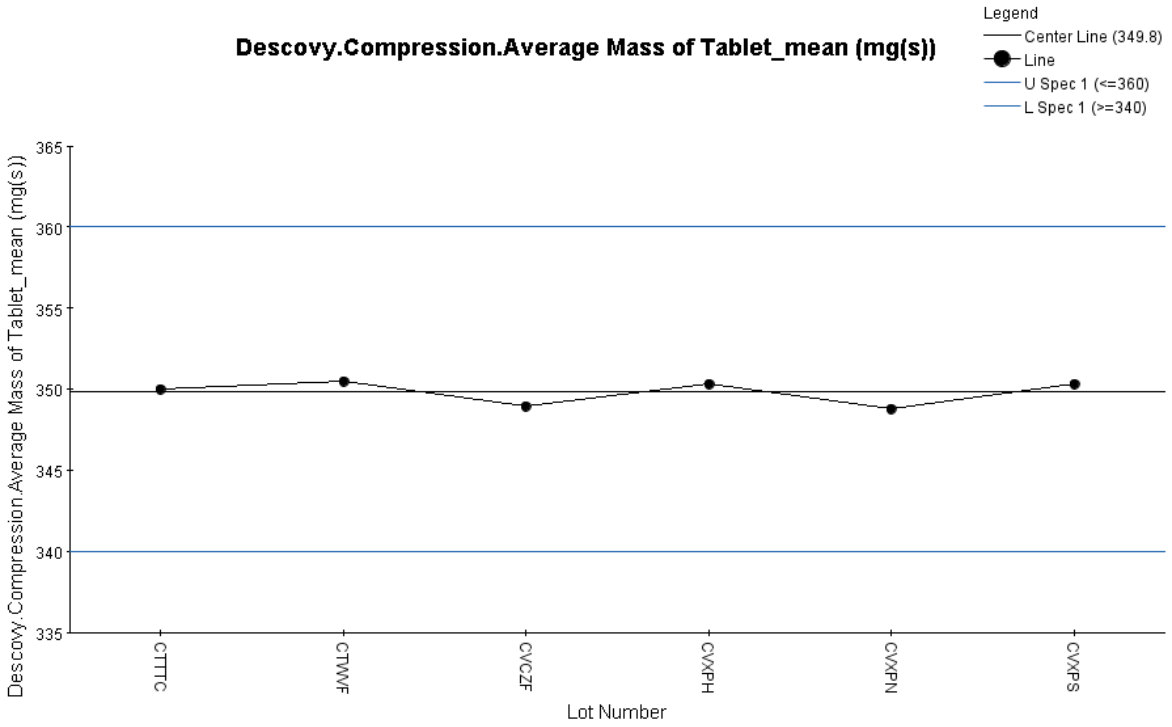

Chart 2: Tablet Hardness during Compression – Patheon TRO (200 mg FTC/25 mg TAF)

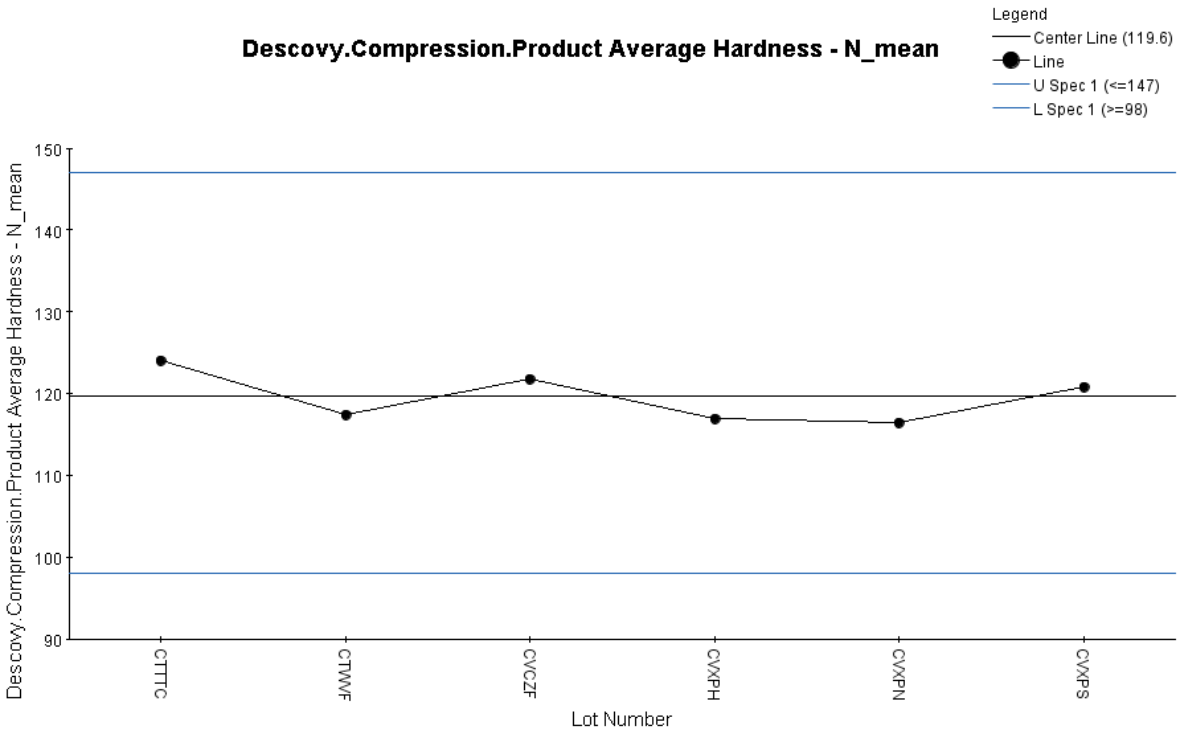

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Chart 3: Tablet Weight during Compression – Rottendorf (200 mg FTC/25 mg TAF)

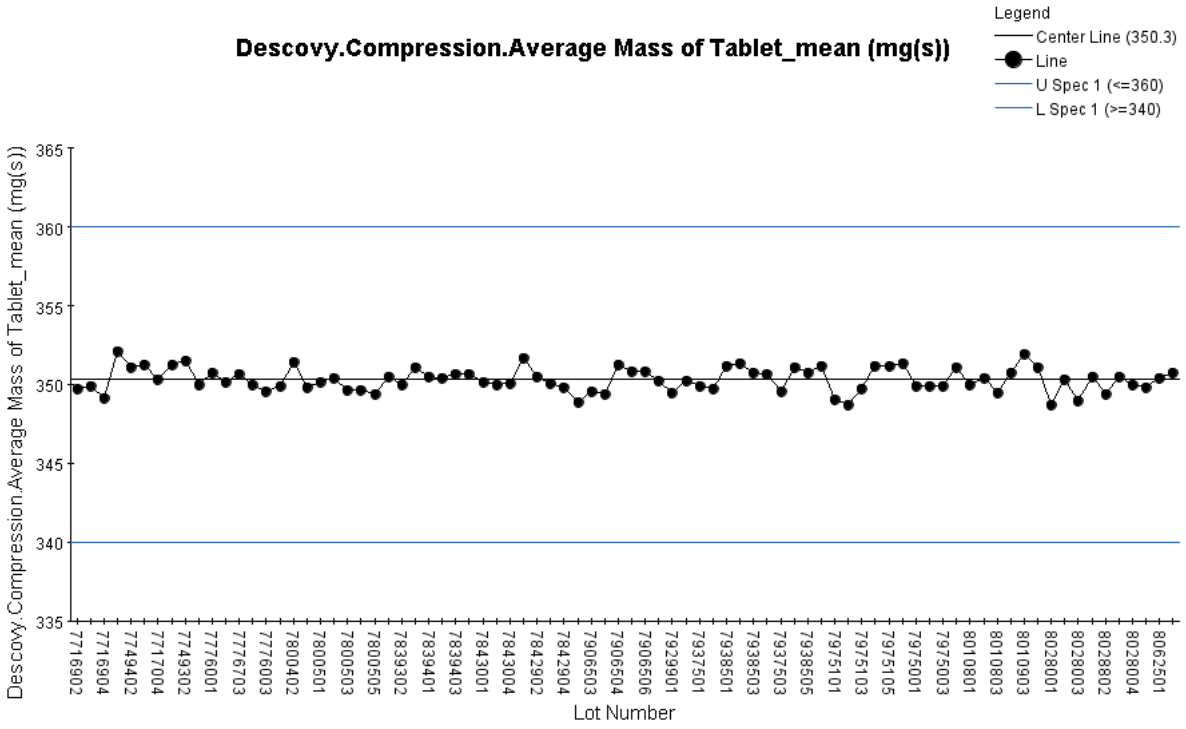

Chart 4: Tablet Hardness during Compression – Rottendorf (200 mg FTC/25 mg TAF)

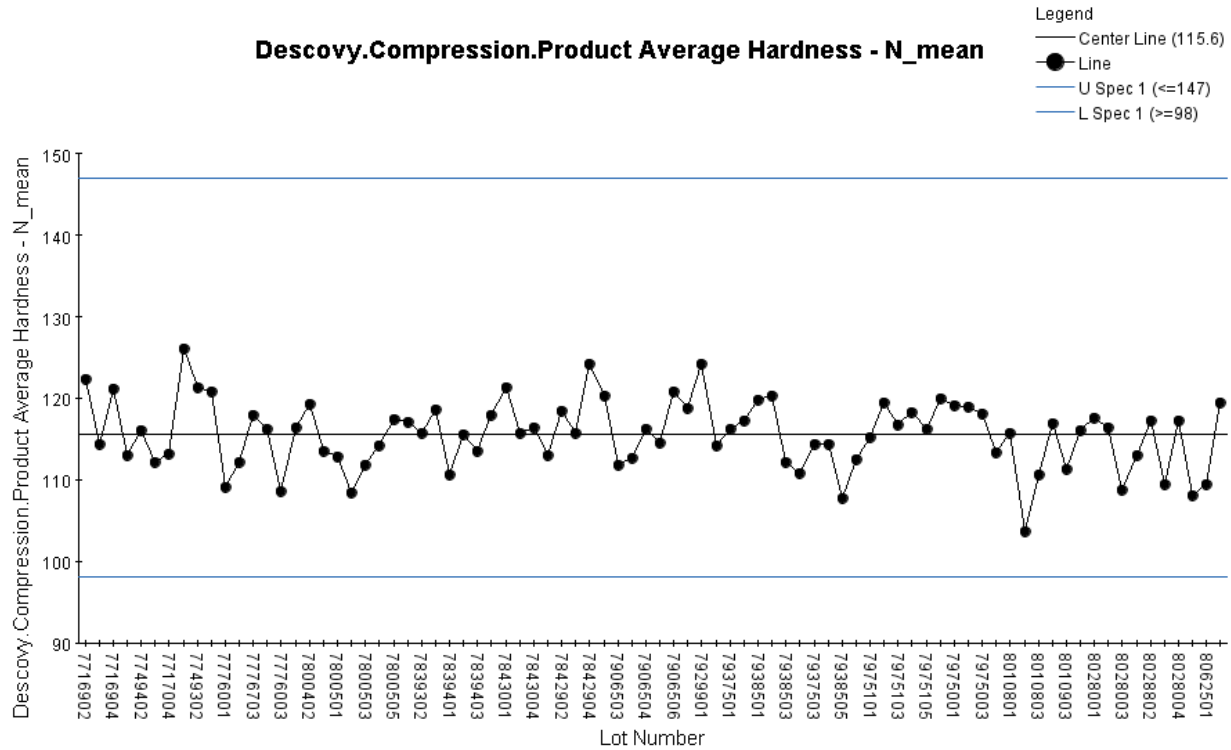

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Chart 5: FTC Assay – Patheon TRO (200 mg FTC/25 mg TAF)

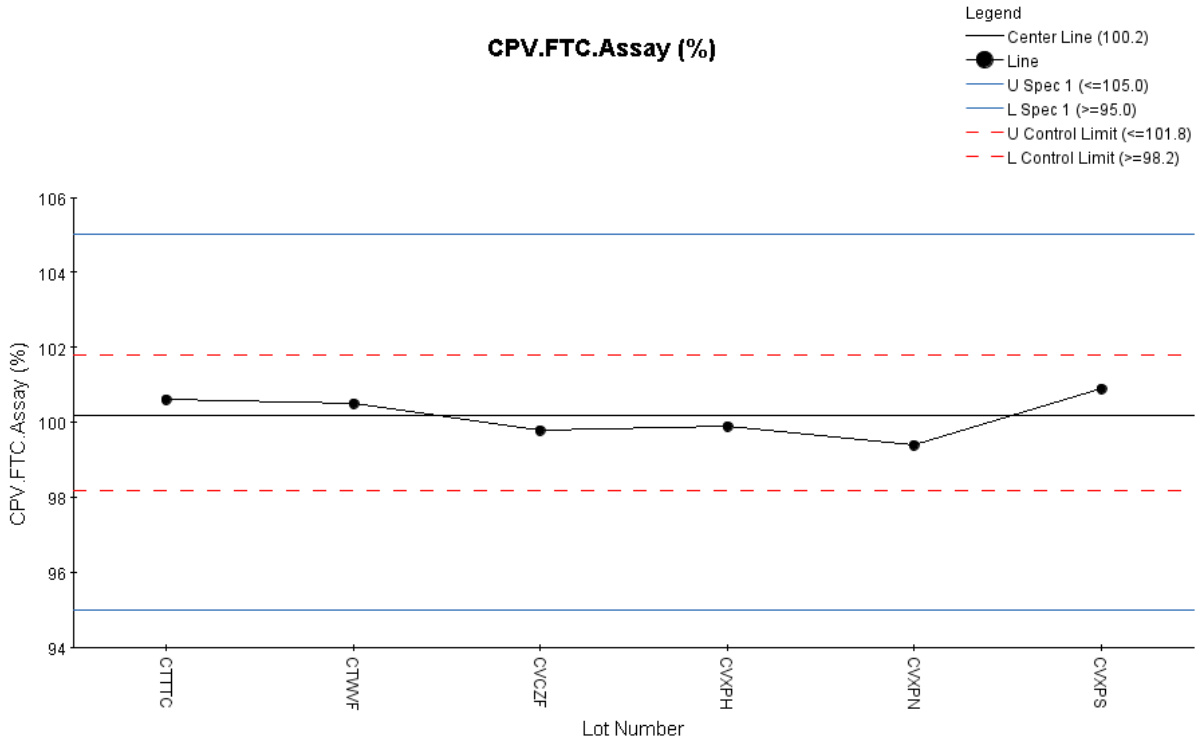

Chart 6: TAF Assay – Patheon TRO (200 mg FTC/25 mg TAF)

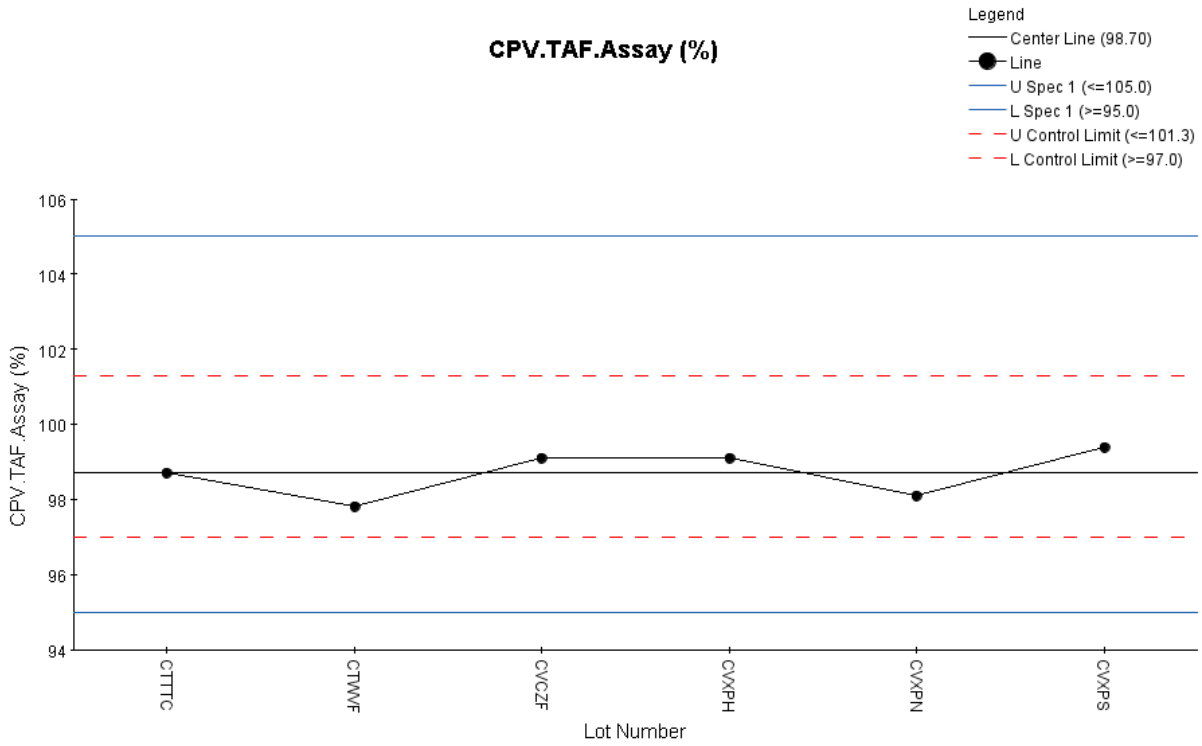

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Chart 7: Total FTC Degradants – Patheon TRO (200 mg FTC/25 mg TAF)

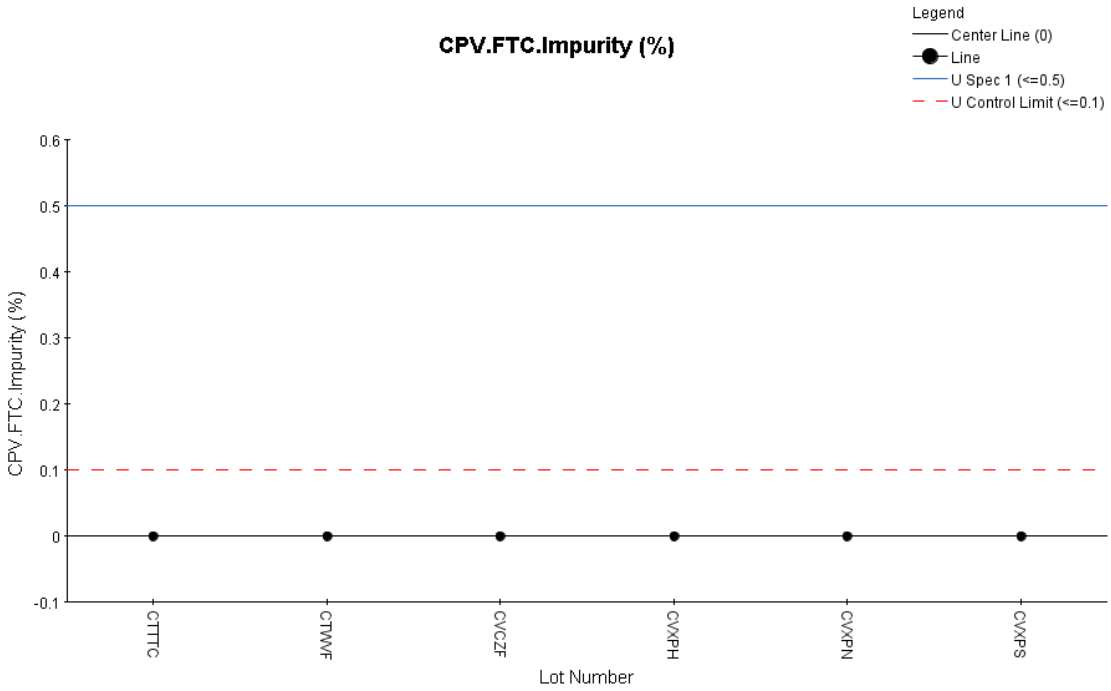

Chart 8: Total TAF Degradants – Patheon TRO (200 mg FTC/25 mg TAF)

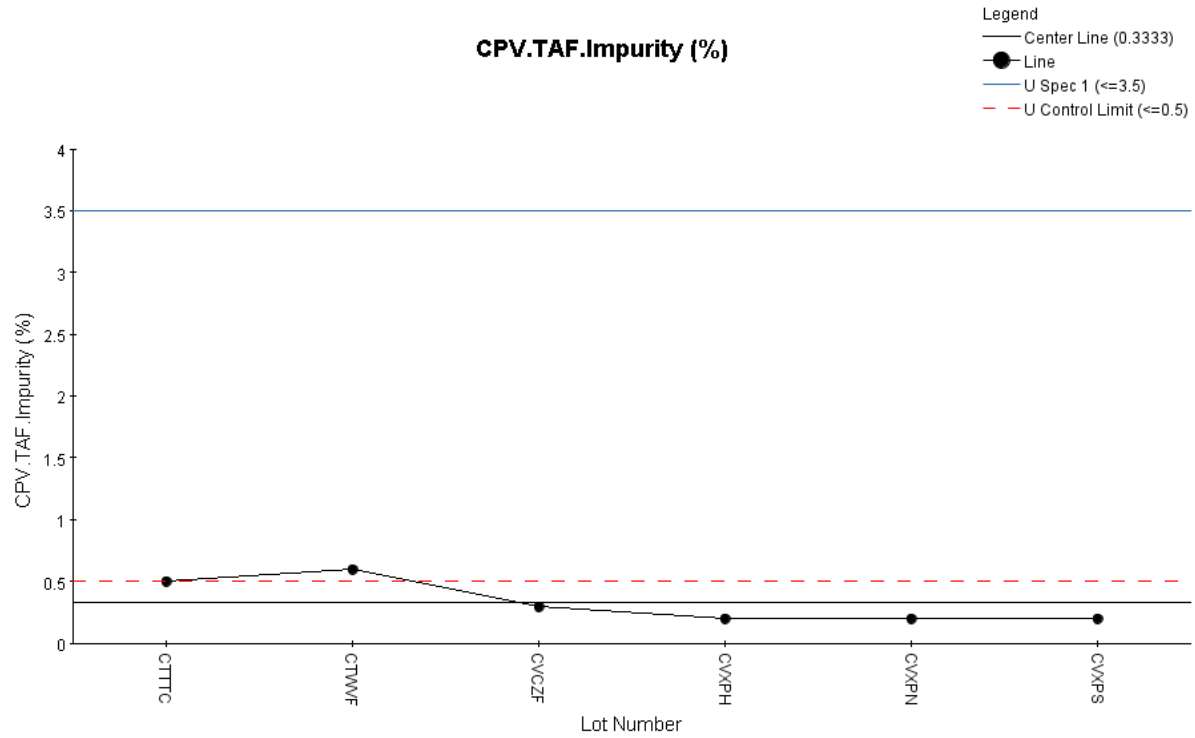

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Chart 9: FTC Dissolution (30 minutes) – Patheon TRO (200 mg FTC/25 mg TAF)

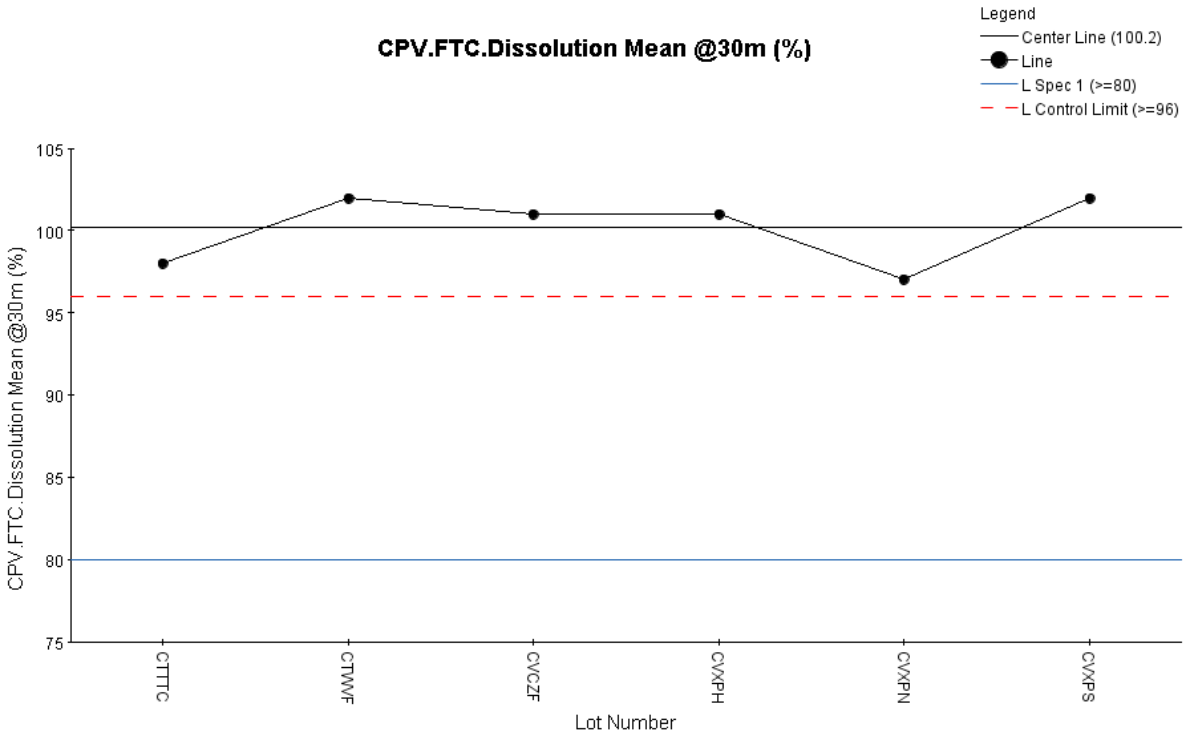

Chart 10: TAF Dissolution (30 minutes) – Patheon TRO (200 mg FTC/25 mg TAF)

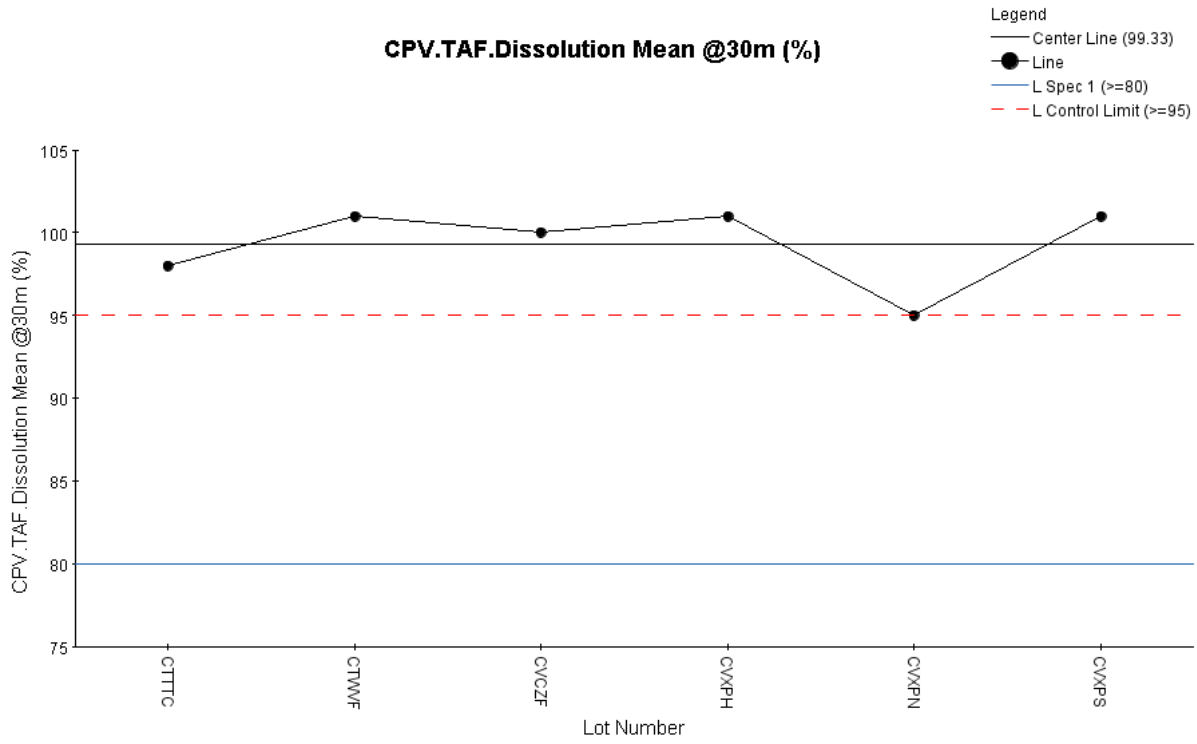

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Chart 11: FTC Content Uniformity – Patheon TRO (200 mg FTC/25 mg TAF)

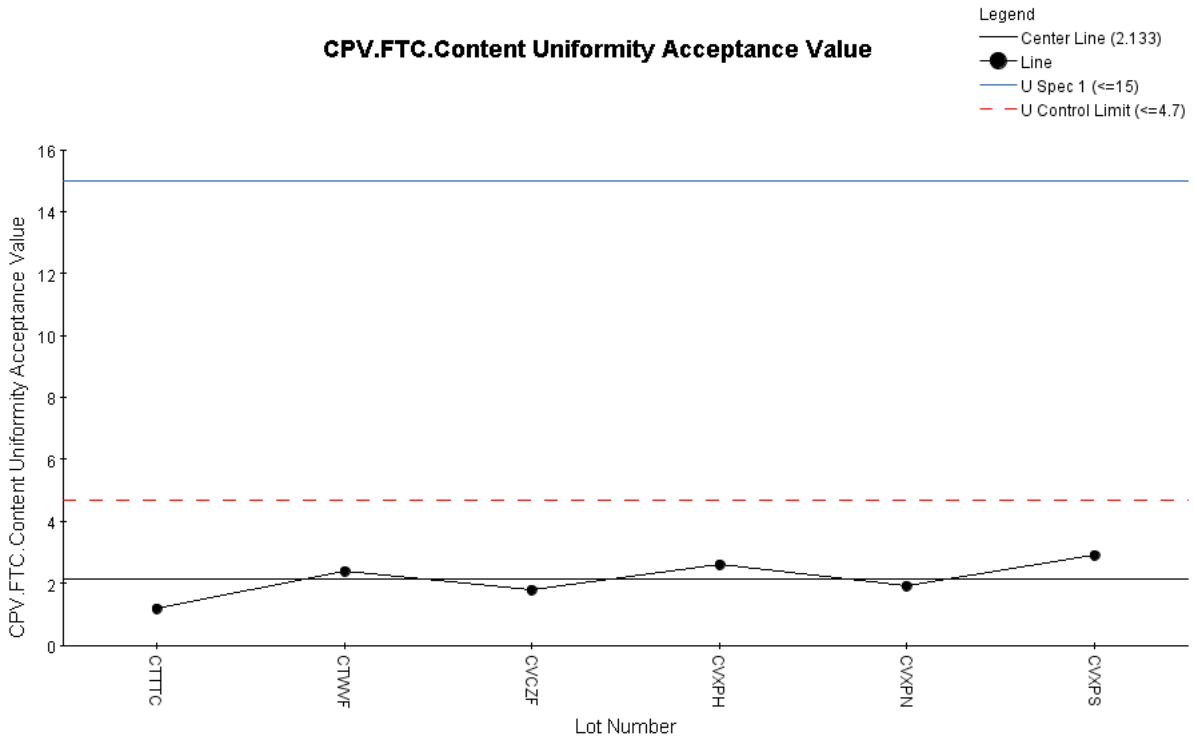

Chart 12: TAF Content Uniformity – Patheon TRO (200 mg FTC/25 mg TAF)

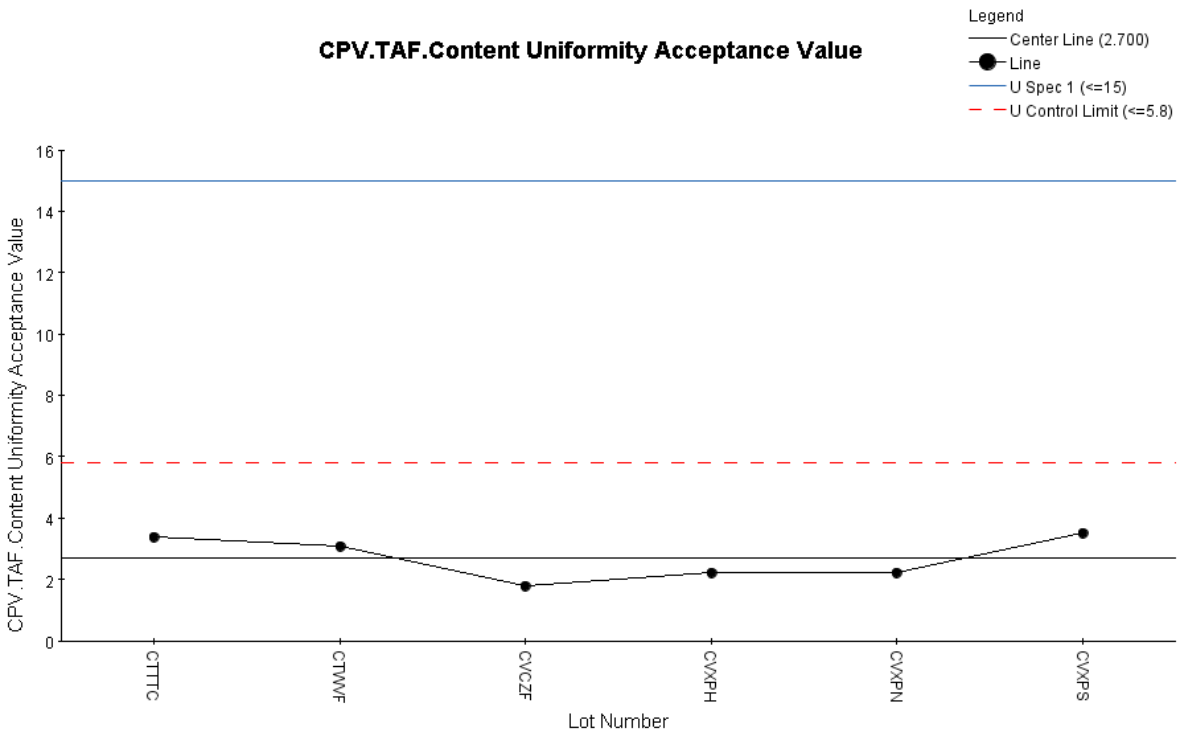

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Chart 13: Water Content – Patheon TRO (200 mg FTC/25 mg TAF)

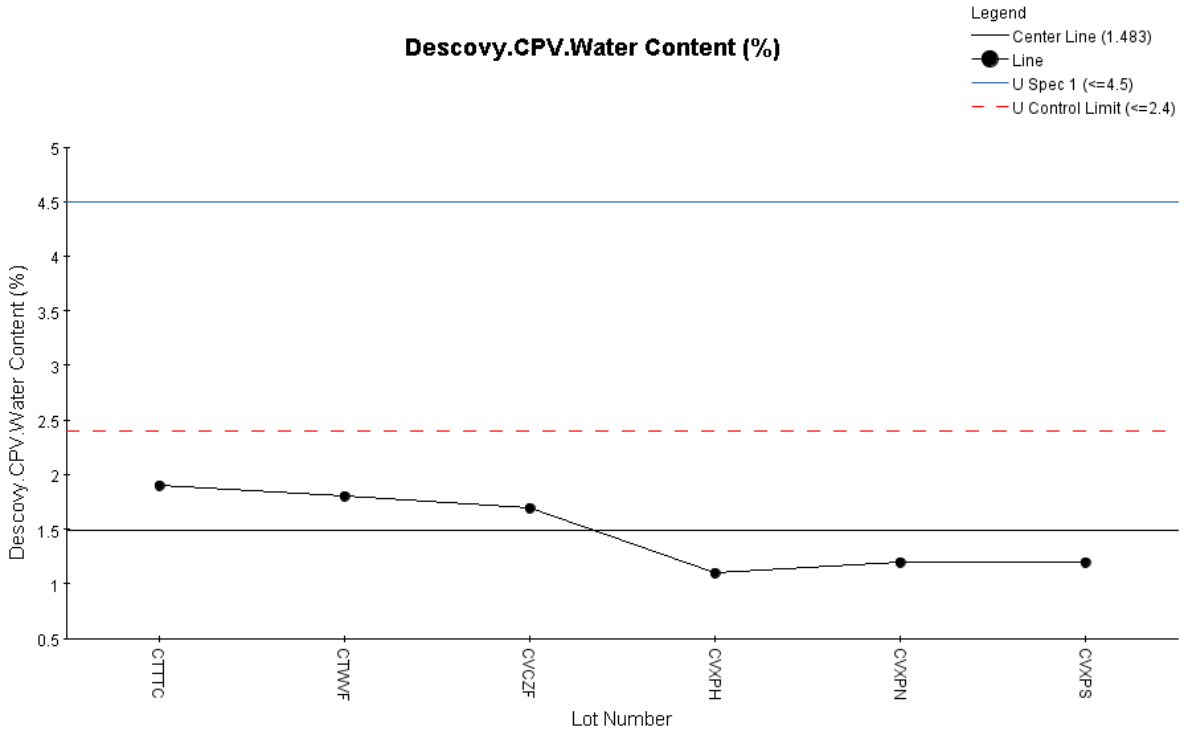

Chart 14: FTC Assay – Rottendorf (200 mg FTC/25 mg TAF)

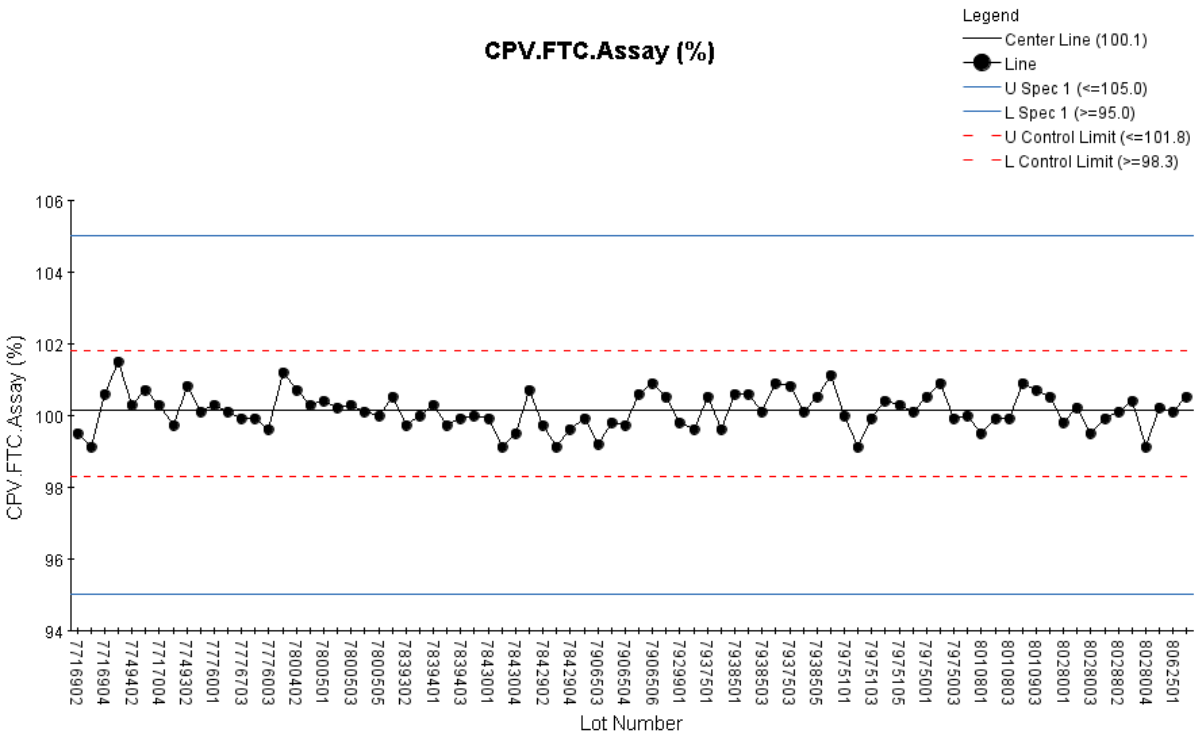

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Chart 15: TAF Assay – Rottendorf (200 mg FTC/25 mg TAF)

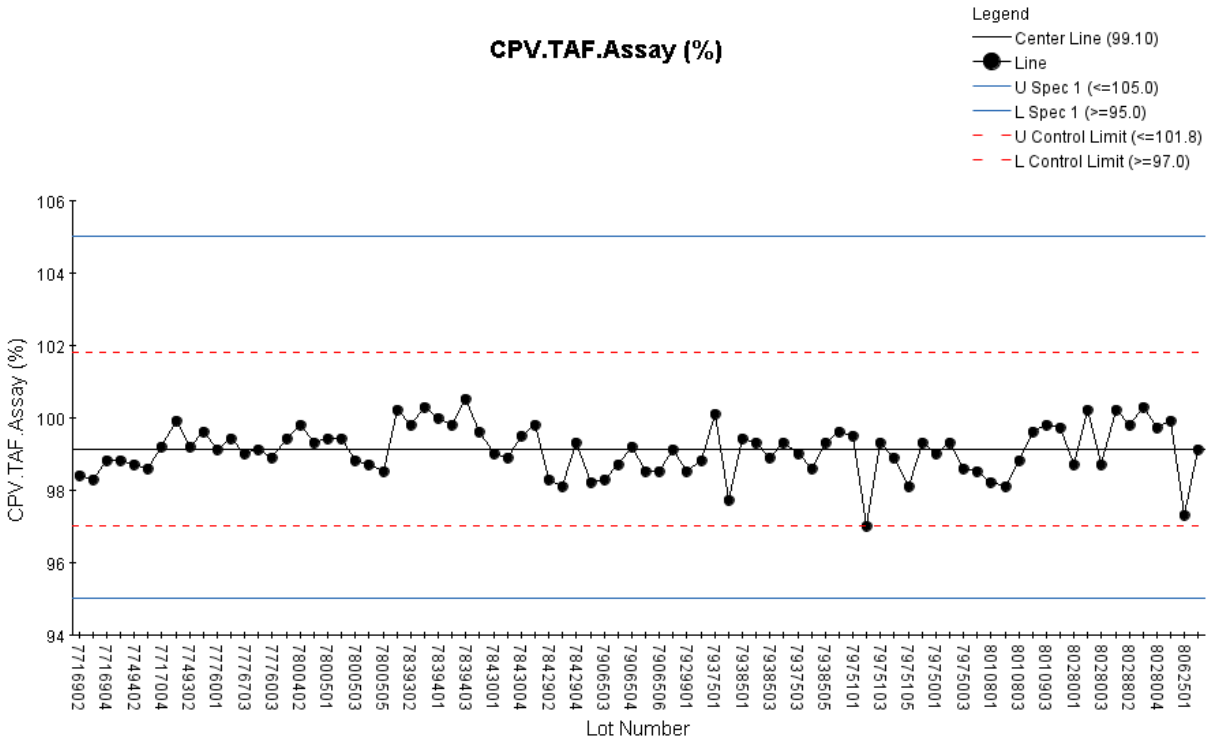

Chart 16: Total FTC Degradants – Rottendorf (200 mg FTC/25 mg TAF)

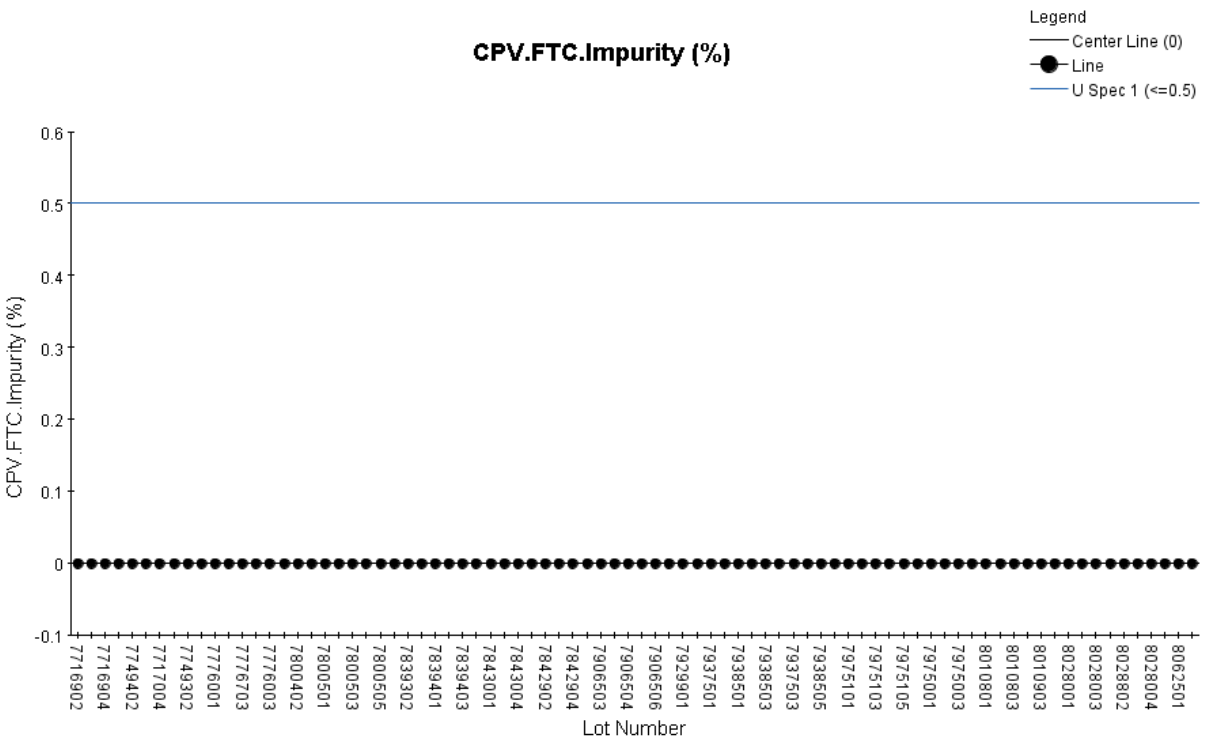

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Chart 17: Total TAF Degradants – Rottendorf (200 mg FTC/25 mg TAF)

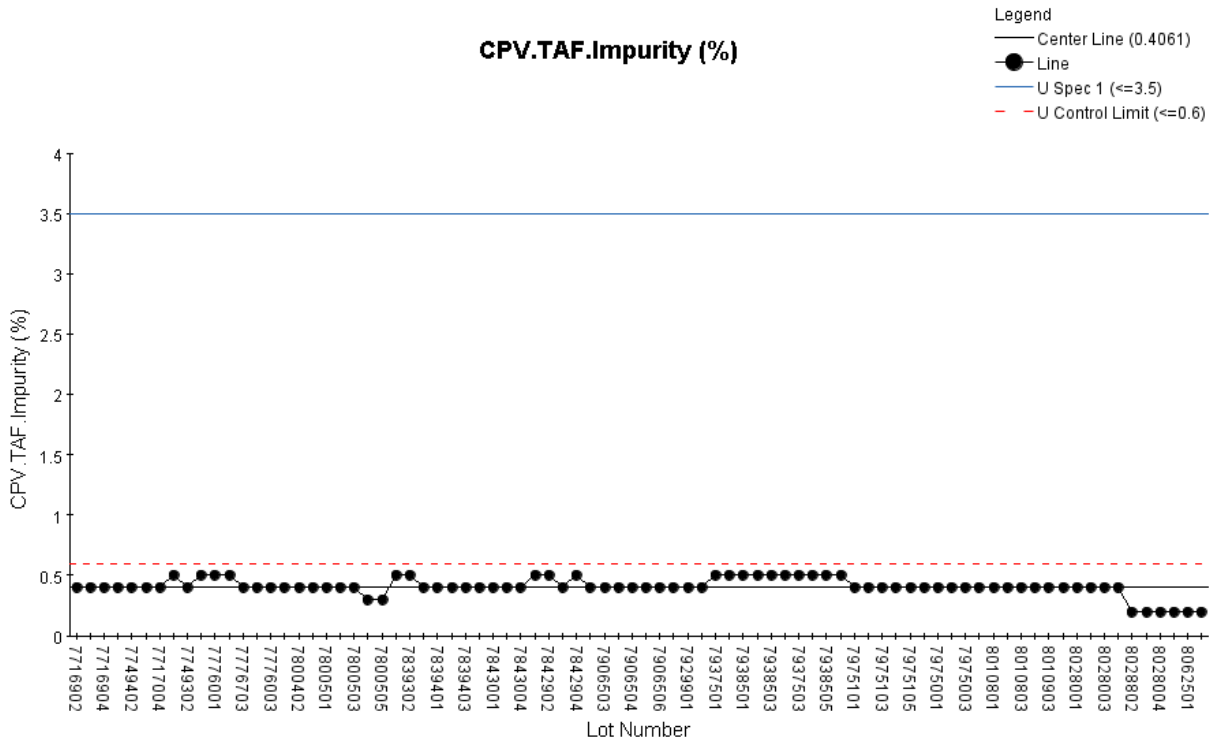

Chart 18: FTC Dissolution (30 minutes) – Rottendorf (200 mg FTC/25 mg TAF)

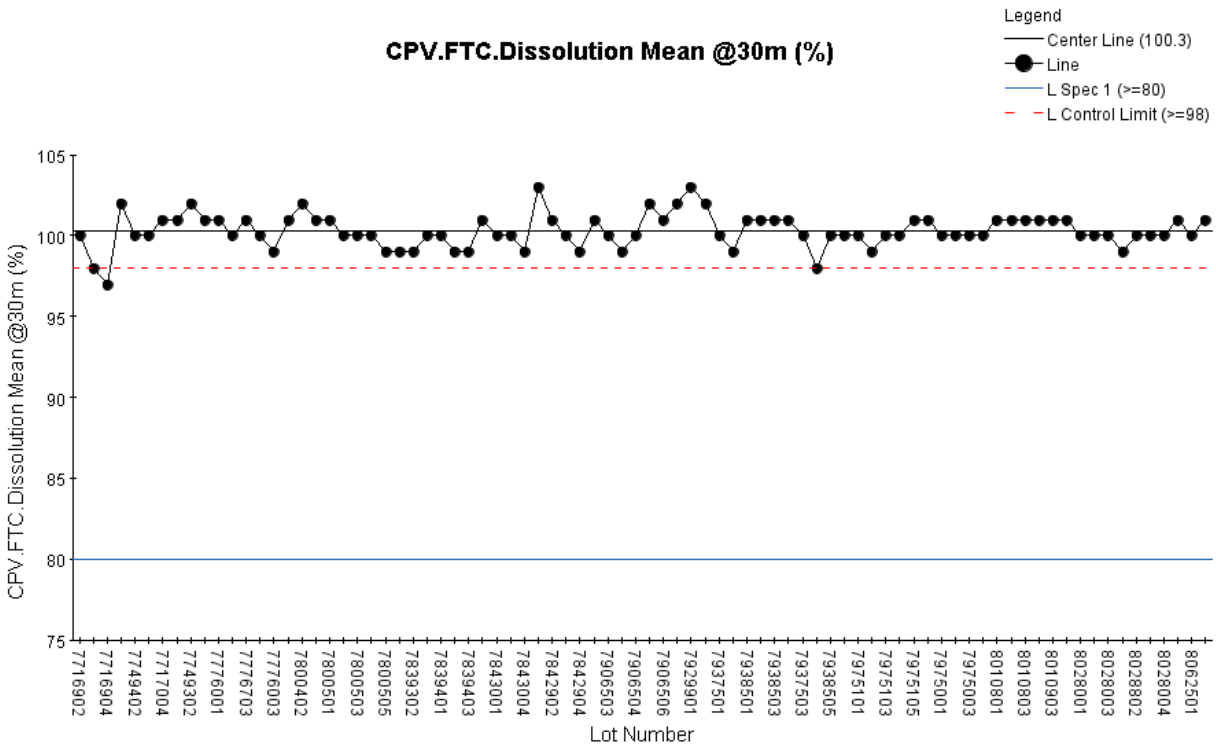

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Chart 19: TAF Dissolution (30 minutes) – Rottendorf (200 mg FTC/25 mg TAF)

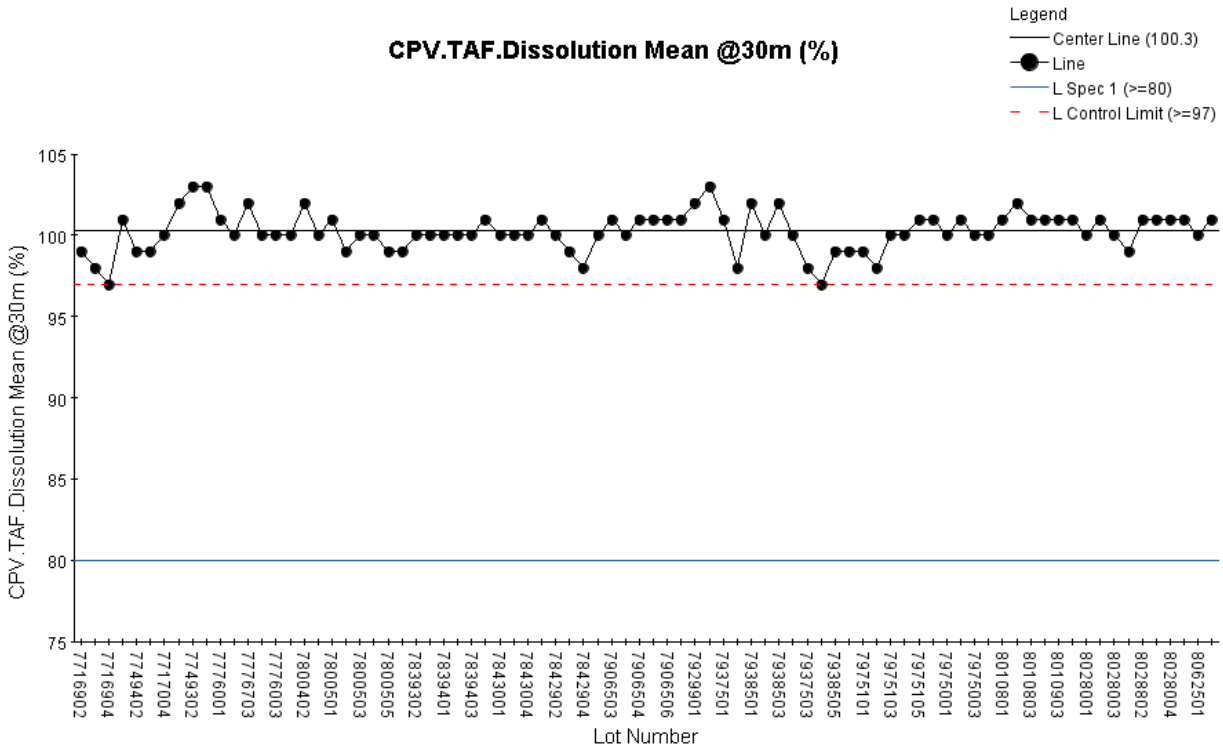

Chart 20: FTC Content Uniformity – Rottendorf (200 mg FTC/25 mg TAF)

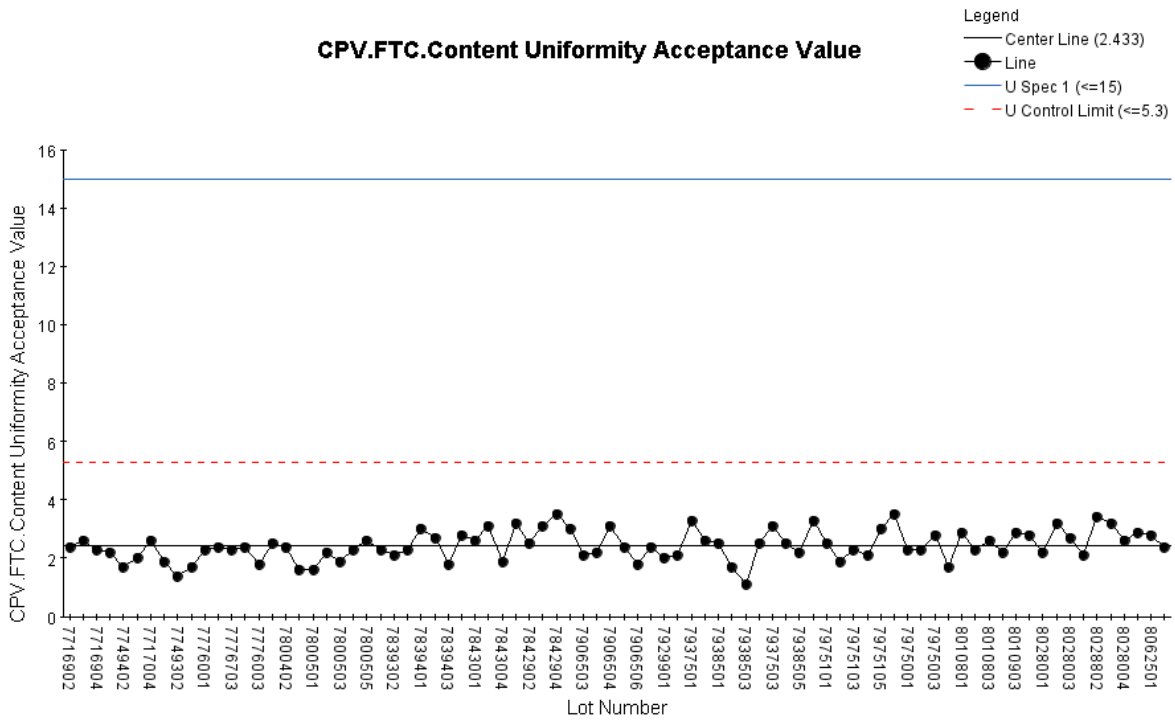

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Chart 21: TAF Content Uniformity – Rottendorf (200 mg FTC/25 mg TAF)

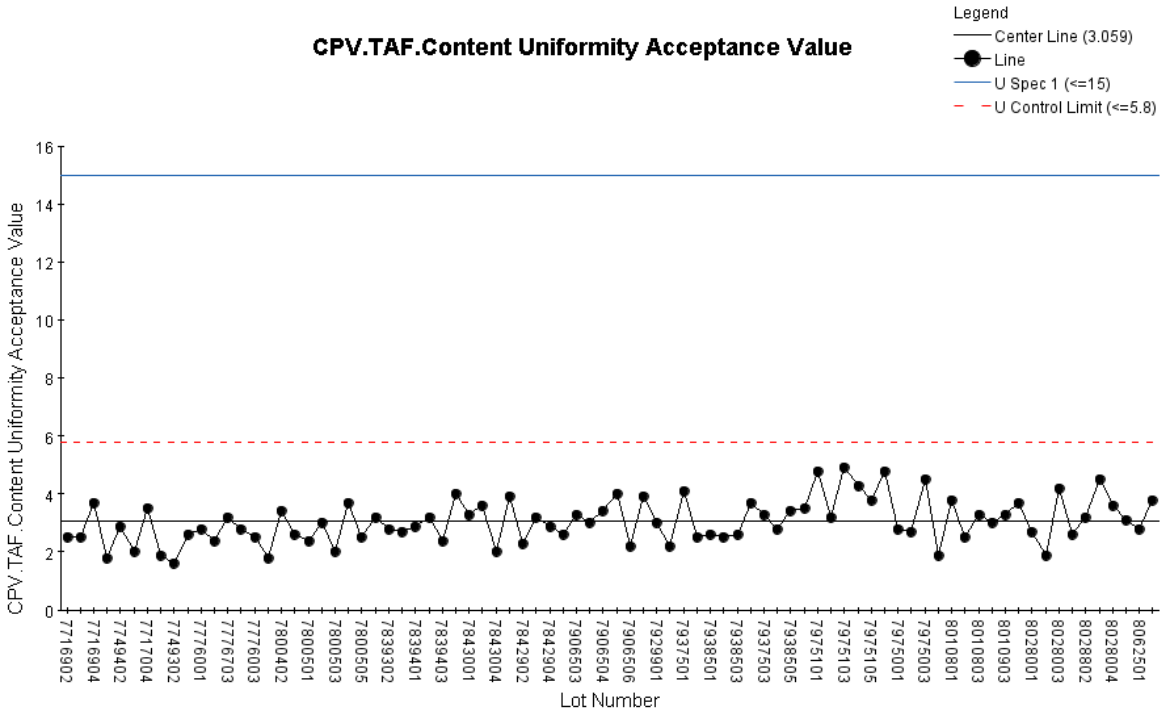
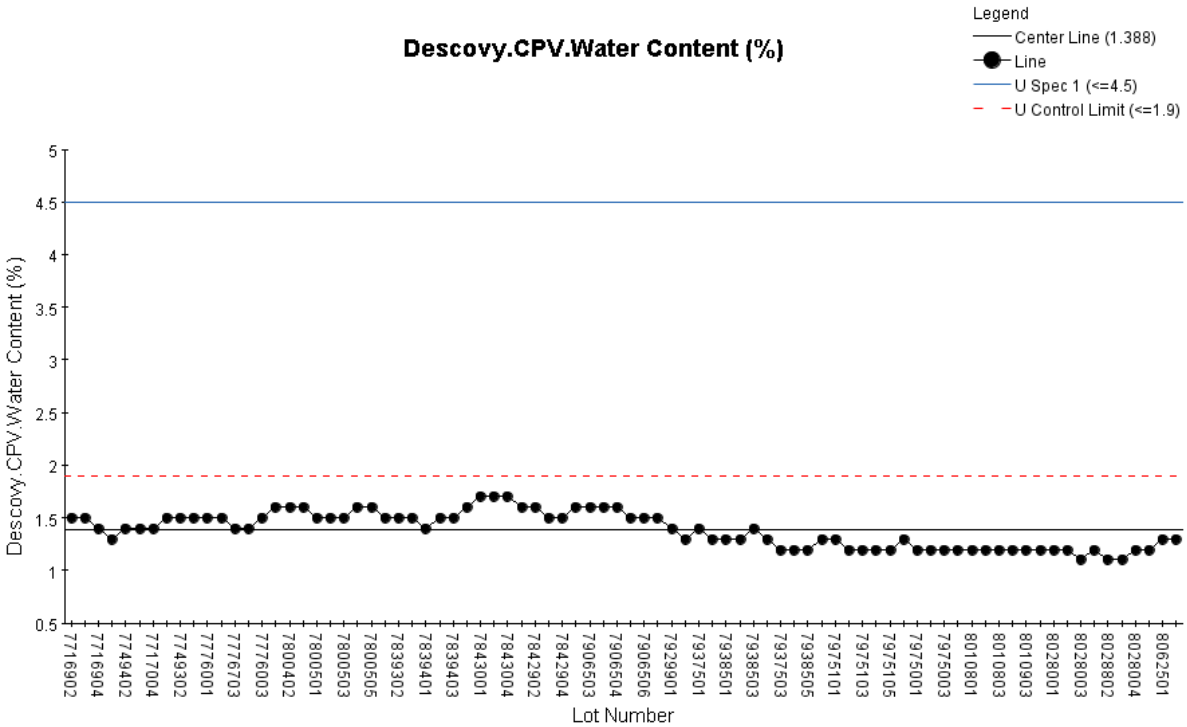


Chart 22: Water Content – Rottendorf (200 mg FTC/25 mg TAF)



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Attachment 3: Microbiology Testing Results for DESCOVY

TBD = To Be Determined

Table 1: Microbial Testing Results for DESCOVY 200 mg FTC/10 mg TAF at Patheon TRO

Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
CTNKV	N	N	N/A
CVDVZ	N	N	N/A
CVMVK	N	N	N/A

Table 2: Microbial Testing Results for DESCOVY 200 mg FTC/25 mg TAF at Patheon TRO

Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
CTTTC	N	N	N/A
CTWVB	N	N	N/A
CTWVF	N	N	N/A
CTWYK	N	N	N/A
CVCZF	N	N	N/A
CVDWG	N	N	N/A
CVVYV	N	N	N/A
CVXPH*	TBD	TBD	TBD
CVXPN*	TBD	TBD	TBD
CVXPS*	TBD	TBD	TBD

* Data not available and will be provided in the next review period

Table 3: Microbial Testing Results for DESCOVY 200 mg FTC/25 mg TAF at Rottendorf

Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
7647005*	N	N	None
7682301*	N	N	None
7682302*	N	N	None
7682303*	N	N	None
7682304*	N	N	None
7682201*	N	N	None
7682305*	N	N	None
7682306*	N	N	None
7682202*	N	N	None
7682203*	N	N	None
7682204*	N	N	None
7560304*	N	N	None
7591505*	N	N	None

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Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
7682205*	N	N	None
7682206*	N	N	None
7682207*	N	N	None
7682208*	N	N	None
7717001*	N	N	None
7717002*	N	N	None
7717003*	N	N	None
7716901*	N	N	None
7716902	N	N	None
7716903	N	N	None
7716904	N	N	None
7749401	N	N	None
7749402	N	Y	Risk Assessment QE-221469 *Purpureocillium Lilacinum* (10 cfu/g) Acceptable Risk
7749403	N	N	None
7717004	N	N	None
7749301	N	N	None
7749302	N	N	None
7749303	N	N	None
7749302	N	N	None
7591505	N	N	None
7776001	N	N	None
7776701	N	N	None
7776702	N	N	None
7776703	N	N	None
7776002	N	N	None
7776003	N	N	None
7800401	N	N	None
7800402	N	N	None
7800403	N	N	None
7800501	N	N	None
7800502	N	N	None
7800503	N	N	None
7800504	N	N	None
7800505	N	N	None
7839301	N	N	None

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Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
7839302	N	N	None
7839303	N	N	None
7839401	N	Y	Risk Assessment QE-226277 *Cladosporium Spp* (10 cfu/g) Acceptable Risk
7839301	N	N	None
7839302	N	N	None
7839303	N	N	None
7839402	N	N	None
7839403	N	N	None
7843001	N	N	None
7843002	N	N	None
7843003	N	N	None
7843004	N	N	None
7842901	N	N	None
7842902	N	N	None
7842903	N	N	None
7842904	N	N	None
7906501	N	N	None
7906502	N	N	None
7906503	N	N	None
7906504	N	N	None
7906505	N	N	None
7906506	N	N	None
7906507	N	N	None
7929901	N	N	None
7929902	N	N	None
7937501	N	N	None
7937502	N	N	None
7938501	N	N	None
7938502	N	N	None
7938503	N	N	None
7938504	N	N	None
7937503	N	N	None
7937504	N	N	None
7938505	N	N	None
7938506	N	N	None
7560304	N	N	None

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Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
7975101	N	N	None
7975102	N	N	None
7975103	N	N	None
7975104	N	N	None
7975105	N	N	None
7975106	N	N	None
7975001	N	N	None
7975002	N	N	None
7975003	N	N	None
7975004	N	N	None
7591501	N	N	None
8010801	N	N	None
8010802	N	N	None
8010803	N	N	None
8010902	N	N	None
8010903	N	N	None
8010904	N	N	None
8010901**	TBD	TBD	TBD
8028001**	TBD	TBD	TBD
8028002**	TBD	TBD	TBD
8028003**	TBD	TBD	TBD
8028801**	TBD	TBD	TBD
8028802**	TBD	TBD	TBD
8028005**	TBD	TBD	TBD
8028004**	TBD	TBD	TBD
8028006**	TBD	TBD	TBD
8062501**	TBD	TBD	TBD
8062502**	TBD	TBD	TBD
8062503**	TBD	TBD	TBD
8062601**	TBD	TBD	TBD
8062504**	TBD	TBD	TBD
8062602**	TBD	TBD	TBD
8062603**	TBD	TBD	TBD
8088801**	TBD	TBD	TBD
8088802**	TBD	TBD	TBD
8088803**	TBD	TBD	TBD

* Lot manufactured during previous review period. Microbial test results were not available during previous review period
** Data not available and will be provided in the next review period

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Table 4: Microbial Testing Results for DESCOVY 120 mg FTC/15 mg TAF at Patheon TRO

Lot Number	TAMC Action Limit Exceeded	TYMC Action Limit Exceeded	Comment
CSVVX*	N	N	None
CTWVC	N	N	None

* Lot manufactured during previous review period. Microbial test results were not available during previous review period.

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Attachment 4: List of Approved Suppliers/Vendors for DESCOVY

Table 1: Approved Suppliers for Components of DESCOVY

Blend Component		Approved Suppliers (City/State/Province, Country of the Vendor Location)	Manufacturing / Packaging Site
Drug Substance	Emtricitabine	Uquifa – Union Quimico Farmaceutica SA (Barcelona, Spain)	Patheon TRO, Rottendorf
		Yuhan Chemical, Inc (Gyeonggi-do, Korea)	Patheon TRO, Rottendorf
		Evonik Nutrition & Care (Dossenheim, Germany)	Patheon TRO, Rottendorf
	Tenofovir alafenamide	Gilead Alberta ULC (Alberta, Canada)	Patheon TRO, Rottendorf
		Esteve Quimica, S.A. (Girona, Spain)	Patheon TRO, Rottendorf
Excipient	Microcrystalline Cellulose (Avicel PH 102)	DuPont Nutrition Ireland (Wallingstown, Little Island, Cork, Ireland)	Patheon TRO, Rottendorf
	Croscarmellose Sodium (Ac-Di-Sol)	DuPont Nutrition Ireland (Wallingstown, Little Island, Cork, Ireland and Newark, DE, USA)	Patheon TRO, Rottendorf
	Lactose Monohydride	DFE Pharma USA LLC (Paramus, NJ, USA)	None
	Magnesium Stearate (Hyqual Code 5712)	SpecGx LLC / Mallinckrodt TM (St. Louis, MO, USA)	Patheon TRO, Rottendorf
		Avantor Performance Materials B.V. (Paris, KY, USA)	None
	Opadry II 85F18422 White	Colorcon Inc. (West Point, PA, USA)	None
	Opadry II 85F97517 Gray	Colorcon Limited (Dartford, Kent, England)	Patheon TRO, Rottendorf
		Colorcon Inc. (West Point, PA, USA)	Patheon TRO, Rottendorf
	Opadry II 85F105057 Blue	Colorcon Limited (Dartford, Kent, England)	Patheon TRO, Rottendorf
		Colorcon Inc. (West Point, PA, USA)	Patheon TRO, Rottendorf

Table 2: Approved Suppliers for Primary and Secondary Packaging Components of DESCOVY

Packaging Component		Approved Suppliers (City/State/Province, Country of the Vendor Location)	Manufacturing / Packaging Site
Primary	HDPE Bottle 60 mL	Drug Plastics and Glass Company Inc. (Boyertown, PA; USA and Valley City, ND, USA)	Patheon TRO, GSI La Verne, PCI Rockford, GSIUC
		Nolato Jaycare Limited (Newcastle upon Tyne, UK)	GSIUC, Rottendorf, GSI La Verne
	Cap 33 mm	Van Blarcom Closures, Inc. (Brooklyn, NY, USA) CONSOLIDATED BOTTLE CORP (Toronto, Canada) DFE Pharma USA LLC (Paramus, NJ, USA)	Patheon TRO, GSI La Verne, PCI Rockford, GSIUC
	Desiccant 3 g	Healthcare Packaging (US) Inc. (Charlotte, NC, USA)	GSIUC, Patheon TRO, PCI Rockford
		Airnov Healthcare Packaging (Belen, NM, USA)	GSI La Verne, GSIUC
	Polyester Fiber Coil	Carolina Absorbent Cotton Co. (Reno, NV; Charlotte, NC, USA)	Patheon TRO, PCI Rockford, GSI La Verne, GSIUC
	15.5mil Base Film	Tekni-Plex (Holland, OH, USA)	PCI Rockford

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Packaging Component		Approved Suppliers (City/State/Province, Country of the Vendor Location)	Manufacturing / Packaging Site
	Blister Peel-push Foil	Constantia (Blythewood, NC, USA)	PCI Rockford
		Constantia Pirk GmbH+ Co.KG (Pirkmuhle, Germany)	PCI Rockford
	Wallet	MM Packaging US Inc. and MM Clayton LLC (Pineville, NC, USA)	PCI Rockford
Secondary	Carton	WestRock Healthcare Packaging Ireland Limited (Dublin, Ireland)	GSIUC, Rottendorf, PCI Ireland
		MM Fiber Packaging Ireland Limited (Dublin and Cork, Ireland)	GSIUC, Rottendorf, PCI Ireland
		Max Solutions (Mississauga, Ontario, Canada)	Patheon TRO
		Marukin Printing Co., Ltd. (Chiba, Japan)	Bushu
	Blister Wallet Outer Card	MM Packaging US Inc. and MM Clayton LLC (Pineville, NC, USA)	PCI Rockford
	Label	Pharmaceutic Litho and Label Co. (Simi Valley, CA, USA)	Patheon TRO, GSI La Verne, PCI Rockford, GSIUC
		Gilead Sciences (S.R.L.) (Milano, Italy)	GSIUC
		Label Craft (Dublin, Ireland)	GSIUC, Rottendorf
		MM Fiber Packaging Ireland Limited (Dublin and Cork, Ireland)	GSIUC, Rottendorf, PCI Ireland
		CCL Label (Toronto, Ontario, Canada)	Patheon TRO, GSI La Verne, PCI Rockford
		MM Packaging US Inc.(Greensboro, NC, USA)	Patheon TRO, Gilead La Verne, PCI Rockford
		Marukin Printing Co., Ltd. (Chiba, Japan)	Patheon TRO, Bushu
		Nosco, Inc (Carrollton, TX, USA and Gurnee, IL, USA)	Patheon TRO, GSI La Verne, PCI Rockford
	Package Insert/Outsert	Pharmaceutic Litho and Label Co. (Simi Valley, CA, USA)	Patheon TRO, GSI La Verne, PCI Rockford
		Apex Graphics (Mississauga, Ontario, Canada)	Patheon TRO, GSI La Verne, PCI Rockford, GSIUC
		Multi-Color Corporation (Mayo, Ireland)	GSIUC, Rottendorf, PCI Ireland
		MM Fiber Packaging Ireland Limited (Dublin and Cork, Ireland)	GSIUC, Rottendorf, PCI Ireland
		Label Craft (Dublin, Ireland)	GSIUC
		MM Packaging US Inc. (Greensboro, NC, USA)	Patheon TRO, GSI La Verne, PCI Rockford
		Asahi Printing Company (Toyama, Japan)	Patheon TRO
		Westrock Consumer Packaging Group LLC (La Grange, IL)	PCI Rockford

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Attachment 5: Facility and Equipment Qualification

GSIUC

The facilities, including utilities and equipment, where DESCOVY is packaged, tested, and stored are maintained in a validated state as per POL-00275, 'GSIUC Policy for the Implementation, Validation, Operation and Support of Local Systems'.

The validation status of all Direct Impact and Regulatory Impact systems utilized to package, test, and store DESCOVY at GSIUC are maintained in the site System Inventory as per SOP-01186, 'System Inventories'.

Periodic reviews of Direct Impact and Regulatory Impact systems are completed per SOP-08456, 'System Periodic Review', to verify that systems remain compliant with regulatory requirements, are fit for intended use and meet GSIUC policies and procedures.

GXPR-02469, 'Primary Packaging Product Validation Status GxPR', lists the equipment used in the Primary Packaging of DESCOVY at GSIUC.

The GSIUC Secondary Packaging Matrix lists the packaging equipment used in the packaging of DESCOVY at GSIUC and is controlled as per SOP-11515, 'Management and Use of the Automated Secondary Packaging Validation Matrix (ASPVM)'.

The Calibration program for critical and non-critical equipment, systems, and facilities at GSIUC is controlled under SOP-02527, 'Calibration Management Procedure'. Management of QC system calibrations is controlled under system specific procedures for the individual QC systems.

Below is a summary of major qualifications and validations at the GSIUC site.

Error! Reference source not found. lists the qualification and validation activities that were performed during the review period.

Table 1: Summary of Validation/Qualification Activities

Validation Type (Facility / Utility / Equipment / System / Process)	System ID (Tag Number)	Description	Reference Document No.
GSIUC			
Utility	EM160	Combined System Release Authorization / IQOQ Summary Report for Environmental Monitoring System EM160, Warehouse Building 12	SRA01 - GSIUC-EVL-0012-05
Utility	EM170	Combined System Release Authorization / IQOQ Summary Report for Environmental Monitoring System EM170, Warehouse Building 12	SRA02 - GSIUC-EVL-0012-05
Utility	MC010 EM150	Combined Qualification Summary Report / System Release Authorization Report for the addition of MC010 Compressed Air System Monitoring Sensors to EMS Panel EM150	SRA - GSIUC-EVL-0012-13
Utility	MC010	Qualification Summary Report for the Installation & Operational Qualification for New Compressed Air Tie-In Points per QE-184795	QSR - GSIUC-EVL-0209-02
Utility	MC010 VG010	System Validation Summary Report for the Small-Scale Manufacturing Facility Development.	VSR - GSIUC-EVL-0481-03
System	MES	Qualification Summary Report for the Installation of MES PAS-X Version 3.1.8 PE3, Werum Project Version 2.1 System in the MES PROD Environment - Stage 2 (Cutover) and Final	SRA02 - GSIUC-EVL-0382-01

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Validation Type (Facility / Utility / Equipment / System / Process)	System ID (Tag Number)	Description	Reference Document No.
		System Release Authorization Report for PAS-X MES 3.1.8 PE3, Werum Project Version 2.1 System	
System	MES	Qualification Summary Report for the Performance Qualification for the Upgrade of the MES System from MES 3.1.8 PE3, Werum Project Version 2.0 to MES 3.1.8 PE3, Werum Project Version 2.1 - Secondary Packaging	QSR09 - GSIUC-EVL-0382-01
System	MES	Qualification Summary Report for the Installation of MES PasX2X Osi Pi Adapters in the PRD Environment for MES EBR	QSR11 - GSIUC-EVL-0382-01
System	MES	Qualification Summary Report for the Performance Qualification for the Upgrade of the MES System from MES 3.1.8 PE3, Werum Project Version 2.0 to MES 3.1.8 PE3, Werum Project Version 2.1 - Primary Packaging	QSR12 - GSIUC-EVL-0382-01
System	MES	Combined Interim System Release Authorization Report for the Release of the EBR to Secondary Packaging Manual Line 3 at GSIUC and Qualification Summary Report for the Installation and Operational Qualification for Full EBR in the MES VAL Environment - Manual Line 3	SRA01 - GSIUC-EVL-0382-05
System	MES	Validation Summary Report for the Upgrade of the MES System from MES 3.1.8 P05 to MES 3.1.8 PE3, Werum Project Version 2.0	VSR - GSIUC-EVL-0018-04
System	MES PPL02	Validation Summary Report for the Introduction of a Primary Packaging Line 2 Interim Electronic Batch Record (EBR) on MES 3.1.8	VSR - GSIUC-EVL-0018-06
Utility	MP010	Combined System Release Authorization Report / PQ Phase 2 Summary Report for Purified Water Generation and Distribution Skids following Rebuild.	SRA1 - GSIUC-EVL-0210-05
System	PIMS	Combined System Release Authorization / Qualification Summary Report for PIMS Server Relocation and Requalification	GSIUC-SRA-0042
System	SAP	System Release Authorization / IQ to Production Summary Report for Antares Interfaces Impacted by GSIUC SAP S4 (Project Bluestream)	SRA - GSIUC-EVL-0003-03
Utility	VG270	System Release Authorization Report for VG270 HVAC for Warehouse Building 12	SRA - GSIUC-EVL-0458-01
System	WCS01	System Release Authorization Report for WCS01, Coldroom in Warehouse Building 12	SRA - GSIUC-EVL-0451-01
System	WSW01	Combined System Release Authorization / IQOQ Summary Report for Sampling Booth 1 (WSW01) System, Warehouse Building 12	SRA01 - GSIUC-EVL-0445-01
System	WSW02	Combined System Release Authorization / IQOQ Summary Report for Sampling Booth 2 (WSW02) System, Warehouse Building 12	SRA01 - GSIUC-EVL-0444-01

GSI La Verne

The facilities, including utilities and equipment, where DESCOVY is packaged, and stored are maintained in a validated state as per SOP-15021, 'Validation Procedure at Gilead La Verne of Local Systems'.

The validation status of all Direct Impact and Regulatory Impact systems utilised to package, and store DESCOVY at GSI La Verne are maintained in the site System Inventory as per GXPR-00939 'Computerized Systems Inventory List at Gilead La Verne'.

Periodic reviews of Direct Impact and Regulatory Impact systems are completed per SOP-10367 'Revalidation/ Requalification of Facilities, Equipment, Systems, and Processes at Gilead La Verne' and SOP-10821 'Computerized-Control and Software-Based System Qualification at Gilead La Verne' to verify that systems remain compliant with regulatory requirements, are fit for intended use and meet GSI La Verne policies and procedures.

GXPR-03538 'Major Equipment and Instrumentation List at Gilead La Verne' lists the equipment used in the packaging of DESCOVY at GSI La Verne.

GXPR-00939 'Computerized Systems Inventory List at Gilead La Verne' lists the equipment used in the Primary Packaging of DESCOVY at GSI La Verne.

The GSI La Verne Secondary Packaging Matrix lists the packaging equipment used in the packaging of DESCOVY at GSI La Verne and is controlled as per GXPR-00939 'Computerized Systems Inventory List at Gilead La Verne'.

The Calibration program for critical and non-critical equipment, systems and facilities at GSI La Verne is controlled under SOP-10411 'Metrology Program at Gilead La Verne'. Management of QC system calibrations is controlled under system specific procedures for the individual QC systems.

Below is a summary of major qualifications and validations at the GSI La Verne site.

Table 2 lists the qualification and validation activities that were performed during the review period.

Table 2: Summary of Validation/Qualification Activities

Validation Type (Facility or System)	Description	Reference Document No.
System	Final Report-Periodic Records Review (PRR) of the Solid Dose Packaging Line (Asset ID 90000033) in Building L50, La Verne Review Period: 12/01/2023 to 11/30/2024	LV-PRR-90000033-0006.01
System	Final Report - Periodic Records Review (PRR) of the Solid Dose Packaging Line # 2 (Asset ID 90000059) in Building L50, La Verne Review Period: 04/01/23 to 03/31/24	LV-PRR-90000059-0002.01

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Attachment 6: Summary of Current Lots on Stability

GILEAD

Stability Regulatory Report for Emtricitabine 120 mg/ Tenofovir Alafenamide 15 mg Tablets

Lot Number	Mfg. Site	Mfg. Date	Batch Size (kg)	Study Initiation Date	Storage Condition	Study Duration (months)	Reported Time Point (months)
CHZBB	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2021	15	13 Oct 21	25°C/60%RH 30°C/75%RH 40°C/75%RH	60 60 6	36 36 6 [a]
CHZBD	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2021	15	13 Oct 21	25°C/60%RH 30°C/75%RH 40°C/75%RH	60 60 6	36 36 6 [a]
CHZBF	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2021	15	13 Oct 21	25°C/60%RH 30°C/75%RH 40°C/75%RH	60 60 6	36 36 6 [a]
CPDSZ	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Mar 2023	15	26 May 23	25°C/60%RH 30°C/75%RH	60 60	12 12
CSVWD	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Feb 2024	15	12 Apr 24	25°C/60%RH 30°C/75%RH	60 60	0 0

[a] This condition was previously reported.

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GILEAD

Stability Regulatory Report for Emtricitabine 200 mg/ Tenofovir Alafenamide 10 mg Tablets

Lot Number	Mfg. Site	Mfg. Date	Batch Size (kg)	Study Initiation Date	Storage Condition	Study Duration (months)	Reported Time Point (months)
CCDZB	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Mar 2019	330	20 May 19	30°C/75%RH	60	36
CFHWP	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Apr 2020	330	12 Jun 20	30°C/75%RH	60	36
CHHPX	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Apr 2021	330	09 Jun 21	30°C/75%RH	36	36
CKZHG	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Feb 2022	330	05 Apr 22	30°C/75%RH	60	24
CPPGG	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2023	120	14 Sep 23	30°C/75%RH	36	12
CSVVS	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Feb 2024	120	12 Apr 24	30°C/75%RH	36	0
6446201	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Jan 2020	330	11 Mar 20	30°C/75%RH	60	36

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Stability Regulatory Report for Emtricitabine 200 mg/ Tenofovir Alafenamide Tablets 25 mg, Blister Packaging

Lot Number	Mfg. Site	Mfg. Date	Batch Size (kg)	Study Initiation Date	Storage Condition	Study Duration (months)	Reported Time Point (months)
CBHKGA	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Feb 2019	330	29 Aug 19	25°C/60%RH 30°C/75%RH 40°C/75%RH	60 60 6	60 60 6 [a]
CCZWWA	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2019	330	10 Mar 20	25°C/60%RH 40°C/75%RH	60 6	48 6 [a]
CCZWXA	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2019	330	10 Mar 20	25°C/60%RH 40°C/75%RH	60 6	48 6 [a]
6351901A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Jul 2019	330	10 Mar 20	25°C/60%RH 40°C/75%RH	60 6	48 6 [a]
6647301A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Sep 2020	330	06 Nov 20	25°C/60%RH	60	48
6830101A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Jun 2021	330	13 Aug 21	25°C/60%RH	60	36
7182205A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Nov 2022	330	08 Mar 23	25°C/60%RH	60	12
7315101A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Mar 2023	330	30 Aug 23	25°C/60%RH	60	12
7682201A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Mar 2024	330	10 Sep 24	25°C/60%RH	60	0

[a] This condition was previously reported.

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Stability Regulatory Report for Emtricitabine 200 mg/ Tenofovir Alafenamide 25 mg Tablets

Lot Number	Mfg. Site	Mfg. Date	Batch Size (kg)	Study Initiation Date	Storage Condition	Study Duration (months)	Reported Time Point (months)
CCPBW	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	May 2019	330	12 Jul 19	30°C/75%RH	60	60
CFSPX	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jun 2020	330	03 Aug 20	30°C/75%RH	60	48
CGZKD	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Feb 2021	330	02 Apr 21	30°C/75%RH	60	36
CHXDY	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jul 2021	330	01 Sep 21	30°C/75%RH	60	36
CKXBK	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Jan 2022	330	18 Mar 22	30°C/75%RH	60	24
CNZYD	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Mar 2023	330	15 May 23	30°C/75%RH	60	12
CSVWB	Patheon, Inc. Toronto Regional Operations (TRO) (Mississauga, Ontario, Canada)	Feb 2024	330	12 Apr 24	30°C/75%RH	60	0

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Stability Regulatory Report for Emtricitabine 200 mg/ Tenofovir Alafenamide 25 mg Tablets

Lot Number	Mfg. Site	Mfg. Date	Batch Size (kg)	Study Initiation Date	Storage Condition	Study Duration (months)	Reported Time Point (months)
6255301	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Feb 2019	330	16 Apr 19	30°C/75%RH	60	60
6583901	Rottendorf Pharma GmbH (Ennigerloh, Germany)	May 2020	330	24 Jul 20	30°C/75%RH	60	48
025624	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Jul 2020	330	22 Oct 20	30°C/75%RH 40°C/75%RH	60 6	48 6 [a]
6766301P	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Mar 2021	330	14 May 21	30°C/75%RH	60	36
7008801P	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Mar 2022	330	29 Apr 22	30°C/75%RH	60	24
7246201A	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Jan 2023	330	12 Jun 23	30°C/75%RH 40°C/75%RH	60 6	18 6 [a]
7630401P	Rottendorf Pharma GmbH (Ennigerloh, Germany)	Jan 2024	330	02 Apr 24	30°C/75%RH	60	0
486327	Takeda GmbH (Oranienburg, Germany)	Oct 2020	330	02 Feb 21	30°C/75%RH 40°C/75%RH	60 6	48 6 [a]
486328	Takeda GmbH (Oranienburg, Germany)	Oct 2020	330	02 Feb 21	30°C/75%RH 40°C/75%RH	60 6	48 6 [a]
486329	Takeda GmbH (Oranienburg, Germany)	Oct 2020	330	02 Feb 21	30°C/75%RH 40°C/75%RH	60 6	48 6 [a]

[a] This condition was previously reported.

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1 TREATMENT OF DATA

All available stability data for lots currently on stability and stored at 30 °C/75%RH were evaluated for DESCOVY 200 mg FTC/10 mg tablets in bottles and DESCOVY 200 mg FTC/25 mg tablets in bottles. As key stability indicators, data for assay, degradation products, and water content are analyzed statistically. Dissolution data are evaluated for trending purposes only. Only lots with five (5) data points or more are included in statistical analysis in order to ensure that there was sufficient data for accurate trend analysis.

For DESCOVY 200 mg FTC/10 mg TAF in bottles, Lots CKZHG and CSVVS currently have less than five (5) data points and are not evaluated statistically. For lots with greater than five (5) data points that have not reached the shelf-life time point, extrapolation of 12 months was utilized for predictions.

At 30 °C/75% RH storage condition, for all Lots of DESCOVY 200 mg FTC/10 mg TAF tablets in bottles that have reached the shelf-life of 36 months, worst case ranges of real time values generated at 30 °C/75% RH are tabulated in Table 1.

For DESCOVY 200 mg FTC/25 mg TAF in bottles, Lots CGZKD, 6766301P, CHXDY, CKXBK, 7008801P, CNZYD, 7630401P, and CSVWB currently have less than five (5) data points and are not evaluated statistically. For lots with greater than five (5) data points that have not reached the shelf-life time point, extrapolation of 12 months was utilized for predictions.

At 30 °C/75% RH storage condition, for all lots of DESCOVY 200 mg FTC/25 mg TAF tablets in bottles that have reached the shelf-life of 48 months, worst case ranges of real time values generated at 30 °C/75% RH are tabulated in Table 2.

All available stability data for lots currently on stability and stored at 25 °C/60%RH were evaluated for DESCOVY 200 mg FTC/25 mg tablets in blister packs. As key stability indicators, data for assay, degradation products, and water content are analyzed statistically. Dissolution data are evaluated for trending purposes only. Only lots with five (5) data points or more are included in statistical analysis in order to ensure that there was sufficient data for accurate trend analysis.

For DESCOVY 200 mg FTC/25 mg TAF in blister packs, Lots 7182205A, 7315101A, and 7682201A currently have less than five (5) data points and are not evaluated statistically. There are no lots with greater than five (5) data points that have not reached the shelf-life time point, so statistical analysis with extrapolation of 12 months for predictions is not performed for DESCOVY 200 mg FTC/25 mg TAF in blister packs.

At 25 °C/60%RH storage condition, for all lots of DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs that have reached the shelf-life of 36 months, worst case ranges of real time values generated at 25 °C/60%RH are tabulated in Table 3.

All available stability data for lots currently on stability and stored at 25 °C/60%RH were evaluated for DESCOVY 120 mg FTC/15 mg tablets in bottles. As key stability indicators, data for assay, degradation products, and water content are analyzed statistically. Dissolution data are evaluated for trending purposes only. Only lots with five (5) data points or more are included in statistical analysis in order to ensure that there was sufficient data for accurate trend analysis.

For DESCOVY 120 mg FTC/15 mg TAF in bottles, Lots CPDSZ and CSVWD currently have less than five (5) data points and are not evaluated statistically. For lots with greater than five (5) data points that have not reached the shelf-life time point, extrapolation of 12 months was utilized for predictions.

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At 25 °C/60%RH storage condition, there are no lots of DESCOVY 120 mg FTC/15 mg TAF tablets in bottles that have reached the shelf-life of 48 months, so worst case ranges of real time values generated at 25 °C/60%RH at shelf-life are not tableted.

Table 1: Analysis at Shelf-life for DESCOVY 200 mg FTC/10 mg TAF Tablets in Bottles at 30 °C/75%RH

Test	Specification Limit	Worst-Case Real-Time Value at Shelf-life	
		FTC	TAF
Assay (%)	95.0 – 105.0 (FTC) 90.0 – 105.0 (TAF)	99.3 – 100.5	94.1 – 95.2
Total Degradation (%)	NMT 1.2 (FTC) NMT 6.0 (TAF)	N/A	4.0%
Main Degradants (%)	NMT 3.00 (PMPA)	N/A	1.59%
	NMT 2.50 (PMPA Anhydride)	N/A	1.59%
Water Content (%)	NMT 4.0	1.2	

NMT = Not More Than

Table 2: Analysis at Shelf-life for DESCOVY 200 mg FTC/25 mg TAF Tablets in Bottles at 30 °C/75%RH

Test	Specification Limit	Worst-Case Real-Time Value at Shelf-life	
		FTC	TAF
Assay (%)	95.0 – 105.0 (FTC) 90.0 – 105.0 (TAF)	99.5 – 100.8	94.4 – 96.9
Total Degradation (%)	NMT 1.2 (FTC) NMT 6.0 (TAF)	N/A	3.3
Main Degradants (%)	NMT 3.00 (PMPA)	N/A	1.46
	NMT 2.50 (PMPA Anhydride)	N/A	1.44
Water Content (%)	NMT 4.0	1.1	

NMT = Not More Than

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Table 3: Analysis at Shelf-life for DESCOVY 200 mg FTC/25 mg TAF Tablets in Blister Packs at 25 °C/60%RH

Test	Specification Limit	Worst-Case Real-Time Value at Shelf-life	
		FTC	TAF
Assay (%)	95.0 – 105.0 (FTC) 90.0 – 105.0 (TAF)	99.1 – 100.8	97.1 – 99.5
Total Degradation (%)	NMT 1.2 (FTC) NMT 6.0 (TAF)	N/A	1.1
Main Degradants (%)	NMT 3.00 (PMPA)	N/A	0.55
	NMT 2.50 (PMPA Anhydride)	N/A	0.36
Water Content (%)	NMT 4.0	0.7	

NMT = Not More Than

For lots that have not reached the shelf-life time point and where no projection is required due to less than five (5) data points available, the real time values at the most recent time point available are summarized. Refer to Table 4 for DESCOVY 200 mg FTC/10 mg TAF tablets in bottles, Table 5 for DESCOVY 200 mg FTC/25 mg TAF tablets in bottles, Table 6 for DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs and Table 7 for DESCOVY 120 mg FTC/15 mg TAF tablets in bottles.

Table 4: Analysis at Most Recent Time Point for DESCOVY 200 mg FTC/10 mg TAF Tablets in Bottles at 30 °C/75%RH

Lot Number	Most Recent Time Point Available Months	Real Time Data					
		FTC Assay (%)	TAF Assay (%)	Total TAF-related Degradation (%)	PMPA (%)	PMPA Anhydride (%)	Water Content (%)
		95.0-105.0	90.0-105.0	NMT 6.0	NMT 3.00	NMT 2.50	NMT 4.0
CKZHG	24	98.7	96.8	2.3	0.99	0.91	1.0
CSVVS	0	99.4	98.9	0.5	0.22	0.13	1.3

NMT = Not More Than

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Table 5: Analysis at Most Recent Time Point for DESCOVY 200 mg FTC/25 mg TAF Tablets in Bottles at 30 °C/75%RH

Lot Number	Most Recent Time Point Available Months	Real Time Data					
		FTC Assay (%)	TAF Assay (%)	Total TAF-related Degradation (%)	PMPA (%)	PMPA Anhydride (%)	Water Content (%)
		95.0-105.0	90.0-105.0	NMT 6.0	NMT 3.00	NMT 2.50	NMT 4.0
CGZKD	36	99.5	96.5	2.3	1.05	0.85	1.0
6766301P	36	99.9	95.7	2.4	1.04	0.99	0.9
CHXDY	36	101.2	97.9	2.1	0.98	0.76	0.9
CKXBK	24	100.4	98.4	1.5	0.73	0.54	0.9
7008801P	24	100.1	98.1	1.4	0.71	0.47	0.9
CNZYD	12	99.2	98.4	1.0	0.53	0.29	0.7
7630401P	0	100.5	98.5	0.4	0.26	0.13	1.2
CSVWB	0	99.8	98.8	0.5	0.25	0.12	1.3

NMT = Not More Than

Table 6: Analysis at Most Recent Time Point for DESCOVY 200 mg FTC/25 mg TAF Tablets in Blister Packs at 25 °C/60%RH

Lot Number	Most Recent Time Point Available Months	Real Time Data					
		FTC Assay (%)	TAF Assay (%)	Total TAF-related Degradation (%)	PMPA (%)	PMPA Anhydride (%)	Water Content (%)
		95.0-105.0	90.0-105.0	NMT 6.0	NMT 3.00	NMT 2.50	NMT 4.0
7182205A	12	100.0	98.8	0.8	0.45	0.21	0.6
7315101A	12	99.5	97.8	0.8	0.46	0.22	0.7
7682201A	0	100.1	100.0	0.4	0.27	0.11	1.4

NMT = Not More Than

Table 7: Analysis at Most Recent Time Point for DESCOVY 120 mg FTC/15 mg TAF Tablets in Bottles at 25 °C/60%RH

Lot Number	Most Recent Time Point Available Months	Real Time Data					
		FTC Assay (%)	TAF Assay (%)	Total TAF-related Degradation (%)	PMPA (%)	PMPA Anhydride (%)	Water Content (%)
		95.0-105.0	90.0-105.0	NMT 6.0	NMT 3.00	NMT 2.50	NMT 4.0
CPDSZ	12	99.6	99.3	0.6	0.39	0.16	0.6
CSVWD	0	100.8	98.2	0.3	0.22	0.11	1.3

NMT = Not More Than

2 STABILITY MODELING AND REGRESSION ANALYSIS

Linear regression analysis of percent label assay, total degradation products, major degradation products, and water content results as a function of time was performed using Discoverant. The resulting regression curves were tested for lot similarity, assessing equality of the slope and zero time point intercepts. If the tests for equality of slope and intercept achieved a 0.25 significance

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level (p-value), the data from the lot were pooled accordingly. For each active and analysis, the predicted result of the mean at shelf-life is determined with corresponding confidence interval predictions. Based on the test and specification, the worst-case confidence intervals of the mean are chosen considering the upper and /or lower confidence intervals limits as appropriate. Refer to Table 8, Table 9, and Table 10 for summaries of the overall worst-case predictions at 12 months beyond the most recent time point available or shelf-life (whichever is shorter) for the parameters assessed. As discussed in the Treatment of Data section, there are no lots with greater than 5 data points that have not reached the shelf-life time point for DESCOVY 200 mg FTC/25 mg TAF in blister packs, so statistical analysis with extrapolation of 12 months for predictions is not performed.

The output for each analysis includes a summary of predicted results at 12 months beyond the most recent time point available for each lot or shelf-life (whichever is shorter) including lower and upper bound of the 95% confidence interval.

Table 8: Analysis at 12 Months Beyond the Most Recent Time Point Available for DESCOVY 200 mg FTC/10 mg TAF Tablets in Bottles at 30 °C/75%RH

Test	Specification Limit	95% Confidence Limit(s) (closest to specification limit)	
		FTC	TAF
Assay (%)	95.0 – 105.0 (FTC) 90.0 – 105.0 (TAF)	97.2 – 99.7 Common Slope Different Intercepts	95.2 – 99.2 Different Slopes Different Intercepts
Total Degradation (%)	NMT 1.2 (FTC) NMT 6.0 (TAF)	N/A	3.2 Different Slopes Different Intercepts
Main Degradants (%)	NMT 3.00 (PMPA)	N/A	1.37 Different Slopes Different Intercepts
	NMT 2.50 (PMPA Anhydride)	N/A	1.05 Different Slopes Different Intercepts
Water Content (%)	NMT 4.0	1.1 Common Slope Common Intercept	

NMT = Not More Than

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Table 9: Analysis at 12 Months Beyond the Most Recent Time Point Available for DESCOVY 200 mg FTC/25 mg TAF Tablets in Bottles at 30 °C/75%RH

Test	Specification Limit	95% Confidence Limit(s) (closest to specification limit)	
		FTC	TAF
Assay (%)	95.0 – 105.0 (FTC) 90.0 – 105.0 (TAF)	99.6 – 100.5 Common Slope Different Intercepts	96.8 – 97.8 Common Slope Different Intercepts
Total Degradation (%)	NMT 1.2 (FTC) NMT 6.0 (TAF)	N/A	2.2 Different Slopes Different Intercepts
Main Degradants (%)	NMT 3.00 (PMPA)	N/A	1.03 Different Slopes Different Intercepts
	NMT 2.50 (PMPA Anhydride)	N/A	0.79 Different Slopes Different Intercepts
Water Content (%)	NMT 4.0	1.1 Common Slope Common Intercept	

NMT = Not More Than

Table 10: Analysis at 12 Months Beyond the Most Recent Time Point Available for DESCOVY 120 mg FTC/15 mg TAF Tablets in Bottles at 25 °C/60%RH

Test	Specification Limit	95% Confidence Limit(s) (closest to specification limit)	
		FTC	TAF
Assay (%)	95.0 – 105.0 (FTC) 90.0 – 105.0 (TAF)	99.5 – 101.9 Common Slope Common Intercept	97.0 – 99.8 Common Slope Different Intercepts
Total Degradation (%)	NMT 1.2 (FTC) NMT 6.0 (TAF)	N/A	1.3 Common Slope Common Intercept
Main Degradants (%)	NMT 3.00 (PMPA)	N/A	0.60 Common Slope Common Intercept
	NMT 2.50 (PMPA Anhydride)	N/A	0.41 Different Slopes Different Intercepts
Water Content (%)	NMT 4.0	0.8 Common Slope Common Intercept	

NMT = Not More Than

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3 STATISTICAL ANALYSIST FOR KEY STABILITY INDICATORS FOR PRODUCT

3.1 DESCOVY 200 mg FTC/10 mg TAF in Bottles at 30 °C/75%RH

3.1.1 Percent Assay (30 °C/75%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and different intercepts for FTC assay. The predicted assay value and confidence interval lower and upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 11.

Table 11: FTC Assay Real Time Data at 36 Months (Specification: 95.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CCDZB	60^	100.2	*	*	*	*
6446201	48^	99.3	*	*	*	*
CFHWP	48^	99.3	*	*	*	*
CHHPX	36	100.5	*	*	*	*
CPPGG	18	N/A	30	100.1	97.2	99.7

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.
^Note: Time point pull date occurred, but samples were not tested. The 48- and 60-month time points are optional time points and since shelf-life will not be extended beyond 36 months, testing was not performed.

The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for TAF assay. The predicted assay value and confidence interval lower and upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 12.

Table 12: TAF Assay Real Time Data at 36 Months (Specification: 90.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CCDZB	60^	95.2	*	*	*	*
6446201	48^	94.5	*	*	*	*
CFHWP	48^	94.1	*	*	*	*
CHHPX	36	94.3	*	*	*	*
CPPGG	18	N/A	30	97.2	95.2	99.2

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.
^Note: Time point pull date occurred, but samples were not tested. The 48- and 60-month time points are optional time points and since shelf-life will not be extended beyond 36 months, testing was not performed.

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3.1.2 Total Degradation (30 °C/75%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for TAF total degradation. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 13.

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC total degradation is therefore not provided.

Table 13: TAF Total Degradation Product Content Real Time Data at 36 Months (Specification: NMT 6.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CCDZB	60^	3.0	*	*	*
6446201	48^	3.7	*	*	*
CFHWP	48^	3.8	*	*	*
CHHPX	36	4.0	*	*	*
CPPGG	18	N/A	30	2.8	3.2

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.
^Note: Time point pull date occurred, but samples were not tested. The 48- and 60-month time points are optional time points and since shelf-life will not be extended beyond 36 months, testing was not performed.

3.1.3 Main Degradants (30 °C/75%RH)

TAF

PMPA is a major degradation product of TAF. The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for PMPA. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 14.

Table 14: PMPA Content Real Time Data at 36 Months (Specification: NMT 3.00%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CCDZB	60^	1.19	*	*	*
6446201	48^	1.43	*	*	*
CFHWP	48^	1.48	*	*	*
CHHPX	36	1.59	*	*	*
CPPGG	18	N/A	30	1.24	1.37

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.
^Note: Time point pull date occurred, but samples were not tested. The 48- and 60-month time points are optional time points and since shelf-life will not be extended beyond 36 months, testing was not performed.

PMPA Anhydride is a major degradation product of TAF. The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts

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for PMPA Anhydride. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 15.

Table 15: PMPA Anhydride Content Real Time Data at 36 Months (Specification: NMT 2.50%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CCDZB	60^	1.26	*	*	*
6446201	48^	1.48	*	*	*
CFHWP	48^	1.63	*	*	*
CHHPX	36	1.59	*	*	*
CPPGG	18	N/A	30	0.92	1.05

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.
^Note: Time point pull date occurred but samples were not tested. The 48- and 60-month time points are optional time points and since shelf-life will not be extended beyond 36 months, testing was not performed.

FTC

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC degradants is therefore not provided.

3.1.4 Water Content (30 °C/75%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and common intercept for water content. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 16.

Table 16: Water Content Real Time Data at 36 Months (Specification: NMT 4.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CCDZB	60^	1.1	*	*	*
6446201	48^	1.2	*	*	*
CFHWP	48^	1.1	*	*	*
CHHPX	36	1.2	*	*	*
CPPGG	18	N/A	30	1.0	1.1

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.
^Note: Time point pull date occurred but samples were not tested. The 48- and 60-month time points are optional time points and since shelf-life will not be extended beyond 36 months, testing was not performed.

3.1.5 Dissolution Individual Results at 30 Minutes (30 °C/75%RH)

For dissolution, the individual dissolution results for all DESCOVY 200 mg FTC/10 mg TAF tablets in bottles at the 30 °C/75% RH storage condition are assessed using the LIMS dissolution range chart. For both FTC and TAF dissolution, all lots on stability passed stage 1 at 30 minutes so no stage 2 testing was performed.

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Output for dissolution analysis includes the following:

LIMS dissolution range chart with individual dissolution results, along with Q, stage 1, stage 2, and stage 3 reference lines for each lot at each time point at each condition.

Refer to Figure 1 and Figure 2 (FTC and TAF, respectively) for all dissolution range charts for DESCOVY 200 mg FTC/10 mg TAF tablets in bottles at the 30 °C/75% RH storage condition.

3.2 DESCOVY 200 mg FTC/25 mg TAF in Bottles at 30 °C/75%RH

3.2.1 Percent Assay (30 °C/75%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and different intercepts for FTC assay. The predicted assay value and confidence interval lower and upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 17.

Table 17: Prediction of FTC Assay at 12 Months Beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: 95.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
6255301	48	99.9	*	*	*	*
CCPBW	48	99.5	*	*	*	*
6583901	48	100.4	*	*	*	*
CFSPX	48	99.5	*	*	*	*
025624	48	100.0	*	*	*	*
486327	48	99.7	*	*	*	*
486328	48	100.8	*	*	*	*
486329	48	100.6	*	*	*	*
7246201A	18	N/A	30	100.0	99.6	100.5

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and different intercepts for TAF assay. The predicted assay value and confidence interval lower and upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 18.

Table 18: Prediction of TAF Assay at 12 Months Beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: 90.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
6255301	48	96.9	*	*	*	*
CCPBW	48	95.4	*	*	*	*
6583901	48	96.7	*	*	*	*

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Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CFSPX	48	95.5	*	*	*	*
025624	48	94.4	*	*	*	*
486327	48	94.5	*	*	*	*
486328	48	95.5	*	*	*	*
486329	48	96.3	*	*	*	*
7246201A	18	N/A	30	97.3	96.8	97.8

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

3.2.2 Total Degradation (30 °C/75%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for TAF total degradation. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 19.

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC total degradation is therefore not provided.

Table 19: Prediction of TAF Total Degradation Product Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 6.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
6255301	48	2.8	*	*	*
CCPBW	48	2.8	*	*	*
6583901	48	2.9	*	*	*
CFSPX	48	3.1	*	*	*
025624	48	3.3	*	*	*
486327	48	3.1	*	*	*
486328	48	3.0	*	*	*
486329	48	2.8	*	*	*
7246201A	18	N/A	30	1.9	2.2

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

3.2.3 Main Degradants (30 °C/75%RH)

TAF

PMPA is a major degradation product of TAF. The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for PMPA. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 20.

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Table 20: Prediction of PMPA Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 3.00%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
6255301	48	1.25	*	*	*
CCPBW	48	1.21	*	*	*
6583901	48	1.33	*	*	*
CFSPX	48	1.46	*	*	*
025624	48	1.34	*	*	*
486327	48	1.34	*	*	*
486328	48	1.36	*	*	*
486329	48	1.31	*	*	*
7246201A	18	N/A	30	0.88	1.03

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

PMPA Anhydride is a major degradation product of TAF. The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for PMPA Anhydride. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 21.

Table 21: Prediction PMPA Anhydride Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 2.50%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
6255301	48	1.10	*	*	*
CCPBW	48	1.03	*	*	*
6583901	48	1.44	*	*	*
CFSPX	48	1.19	*	*	*
025624	48	1.34	*	*	*
486327	48	1.23	*	*	*
486328	48	1.16	*	*	*
486329	48	1.11	*	*	*
7246201A	18	N/A	30	0.62	0.79

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

FTC

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC degradants is therefore not provided.

3.2.4 Water Content (30 °C/75%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and common intercept for water content. The predicted value and confidence

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interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 30 °C/75% RH storage condition is provided in Table 22.

Table 22: Prediction of Water Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 4.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
6255301	48	1.1	*	*	*
CCPBW	48	1.0	*	*	*
6583901	48	1.1	*	*	*
CFSPX	48	1.1	*	*	*
025624	48	1.1	*	*	*
486327	48	1.0	*	*	*
486328	48	1.0	*	*	*
486329	48	1.0	*	*	*
7246201A	18	N/A	30	0.9	1.0

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

3.2.5 Dissolution Individual Results at 30 Minutes (30 °C/75%RH)

For dissolution, the individual dissolution results for all DESCOVY 200 mg FTC/25 mg TAF tablets in bottles at the 30 °C/75% RH storage condition are assessed using the LIMS dissolution range chart. For both FTC and TAF dissolution, all lots on stability passed stage 1 at 30 minutes so no stage 2 testing was performed.

Output for dissolution analysis includes the following:

LIMS dissolution range chart with individual dissolution results, along with Q, stage 1, stage 2, and stage 3 reference lines for each lot at each time point at each condition.

Refer to Figure 3 and Figure 4 (FTC and TAF, respectively) for all dissolution range charts for DESCOVY 200 mg FTC/25 mg TAF tablets in bottles at the 30 °C/75% RH storage condition.

3.3 DESCOVY 200 mg FTC/25 mg TAF in Blister Packs at 25 °C/60%RH

3.3.1 Percent Assay (25 °C/60%RH)

There are no lots with greater than 5 data points that have not reached the shelf-life time point. Therefore, statistical analysis with extrapolation of 12 months for predictions is not performed. The real time data for FTC assay at 36 months for each lot at 25 °C/60% RH storage conditions are reported in Table 23.

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Table 23: Prediction of FTC Assay at 12 Months Beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: 95.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CBHKGA	60	99.1	*	*	*	*
CCZWWA	48	100.8	*	*	*	*
CCZWXA	48	99.3	*	*	*	*
6351901A	48	99.4	*	*	*	*
6647301A	48	100.4	*	*	*	*
6830101A	36	99.3	*	*	*	*

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.

There are no lots with greater than five (5) data points that have not reached the shelf-life time point. Therefore, statistical analysis with extrapolation of 12 months for predictions is not performed. The real time data for TAF assay at 36 months for each lot at 25 °C/60% RH storage condition are reported in Table 24.

Table 24: Prediction of TAF Assay at 12 Months Beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: 90.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CBHKGA	60	98.6	*	*	*	*
CCZWWA	48	99.5	*	*	*	*
CCZWXA	48	97.1	*	*	*	*
6351901A	48	98.7	*	*	*	*
6647301A	48	99.3	*	*	*	*
6830101A	36	98.4	*	*	*	*

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.

3.3.2 Total Degradation (25 °C/60%RH)

There are no lots with greater than 5 data points that have not reached the shelf-life time point. Therefore, statistical analysis with extrapolation of 12 months for predictions is not performed. The real time data for TAF total degradation at 36 months for each lot at 25 °C/60% RH storage condition is reported in Table 25.

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC total degradation is therefore not provided.

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Table 25: Prediction of TAF Total Degradation Product Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 6.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CBHKGA	60	0.9	*	*	*
CCZWWA	48	1.1	*	*	*
CCZWXA	48	1.1	*	*	*
6351901A	48	1.0	*	*	*
6647301A	48	0.9	*	*	*
6830101A	36	1.0	*	*	*

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.

3.3.3 Main Degradants (25 °C/60%RH)

TAF

PMPA is a major degradation product of TAF. There are no lots with greater than 5 data points that have not reached the shelf-life time point. Therefore, statistical analysis with extrapolation of 12 months for predictions is not performed. The real time data for PMPA at 36 months for each lot at 25 °C/60% RH storage condition is reported in Table 26.

Table 26: Prediction of PMPA Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 3.00%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CBHKGA	60	0.44	*	*	*
CCZWWA	48	0.55	*	*	*
CCZWXA	48	0.51	*	*	*
6351901A	48	0.49	*	*	*
6647301A	48	0.48	*	*	*
6830101A	36	0.50	*	*	*

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.

PMPA Anhydride is a major degradation product of TAF. There are no lots with greater than 5 data points that have not reached the shelf-life time point. Therefore, statistical analysis with extrapolation of 12 months for predictions is not performed. The real time data for PMPA Anhydride at 36 months for each lot at 25 °C/60% RH storage condition is reported in Table 27.

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Table 27: Prediction PMPA Anhydride Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 2.50%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CBHKGA	60	0.30	*	*	*
CCZWWA	48	0.36	*	*	*
CCZWXA	48	0.33	*	*	*
6351901A	48	0.31	*	*	*
6647301A	48	0.29	*	*	*
6830101A	36	0.30	*	*	*

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.

FTC

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC degradants is therefore not provided.

3.3.4 Water Content (25 °C/60%RH)

There are no lots with greater than 5 data points that have not reached the shelf-life time point. Therefore, statistical analysis with extrapolation of 12 months for predictions is not performed. The real time data for water content at 36 months for each lot at 25 °C/60% RH storage condition is reported in Table 28.

Table 28: Prediction of Water Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 4.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 36 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CBHKGA	60	0.6	*	*	*
CCZWWA	48	0.6	*	*	*
CCZWXA	48	0.6	*	*	*
6351901A	48	0.6	*	*	*
6647301A	48	0.6	*	*	*
6830101A	36	0.7	*	*	*

*Note: Real time data at 36 months reported. No projection required for lots tested at the shelf-life of 36 months.

3.3.5 Dissolution Individual Results at 30 Minutes (25 °C/60%RH)

For dissolution, the individual dissolution results for all DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs at the 25 °C/60% RH storage condition are assessed using the LIMS dissolution range chart. For both FTC and TAF dissolution, all lots on stability passed stage 1 at 30 minutes so no stage 2 testing was performed.

Output for dissolution analysis includes the following:

LIMS dissolution range chart with individual dissolution results, along with Q, stage 1, stage 2, and stage 3 reference lines for each lot at each time point at each condition.

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Refer to Figure 5 and Figure 6 (FTC and TAF, respectively) for all dissolution range charts for DESCOVY 200 mg FTC/25 mg TAF tablets in blister packs at the 25 °C/60% RH storage condition.

3.4 DESCOVY 120 mg FTC/15 mg TAF in Bottles at 25 °C/60%RH

3.4.1 Percent Assay (25 °C/60%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and common intercepts for FTC assay. The predicted assay value and confidence interval lower and upper bound predictions at 12 months beyond the most recent time point available for each lot at 25 °C/60% RH storage condition is provided in Table 29.

Table 29: Prediction of FTC Assay at 12 Months Beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: 95.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CHZBB	36	*	48	100.7	99.5	101.9
CHZBD	36	*	48	100.7	99.5	101.9
CHZBF	36	*	48	100.7	99.5	101.9

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and different intercepts for TAF assay. The predicted assay value and confidence interval lower and upper bound predictions at 12 months beyond the most recent time point available for each lot at 25 °C/60% RH storage condition is provided in Table 30.

Table 30: Prediction of TAF Assay at 12 Months Beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: 90.0%-105.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Lower Bound (95% Confidence Interval) %	Upper Bound (95% Confidence Interval) %
CHZBB	36	*	48	98.0	97.0	99.0
CHZBD	36	*	48	98.8	97.8	99.8
CHZBF	36	*	48	98.3	97.3	99.2

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

3.4.2 Total Degradation (25 °C/60%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and common intercepts for TAF total degradation. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 25 °C/60% RH storage condition is provided in Table 31.

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC total degradation is therefore not provided.

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Table 31: Prediction of TAF Total Degradation Product Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 6.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CHZBB	36	*	48	1.2	1.3
CHZBD	36	*	48	1.2	1.3
CHZBF	36	*	48	1.2	1.3

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

3.4.3 Main Degradants (25 °C/60%RH)

TAF

PMPA is a major degradation product of TAF. The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and common intercepts for PMPA. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 25 °C/60% RH storage condition is provided in Table 32.

Table 32: Prediction of PMPA Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 3.00%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CHZBB	36	*	48	0.55	0.60
CHZBD	36	*	48	0.55	0.60
CHZBF	36	*	48	0.55	0.60

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

PMPA Anhydride is a major degradation product of TAF. The best fit model for pooling of data accepted at the significance level of 0.25 is different slopes and different intercepts for PMPA Anhydride. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 25 °C/60% RH storage condition is provided in Table 33.

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Table 33: Prediction PMPA Anhydride Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 2.50%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CHZBB	36	*	48	0.38	0.41
CHZBD	36	*	48	0.37	0.40
CHZBF	36	*	48	0.35	0.37

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

FTC

There was no degradation reported for FTC so statistical analysis is not required in accordance with ICH Q1E. Evaluation of FTC degradants is therefore not provided.

3.4.4 Water Content (25 °C/60%RH)

The best fit model for pooling of data accepted at the significance level of 0.25 is common slope and common intercept for water content. The predicted value and confidence interval upper bound predictions at 12 months beyond the most recent time point available for each lot at 25 °C/60% RH storage condition is provided in Table 34.

Table 34: Prediction of Water Content at 12 Months beyond the Most Recent Time Point Available Up to the Shelf-life (Specification: NMT 4.0%)

Lot Number	Most Recent Time Point Available Months	Real Time Data at 48 Months	12 Month Projection Month	Prediction %	Upper Bound (95% Confidence Interval) %
CHZBB	36	*	48	0.4	0.8
CHZBD	36	*	48	0.4	0.8
CHZBF	36	*	48	0.4	0.8

*Note: Real time data at 48 months reported. No projection required for lots tested at the shelf-life of 48 months.

3.4.5 Dissolution Individual Results at 30 Minutes (25 °C/60%RH)

For dissolution, the individual dissolution results for all DESCOVY 120 mg FTC/15 mg TAF tablets in bottles at the 25 °C/60% RH storage condition are assessed using the LIMS dissolution range chart. As shown in Table 35, in total, one time point for one commercial lot went to stage 2 testing for TAF dissolution during this review period. No lots on stability went beyond stage 2 USP requirement (where average of 12 tablets is NLT Q=80% at 30 minutes and no tablet is less than Q – 15 (65%, Stage 2).

Table 35: Dissolution Summary for Commercial Lots Tested beyond Stage 1

Lot Number	Manufacturer	Time Points (Months)	Stage Tested	Testing Attributes
CHZBB	Patheon TRO	36	2	TAF

Output for dissolution analysis includes the following:

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LIMS dissolution range chart with individual dissolution results, along with Q, stage 1, stage 2, and stage 3 reference lines for each lot at each time point at each condition.

Refer to Figure 7 and Figure 8 (FTC and TAF, respectively) for all dissolution range charts for DESCOVY 120 mg FTC/15 mg TAF tablets in bottles at the 25 °C/60% RH storage condition

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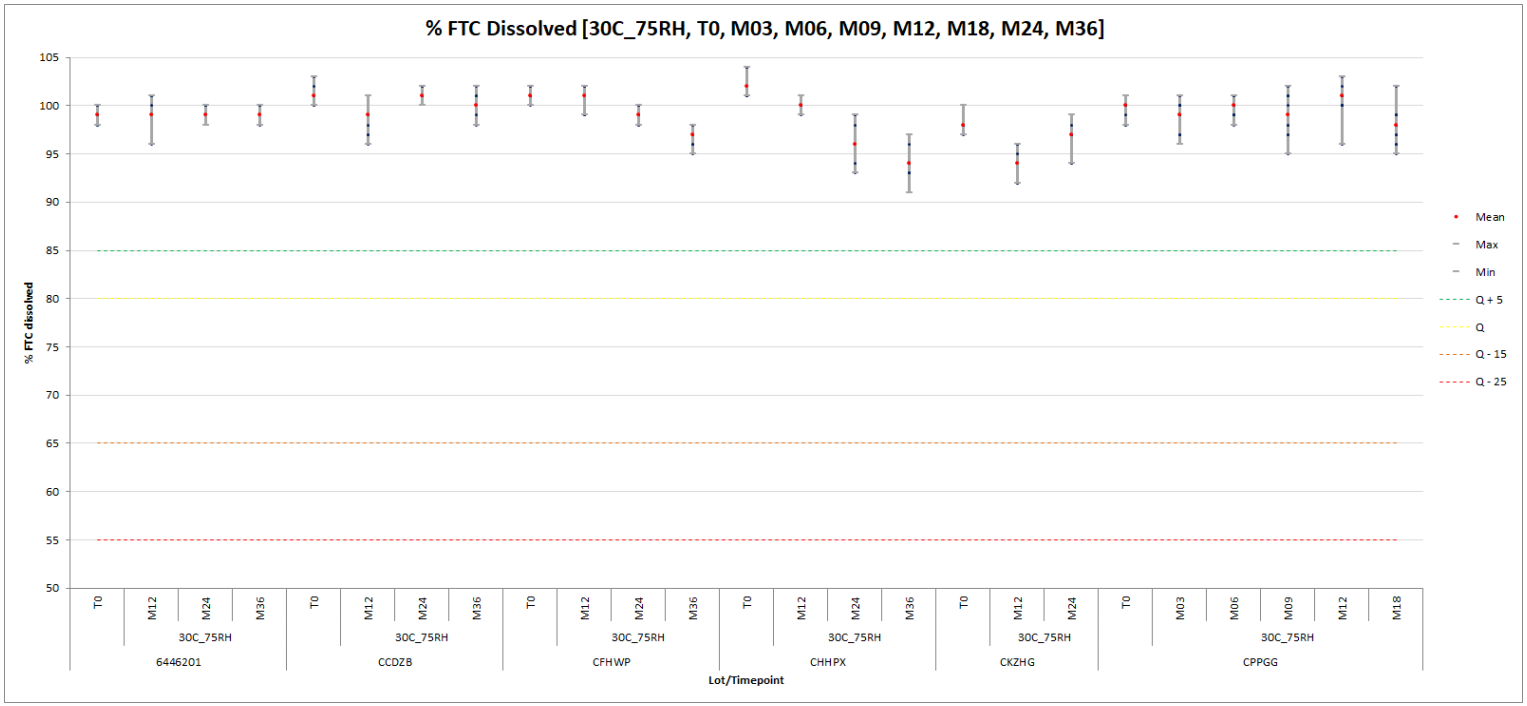
4 DISSOLUTION ANALYSIS

4.1 DESCOVY 200 mg FTC/10 mg TAF in Bottles Stored at 30 °C/75%RH

4.1.1 FTC Dissolution Individual Results Summary (30 °C/75%RH)

Figure 1: FTC Dissolution Individual Results Summary (30 °C/75%RH)



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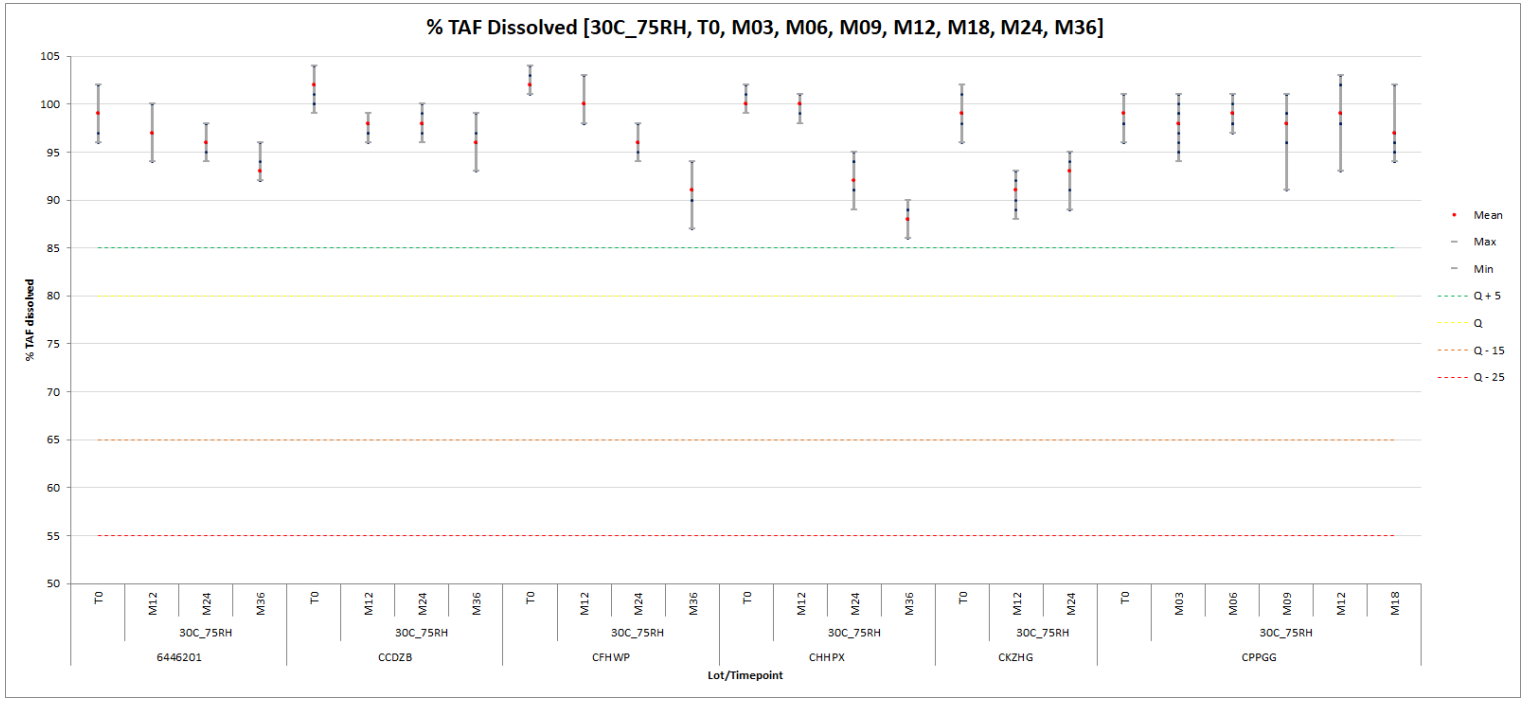
4.1.1 TAF Dissolution Individual Results Summary (30 °C/75%RH)

Figure 2: TAF Dissolution Individual Results Summary (30 °C/75%RH)



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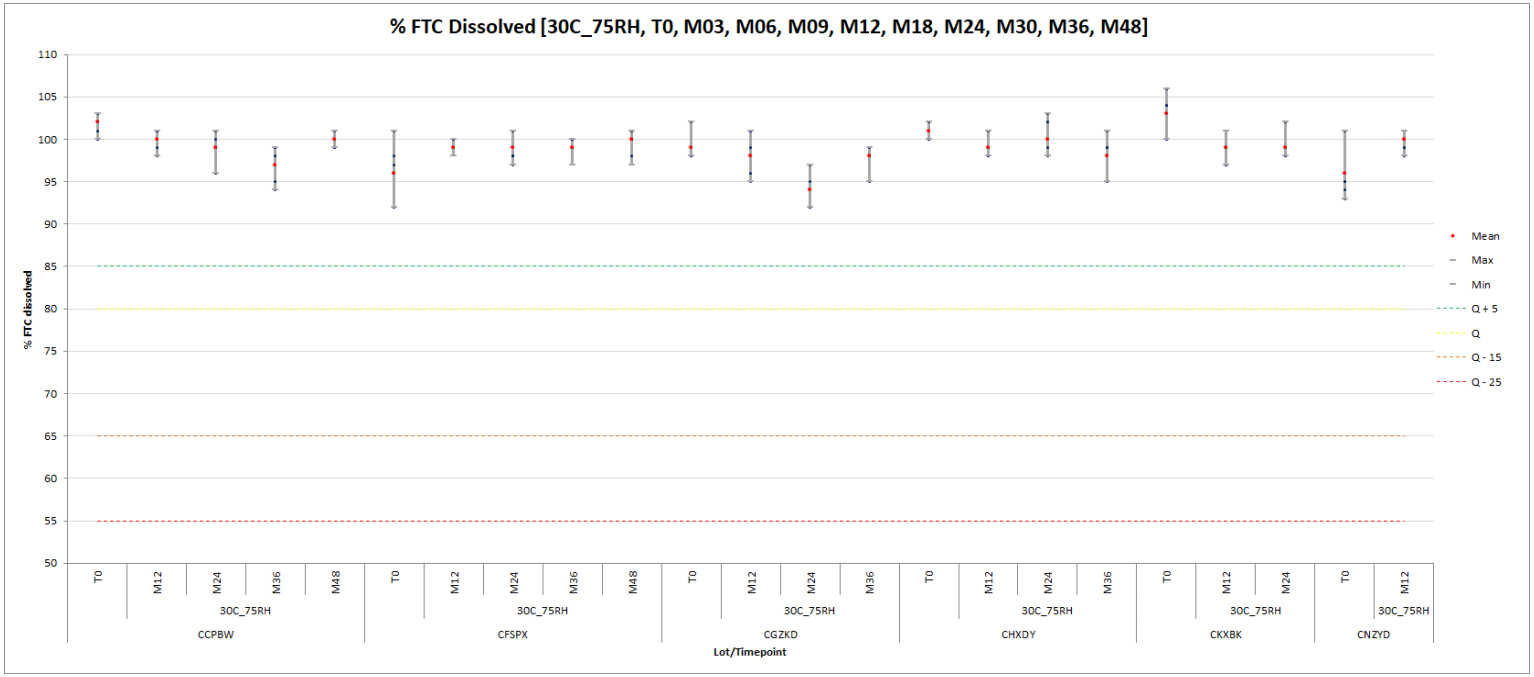
4.2 DESCOVY 200 mg FTC/25 mg TAF in Bottles Stored at 30 °C/75%RH

4.2.1 FTC Dissolution Individual Results Summary (30 °C/75%RH)

Figure 3: FTC Dissolution Individual Results Summary (30 °C/75%RH)



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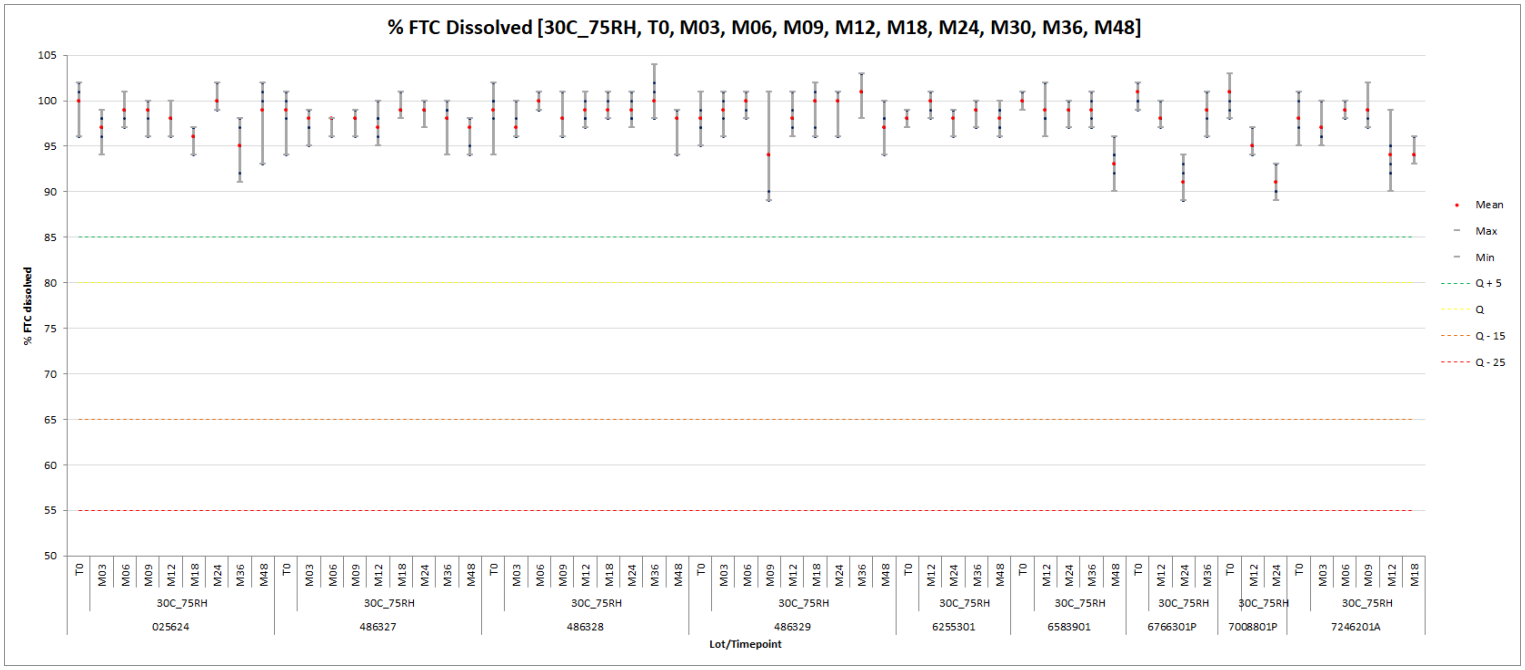
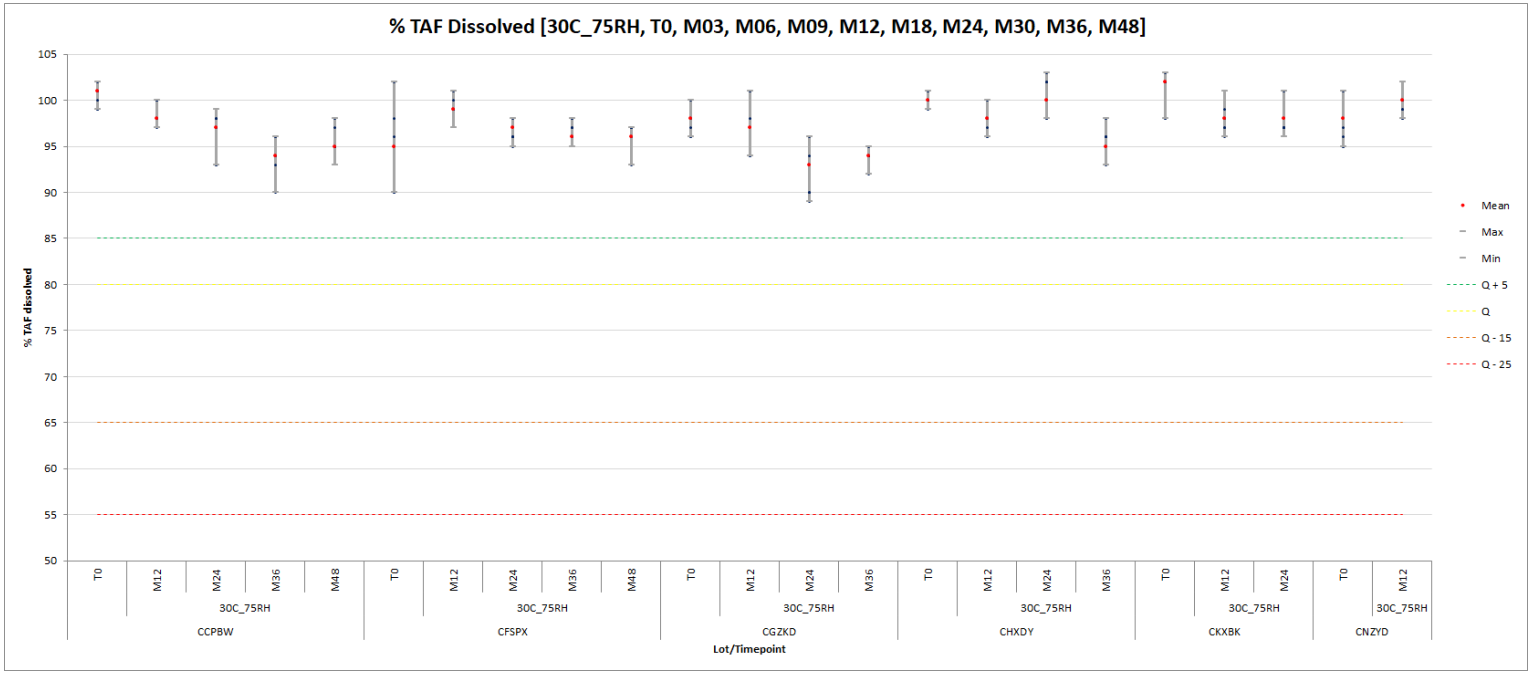
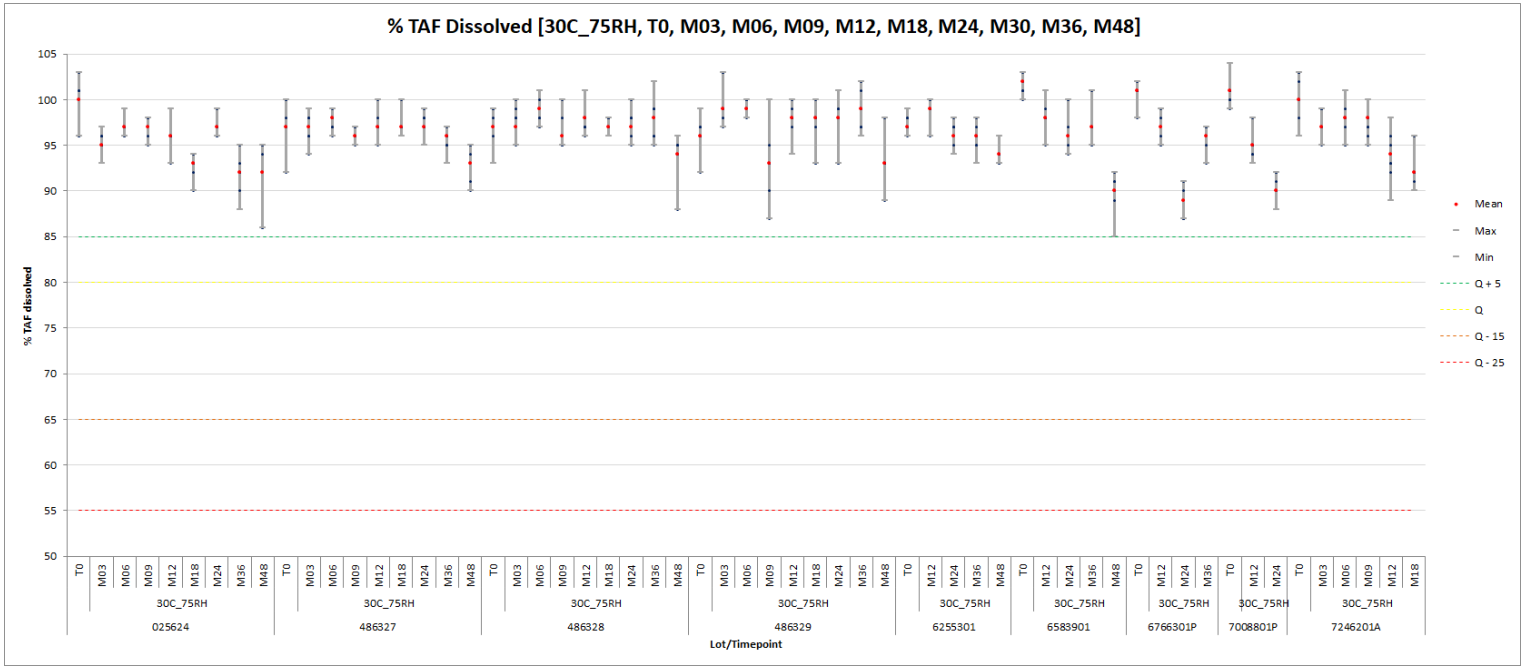


4.2.2 TAF Dissolution Individual Results Summary (30 °C/75%RH)

Figure 4: TAF Dissolution Individual Results Summary (30 °C/75%RH)





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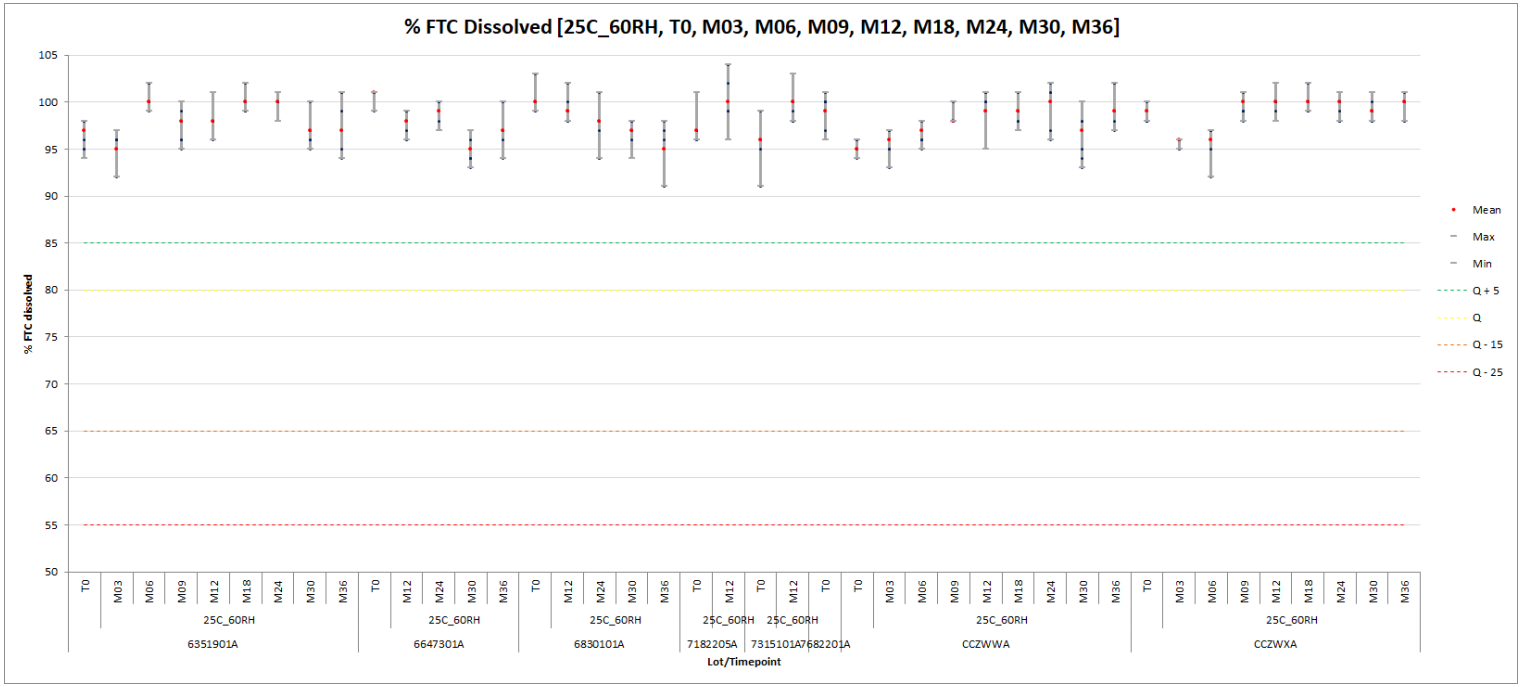
4.3 DESCOVY 200 mg FTC/25 mg TAF in Blister Packs Stored at 25 °C/60%RH

4.3.1 FTC Dissolution Individual Results Summary (25 °C/60%RH)

Figure 5: FTC Dissolution Individual Results Summary (25 °C/60%RH)



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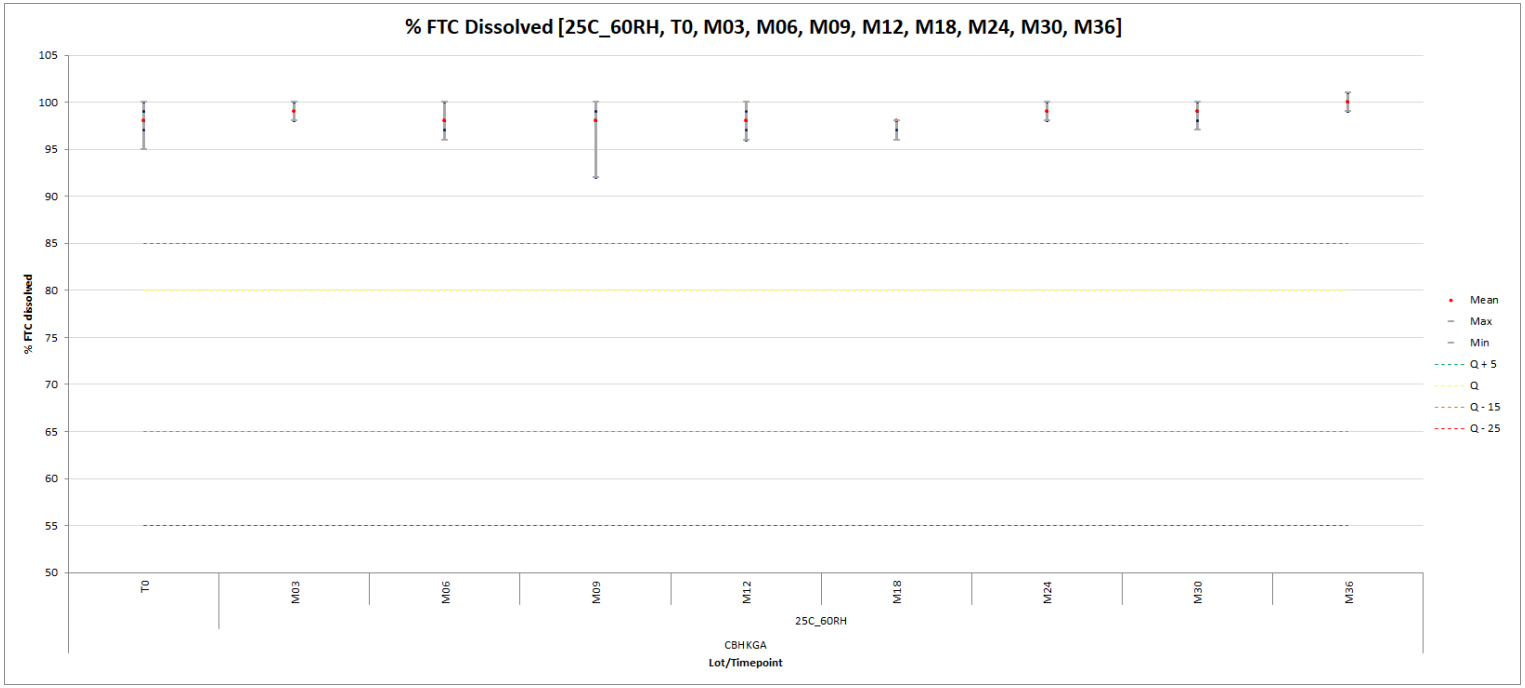

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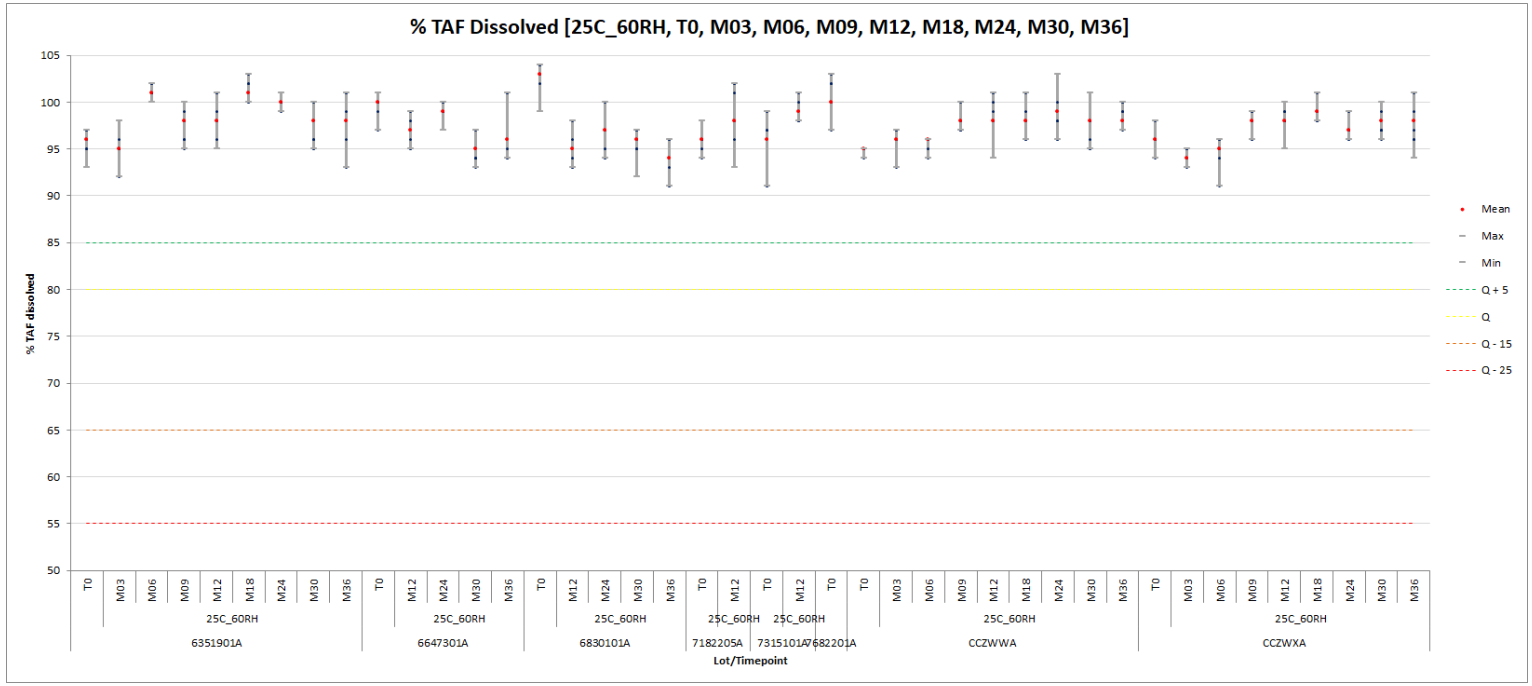
4.3.2 TAF Dissolution Individual Results Summary (25 °C/60%RH)

Figure 6: TAF Dissolution Individual Results Summary (25 °C/60%RH)



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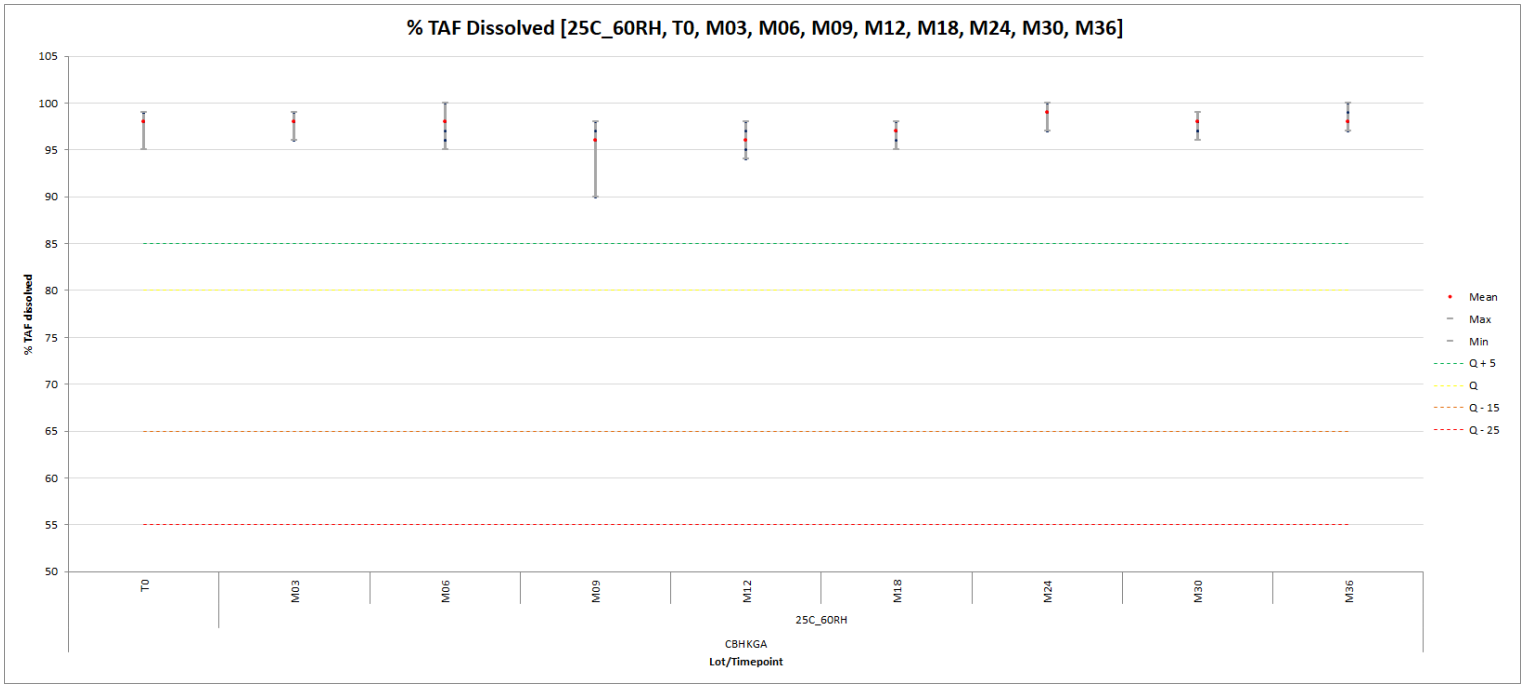
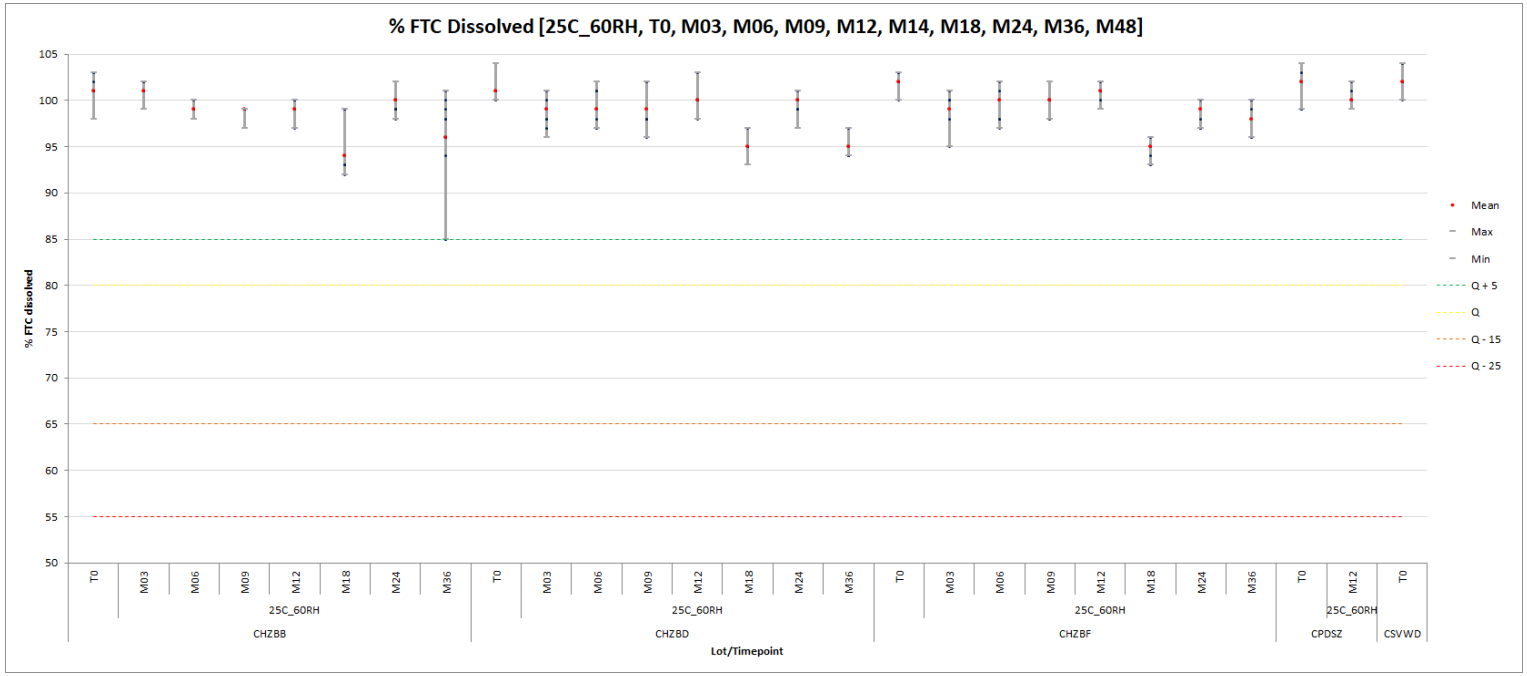


4.4 DESCOVY 120 mg FTC/15 mg TAF in Bottles Stored at 25 °C/60%RH

4.4.1 FTC Dissolution Individual Results Summary (25 °C/60%RH)

Figure 7: FTC Dissolution Individual Results Summary (25 °C/60%RH)



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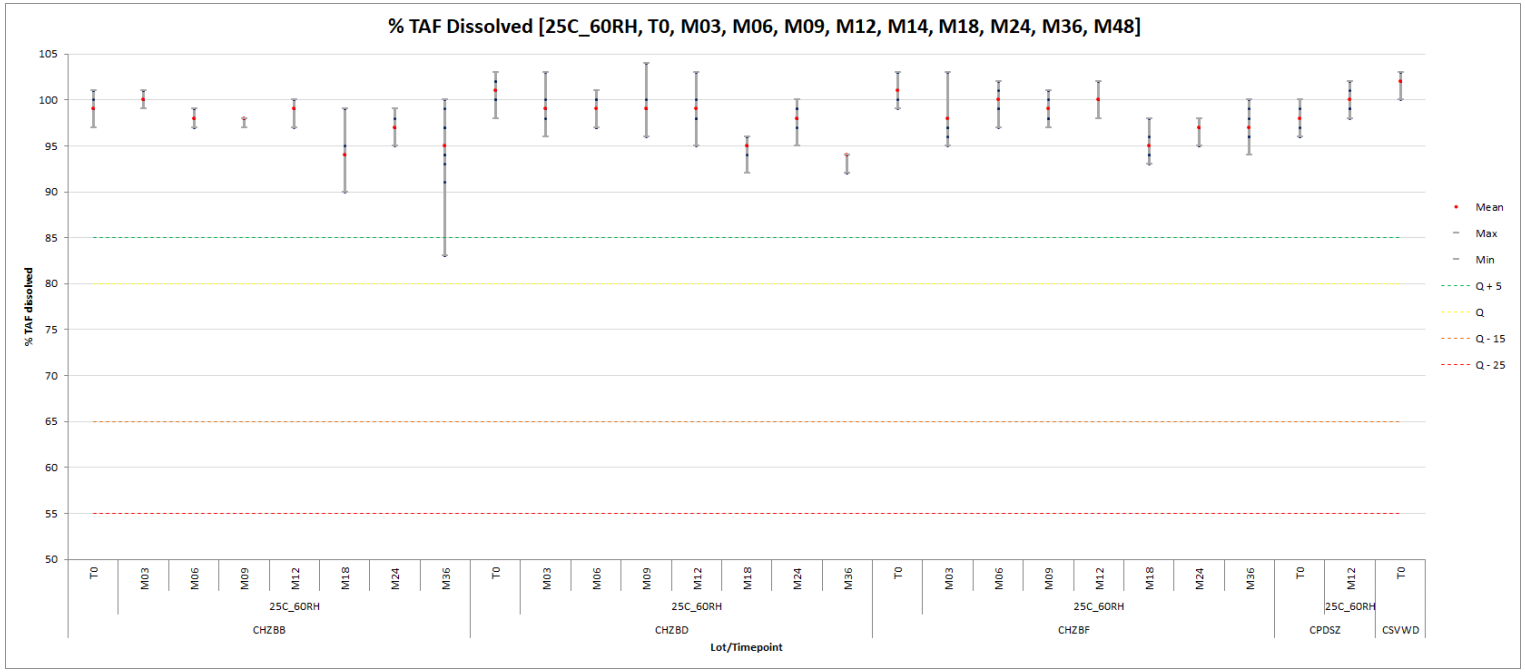
4.4.2 TAF Dissolution Individual Results Summary (25 °C/60%RH)

Figure 8: TAF Dissolution Individual Results Summary (25 °C/60%RH)



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Attachment 8: Release and In Process Data from Previous Review Period

Table 1: Lots Trended – DESCOVY 200 mg FTC/25 mg TAF - Rottendorf

Bulk Lot Number	Manufacture Date	BTSK Lot Number	BTSK Release Date	Comment
7560304	15-Nov-23	7560304P	N/A	None
7591505	05-Dec-23	7591505P	N/A	None
7647005	15-Feb-24	N/A	N/A	None
7682301	27-Feb-24	7682301P	31-May-24	None
7682302	27-Feb-24	7682302P	28-May-24	None
7682303	28-Feb-24	7682303P	23-May-24	None
7682304	28-Feb-24	7682304P	20-May-24	None
7682201	04-Mar-24	N/A	N/A	None
7682305	04-Mar-24	7682305P	20-May-24	None
7682306	04-Mar-24	7682306P	17-Jun-24	None
7682202	12-Mar-24	N/A	N/A	None
7682203	12-Mar-24	N/A	N/A	None
7682204	12-Mar-24	N/A	N/A	None
7682205	25-Mar-24	N/A	N/A	None
7682206	25-Mar-24	N/A	N/A	None
7682207	25-Mar-24	N/A	N/A	None
7682208	25-Mar-24	N/A	N/A	None
7716901	02-Apr-24	N/A	N/A	None
7717001	02-Apr-24	7717001P	25-Jun-24	None
7717002	02-Apr-24	7717002P	21-Jun-24	None
7717003	02-Apr-24	7717003P	11-Jul-24	None

Table 2: Lots Trended – DESCOVY 120 mg FTC/15 mg TAF – Patheon TRO

Bulk Lot Number	Manufacture Date	BTSK Lot Number	BTSK Release Date	Comment
CSVVX	**20-Feb-24**	CSVWD	26-Apr-24	None

Table 3: In-Process Data for DESCOVY 200 mg FTC/25 mg TAF - Rottendorf

Mfg. Site	Test	Limits	Mean	Minimum	Maximum	Chart Reference
Rottendorf	Tablet Weight during Compression (mg)	340 – 360	350	349	351	Chart 1
	Tablet Hardness during Compression (N)	98 - 147	120	109	127	Chart 2

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Table 4: In-Process Data for DESCOVY 120 mg FTC/15 mg TAF – Patheon TRO

Lot Number	Individual Tablet Weight during Compression (mg)	Average Tablet Weight during Compression (mg)	Tablet Hardness during Compression (kp)
	200 – 220	204 – 216	4 - 10
CSVVX	206 – 218	211	7.3

Table 5: Release Data Summary for DESCOVY 200 mg FTC/25 mg TAF - Rottendorf

Mfg. Site	Test	Limits	Mean	Minimum	Maximum	Chart Reference
Rottendorf	Assay – FTC (%)	95.0 – 105.0	100.0	99.2	101.0	Chart 3
	Assay – TAF (%)	95.0 – 105.0	98.9	97.8	100.2	Chart 4
	Total FTC Degradation (%)	NMT 0.5	0.0	0.0	0.0	Chart 5
	Total TAF Degradation (%)	NMT 3.5	0.4	0.4	0.5	Chart 6
	Dissolution (%) – FTC (30 minutes)	Q = 80	100	98	101	Chart 7
	Dissolution (%) – TAF (30 minutes)	Q = 80	99	97	101	Chart 8
	Content Uniformity – FTC	NMT 15.0	2.3	1.3	3.1	Chart 9
	Content Uniformity – TAF	NMT 15.0	2.9	2.0	4.1	Chart 10
	Water Content (%)	NMT 4.5	1.4	1.2	1.6	Chart 11

NMT = Not More Than

Table 6: Release Data for DESCOVY 120 mg FTC/15 mg TAF – Patheon TRO

Lot Number	Assay (%)		Total Degradation (%)		Dissolution (%) (30 minutes)		Content Uniformity		Water Content (%)
	FTC	TAF	FTC	TAF	FTC	TAF	FTC	TAF	
	95.0 – 105.0		NMT 0.5	NMT 3.5	Q = 80		NMT 15.0		NMT 4.5
CSVVX	100.8	98.2	0	0.3	102	102	1.5	2.1	1.3

NMT = Not More Than

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Chart 1: Tablet Weight during Compression – Rottendorf (200 mg FTC/25 mg TAF)

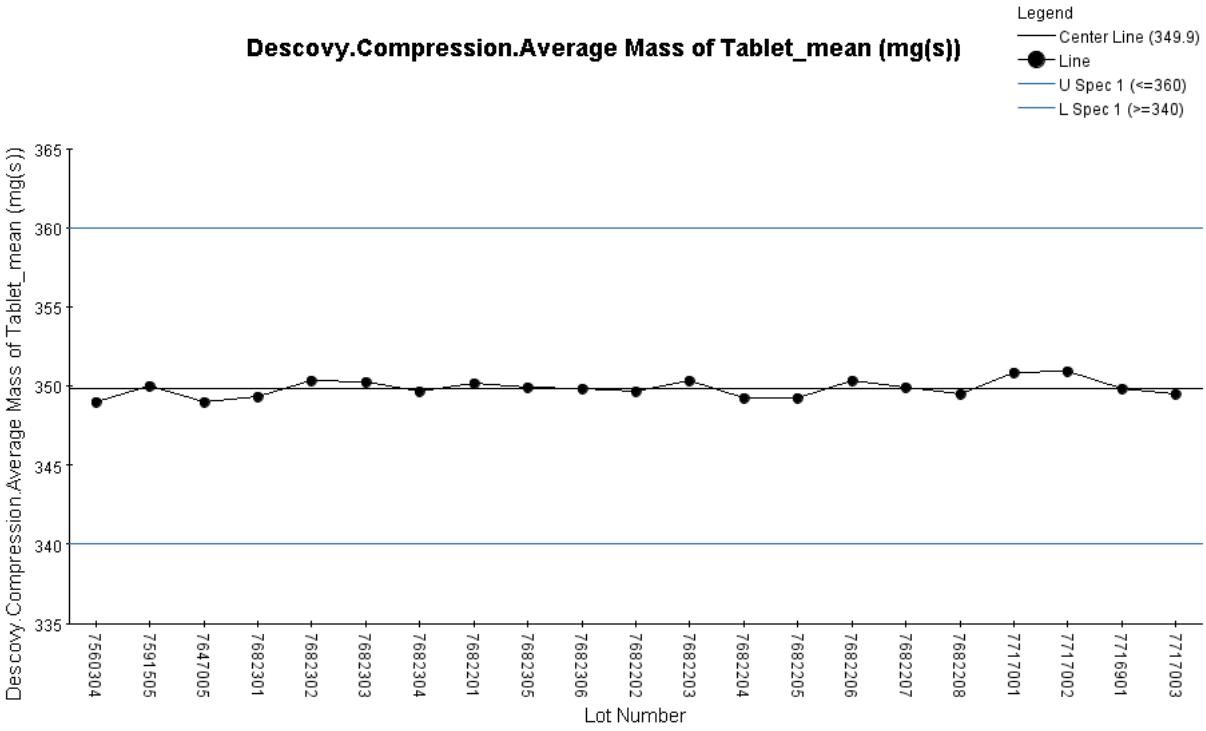

Chart 2: Tablet Hardness during Compression – Rottendorf (200 mg FTC/25 mg TAF)

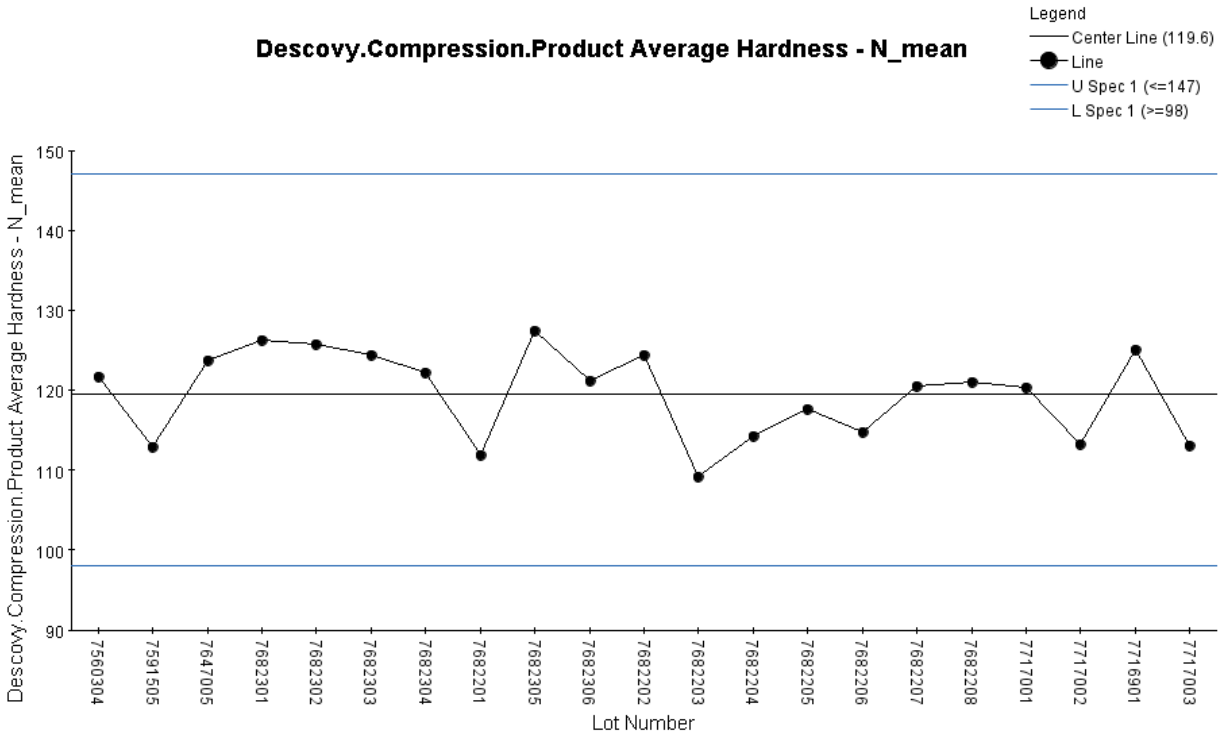

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Chart 3: FTC Assay – Rottendorf (200 mg FTC/25 mg TAF)

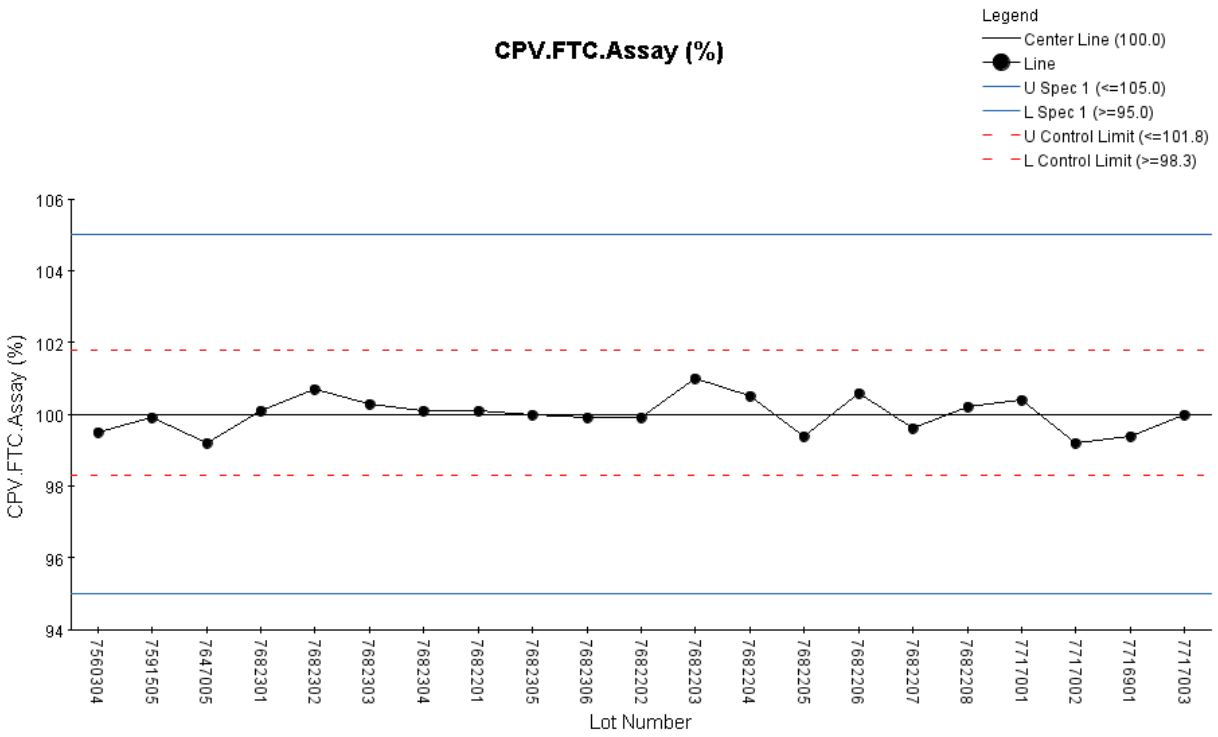

Chart 4: TAF Assay – Rottendorf (200 mg FTC/25 mg TAF)

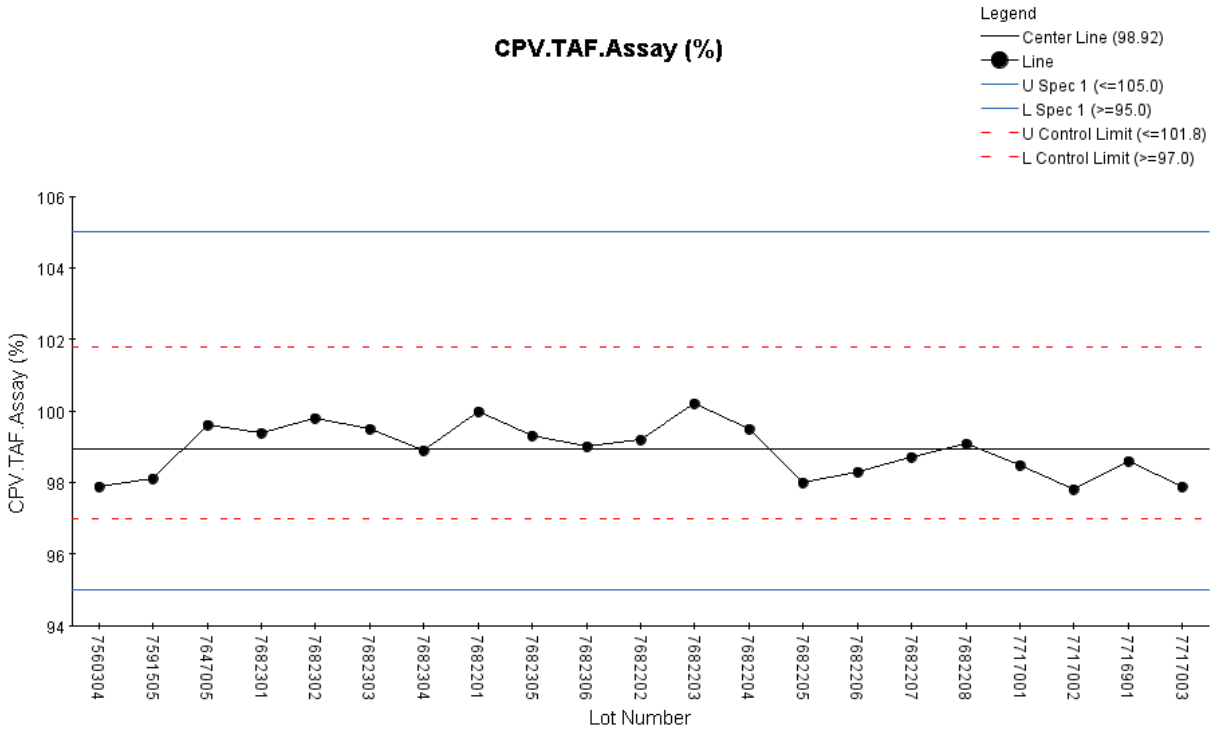

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Chart 5: Total FTC Degradants – Rottendorf (200 mg FTC/25 mg TAF)

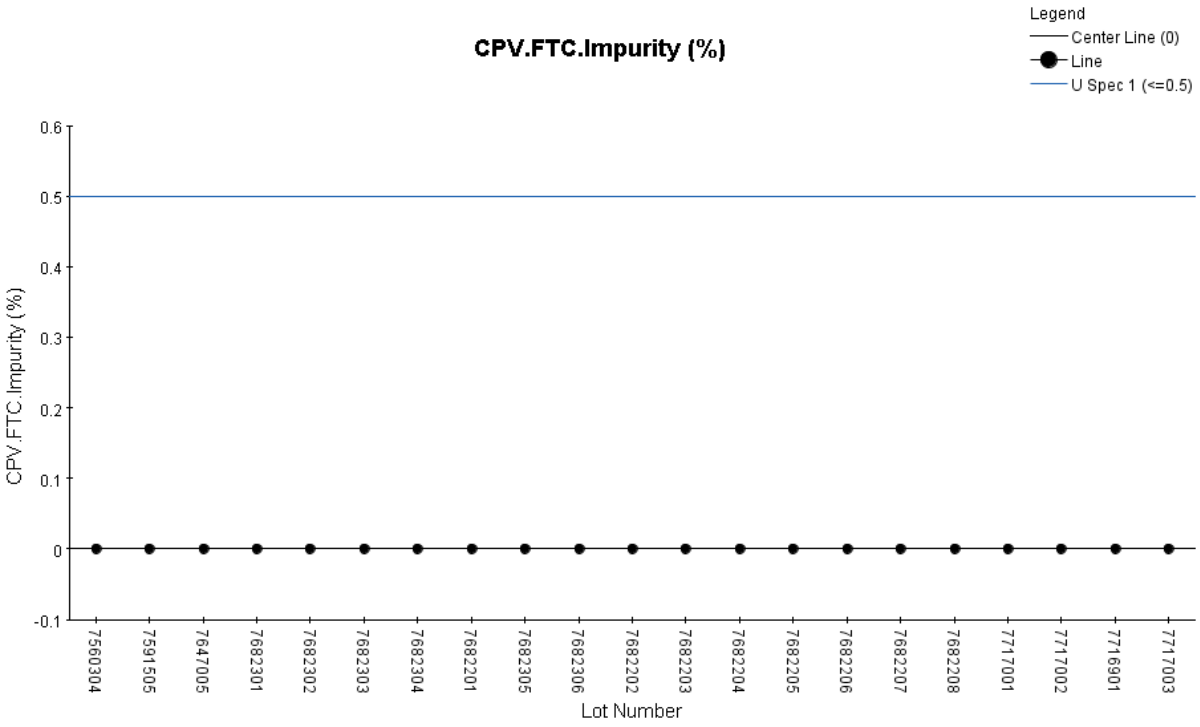

Chart 6: Total TAF Degradants – Rottendorf (200 mg FTC/25 mg TAF)

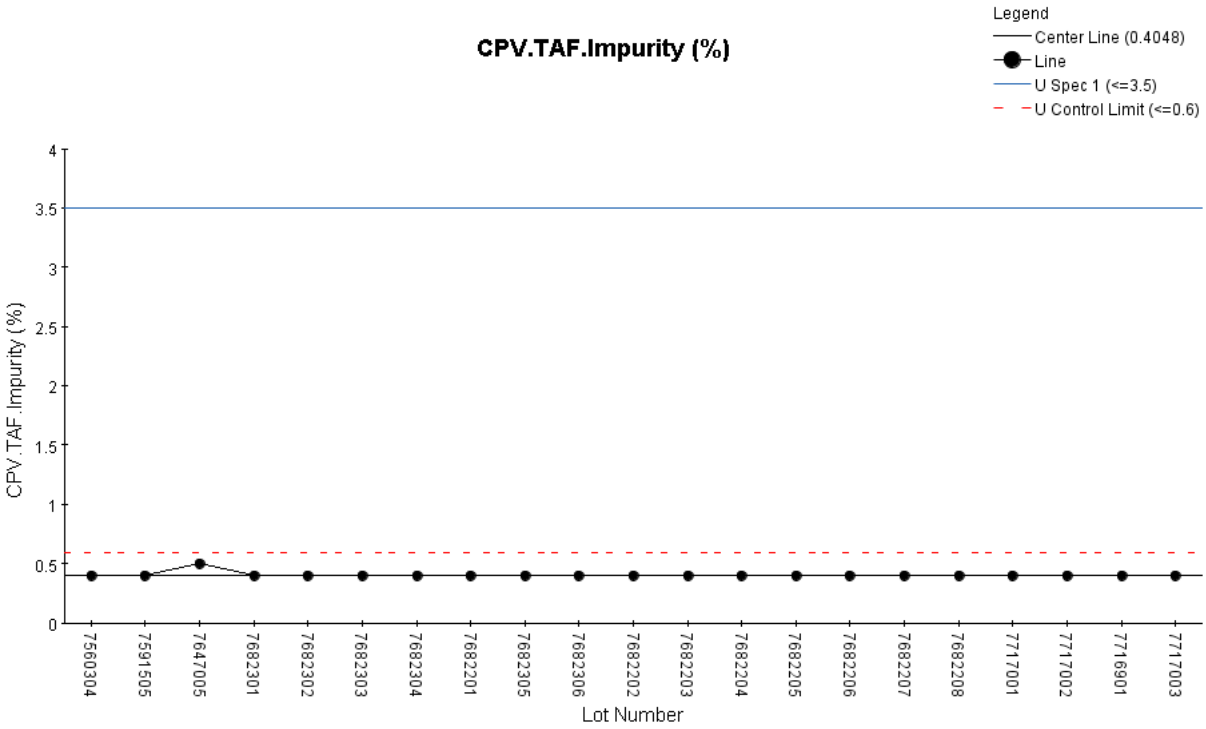

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Chart 7: FTC Dissolution (30 minutes) – Rottendorf (200 mg FTC/25 mg TAF)

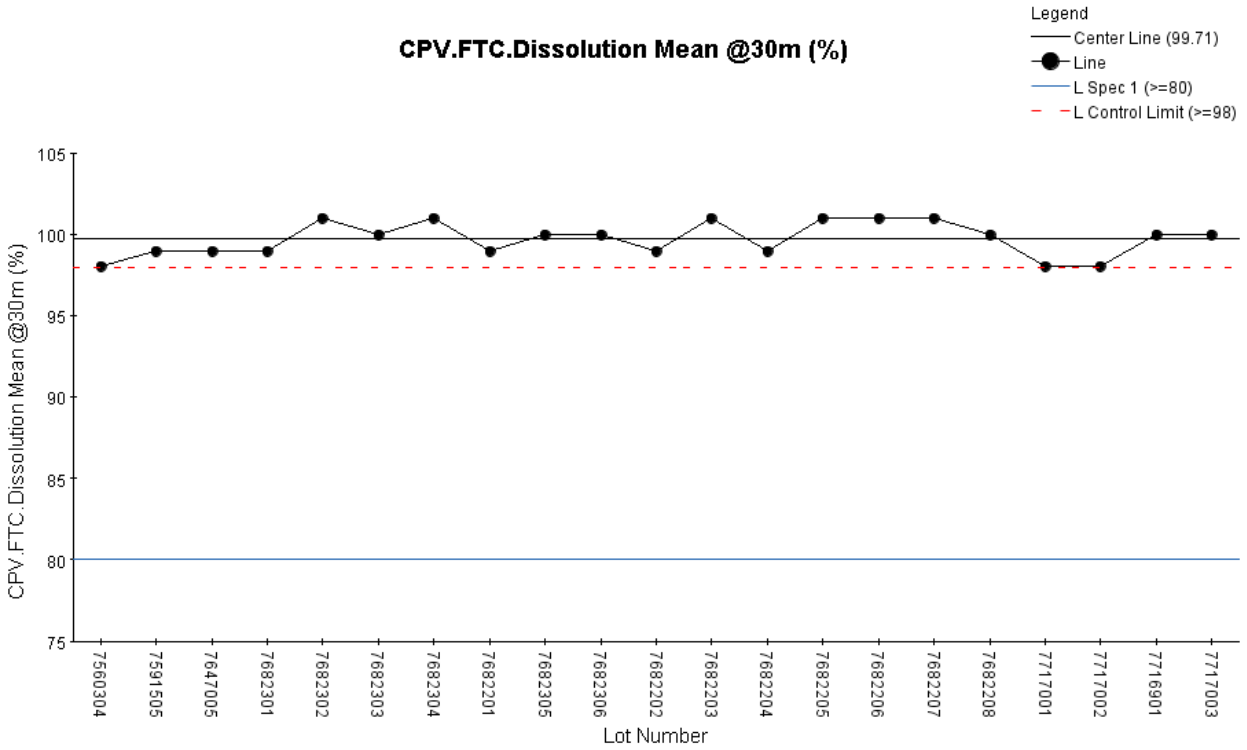

Chart 8: TAF Dissolution (30 minutes) – Rottendorf (200 mg FTC/25 mg TAF)

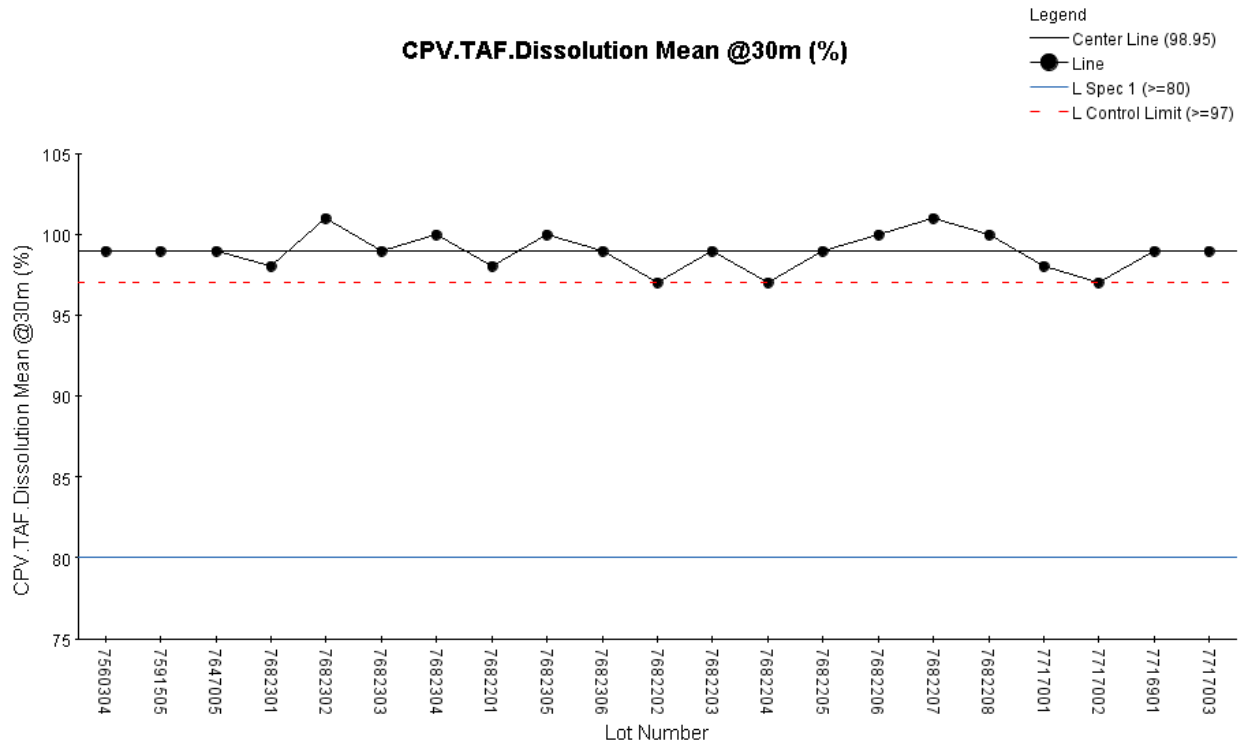

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Chart 9: FTC Content Uniformity – Rottendorf (200 mg FTC/25 mg TAF)

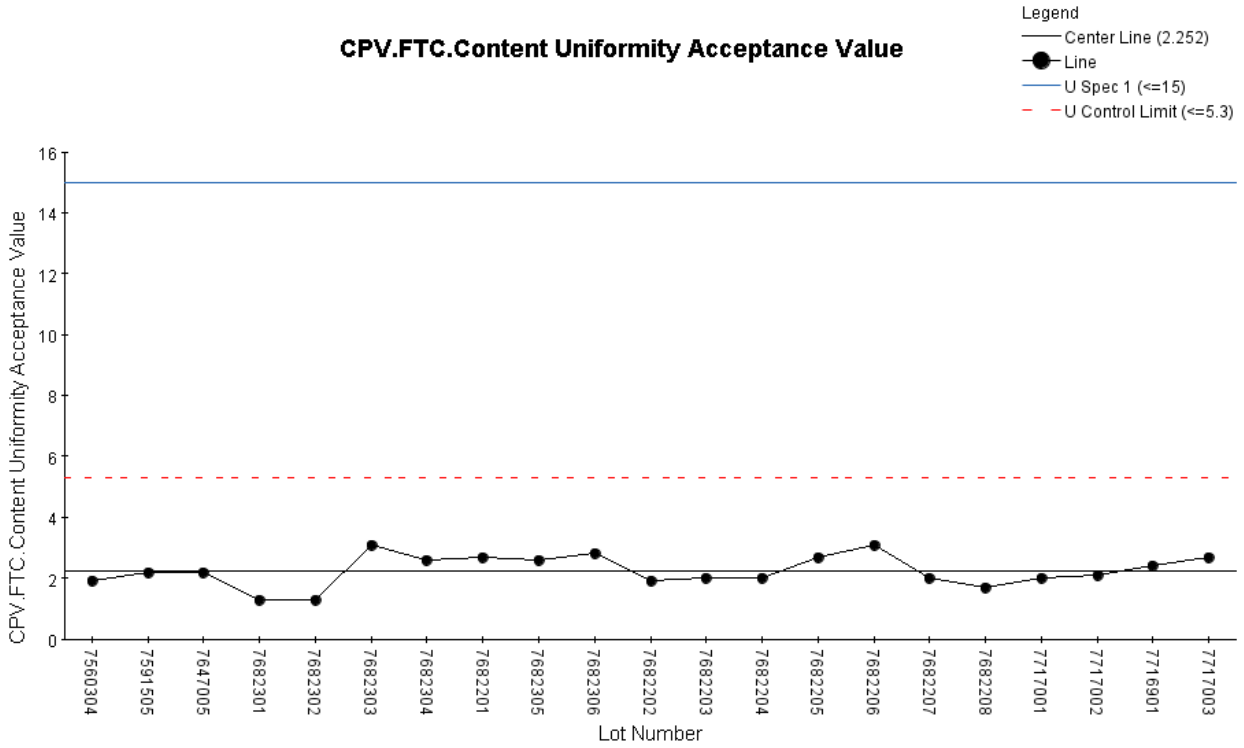

Chart 10: TAF Content Uniformity – Rottendorf (200 mg FTC/25 mg TAF)

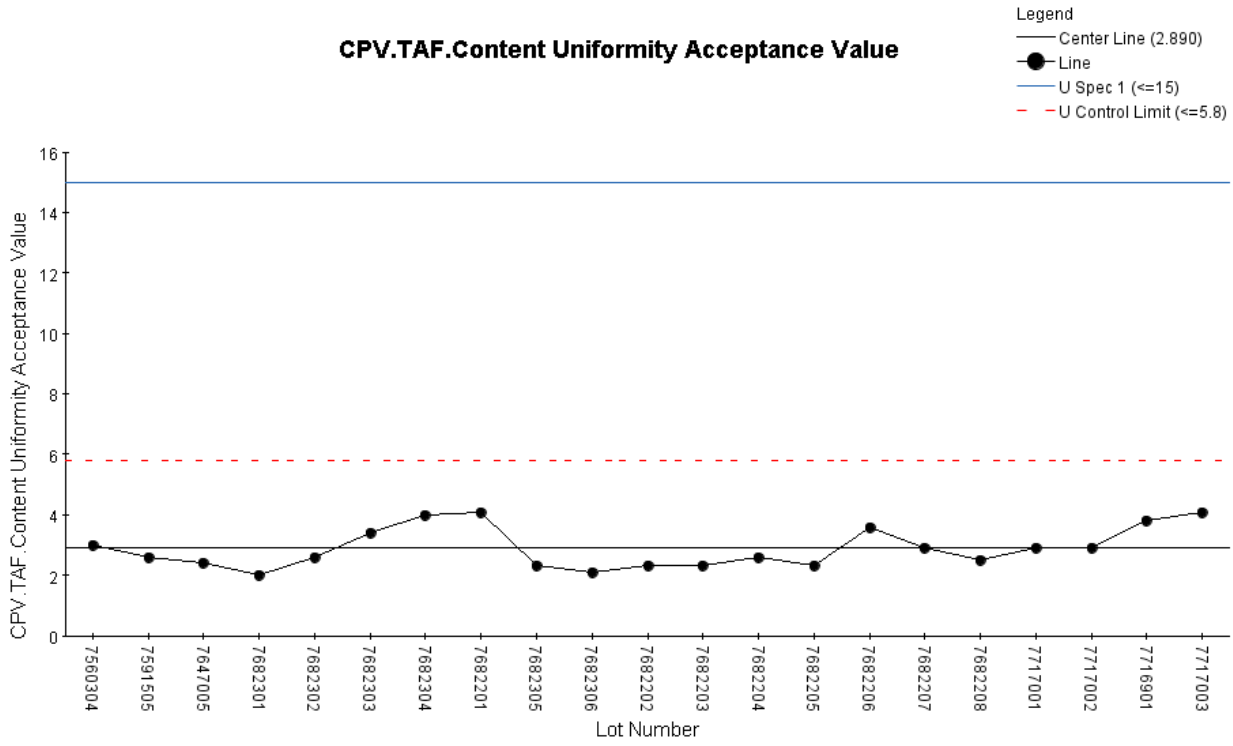

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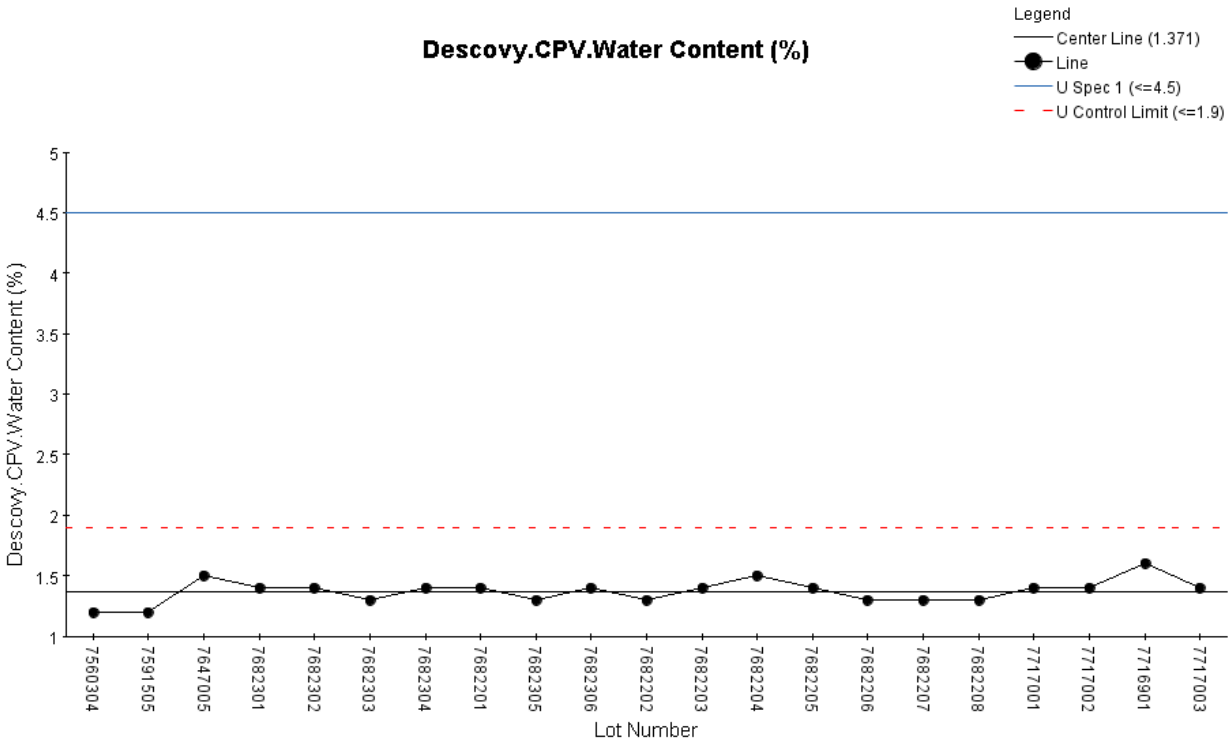
Chart 11: Water Content – Rottendorf (200 mg FTC/25 mg TAF)



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Attachment 9: Imported Lots

Table 1: Imported Lots – Patheon TRO (200 mg/25 mg) - Mexico

FG Part Number	FG Lot Number	FG Release Date	Comment
6195894171	CTDWK	07-Jun-2024	None
6195894171	CVCYC	17-Oct-2024	None
6195894171	CVCYD	03-Jan-2025	None
6195894171	CVHZF	27-Mar-2025	None

Table 2: Imported Lots – Patheon TRO (200 mg/10 mg) - Mexico

FG Part Number	FG Lot Number	FG Release Date	Comment
6195894161	CTDWG	12-Jul-2024	None
6195894161	CVMZV	27-Mar-2025	None

Table 3: Imported Lots – Patheon TRO (200 mg/25 mg) - Colombia

FG Part Number	FG Lot Number	FG Release Date	Comment
6195894351	CSXVD	25-Jun-2024	None
6195894351	CVVYX	31-Mar-2025	None

Table 4: Imported Lots – Patheon TRO (200 mg/10 mg) – Colombia

FG Part Number	FG Lot Number	FG Release Date	Comment
6195894341	CSXVC	28-Jun-2024	None
6195894341	CTDWD	04-Jul-2024	None
6195894341	CTTVX	15-Oct-2024	None
6195894341	CTXHC	10-Jan-2025	None

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Approved By | Verdict	Capacity | Date Approved
Jennifer Cheung, VP, Quality Approve	QA/Compliance Approval 30-May-2025 20:57:49 GMT+0000
Sue Liu, Exec Director, Quality Approve	QA/Compliance Approval 30-May-2025 23:37:22 GMT+0000
Kim Nguyen, Assoc Director, Quality Assurance Approve	Author Approval 31-May-2025 00:24:44 GMT+0000
Caragh Stack, Sr Director, Quality Approve	Functional Approval 03-Jun-2025 09:38:07 GMT+0000
Susmitha Sunkara, Sr Director, Quality Approve	QA/Compliance Approval 03-Jun-2025 10:57:41 GMT+0000