Extractables Test Strategy

(For External Distribution)

26 April 2022
Revision 07

Section 1: Background

Saint-Gobain has maintained an extractables testing program to support our customers since 2015 with some alignment to the "Standardized Extractables Testing Protocol for Single Use Systems in Biomanufacturing" published in Pharmaceutical Engineering, November / December 2014, volume 34, No 6. The program has included the following parameters used to produce the extractable profiles for our products:

- Solvents: 70% EtOH and DI Water
- Temperature: 70°C
- Duration: 24 hours
- Process Conditions: post-gamma irradiation and autoclave (as applicable based on the product's intended use)

Saint-Gobain recognizes the parameters used to evaluate our products prior to 2019 have not been fully aligned with the Biophorum Best Practices Guide nor the upcoming USP <665> requirements. Additionally, they may not provide a thorough panel of information required by our end-users for evaluating the toxicological safety of their finished goods (e.g. drug product). To strive to meet the needs of the market, Saint-Gobain has provided herein our revised approach to performing a comprehensive extractables analysis. The Saint-Gobain approach described in this strategy includes:

- grouping products into the product families,
- solvent selection using the Biophorum Best Practices Guide for Extractables Testing of Single Use Components published in April 2020 and upcoming USP <665> as a guide,
- timelines for publication of each product family's extractable report, and
- change control commitment as it relates to extractable testing and Saint-Gobain's position on a continuous extractable profile monitoring program

Section 2: Table of Contents

Section 3: Scope and Rationale

Table 1: *Scope / Product Family Rationales / Daisy Chain Strategy*

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
C-Flex®	C-Flex® 001	Extruded Tubing Overmolding	R70-001-000 001-XXX-X 001-XXX-XS 001-XXX-XM X = numeric character S= spool M = mini-spool	C-Flex® 072	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072 and C-Flex® 001, it has been concluded that the extractable profile for C-Flex® 072 can rationally be used to support Single Use Systems (SUS) containing C-Flex® 001. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
	C-Flex® 003	Extruded Tubing Overmolding	R70-003-000 003-XXX-X 003-XXX-XS 003-XXX-XM X = numeric character S= spool M = mini-spool	C-Flex® 072	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072 and C-Flex® 003, it has been concluded that the extractable profile for C-Flex® 072 can rationally be used to support Single Use Systems (SUS) containing C-Flex® 003. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
C-Flex® - Continued	C-Flex® 050	Extruded Tubing	R70-050-000 050-XXX-X 050-XXX-XS 050-XXX-XM X = numeric character S= spool M = mini-spool	C-Flex® 082	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 082 and C-Flex® 050, it has been concluded that the extractable profile for C-Flex® 082 can rationally be used to support Single Use Systems (SUS) containing C-Flex® 050. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
	C-Flex® 072	Extruded Tubing Overmolding Diptube	R70-072-000 072-XXX-X 072-XXX-XS 072-XXX-XM X = numeric character S= spool M = mini-spool	C-Flex® 072	Each of these three product families will be tested independently. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile per product family. NOTE: Tubing will not have ink on the OD of the tubing. Rationale: 99+% of the SUS assemblies produced do not contain ink on the OD of the tubing. Further, 80+% of the bulk, non-sterile tubing sold to OEMs do not contain ink on the OD of the tubing. As such, only tubing containing no ink will be supported within this testing program.
	C-Flex® 082	Extruded Tubing Overmolding Diptube	R70-082-000 082-XXX-X 082-XXX-XS 082-XXX-XM	C-Flex® 082	
	C-Flex® 374	Extruded Tubing Overmolding Diptube	R70-374-000 374-XXX-X 374-XXX-XS	C-Flex® 374	

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
C-Flex® - Continued	C-Flex® 376	Extruded Tubing Overmolding Diptube	R70-376-000 376-XXX-X	C-Flex® 072 C-Flex® 374	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072, C-Flex® 374 and C-Flex® 376, it has been concluded that the extractable profile for C-Flex® 072 and C-Flex® 374 can rationally be combined and used to support Single Use Systems (SUS) containing C-Flex® 376. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
	C-Flex® 377	Flexjoint	The resin is extruded into cut lengths used to construct flexjoints	C-Flex® 072 C-Flex® 374	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072, C-Flex® 374 and C-Flex® 377, it has been concluded that the extractable profile for C-Flex® 072 and C-Flex® 374 can rationally be combined and used to support Single Use Systems (SUS) containing C-Flex® 377. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.

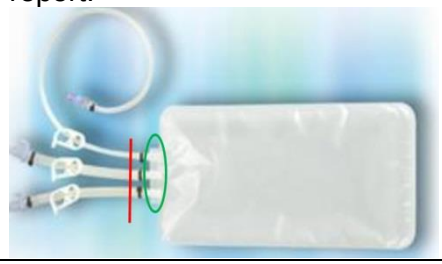
	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Sani-Tech ®	STHT-C	Tubing Diptube	Refer to product description on drawing for STHT-C or STHT-65 reference	STHT-C	This product family will be tested. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile.
	STHT-65	Tubing	Refer to product description on drawing for STHT-65 reference	STHT-C	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of STHT-C and STHT-65, it has been concluded that the extractable profile for STHT-C can rationally be used to support Single Use Systems (SUS) containing STHT-65. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
	STHT-R	Tubing	Refer to product description on drawing for STHT-R reference	STHT-R	This product family will be tested.

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Sani-Tech® (Continued)	Ultra-C	Tubing Diptube	Refer to product description on drawing for Ultra-C reference	Ultra-C	This product family will be tested. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile.
	Ultra 65	Tubing	Refer to product description on drawing for Ultra-65 reference	Ultra-C	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of Ultra-C and Ultra-65, it has been concluded that the extractable profile for Ultra-C can rationally be used to support Single Use Systems (SUS) containing Ultra-65. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
	SPT-60L	Tubing	Refer to product description on drawing for Sani-Tech® SPT-60L	Sani-Tech® SPT-60L	This product family will be tested. NOTE: The drawing or tubing product label MUST specifically indicate the brand Sani-Tech® in order for this extractable report to be applicable. The Pure-Fit® SPT-60L brand not in scope will be described on the drawing as SPT-60L or Pure-Fit® SPT-60L.

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Pure-Fit®	SPT-50	Tubing	Refer to product description on drawing for SPT-50	SPT-50	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of SPT-50 and SPT-60, it has been concluded that the extractable profile for SPT-50 can rationally be used to support Single Use Systems (SUS) containing SPT-50 and SPT-60. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
	SPT-60	Tubing	Refer to product description on drawing for SPT-60	SPT-50	

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Tygon® (Continued)	Tygon® 3350	Tubing Diptube	ABWXXXXXX X = numeric character	Tygon® 3350	This product family will be tested. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile.
	Tygon® 3370IB	Tubing	AHJXXXXXXX X = numeric character	Tygon® 3350 STHT-R	After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of Tygon 3370IB, Tygon® 3350 and STHT-R, it has been concluded that the extractable profile for Tygon® 3350 and STHT-R can be combined to represent the worst case extractable profile to support Single Use Systems (SUS) containing Tygon® 3370IB. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.
PharmaFluor®	PharmaFluor® FEP	Tubing	PCAMGXXXXX PH100XXXXXX PHFE6XXXXXX PH6303XXXXX PCFE6XXXXXX X = numeric character 7 to 13 characters in length	PharmaFluor® FEP	This product family will be tested at the 21-day time point only. This reduction in testing is to substantiate the recommendation to the FDA to place FEP on the GRAS list.

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
PharMed®	PharMed® BPT	Tubing	AY2XXXXX X = numeric character	PharMed® BPT	This product family will be tested.
PharmaPure®	PharmaPure®	Tubing	AL2XXXXX X = numeric character	PharmaPure®	This product family will be tested.
FEP Cell Therapy Storage Bags	VueLife® Bags (All sizes)	Cell Therapy Bag Gene Therapy Bag Bioprocess Bag Cold Storage Bag	VueLife® Bags	VueLife® AC Bags	The VueLife® Bag has been tested using DSMO, DI water and 70% EtOH each analyzed @ 70°C for 24 hours. The VueLife® Bag assemblies containing a ND-100-80 tube set were analyzed at 24 hours and 21 days using DI water, low pH and high pH after assemblies were autoclaved. (Refer to the extractables information page to request this report.) VueLife AC Bag assembly with ND-100-65 tube set will be tested.
	VueLife® AC Bags (All sizes)	Cell Therapy Bag Gene Therapy Bag Bioprocess Bag Cold Storage Bag	VueLife® AC Bags		
	KryoSure® Bags (All sizes)	Cell Therapy Bag Gene Therapy Bag Bioprocess Bag Cold Storage Bag	KryoSure® Bags		

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Bioprocess Bags	Bioprocess Bag (All sizes)	Single Use Bioprocess Bag	K(a)(a)XXXXX K = chamber (a) = alpha character X = numeric character	12 mil Bioprocess Bag	This product family will be tested. The bag will be clamped as illustrated by the red line. The ports, tubing and bag will be subjected to the conditions outlined herein. The exact tubing on the bag assembly will be stated in the extractable report. 
Sterile Grade Filters	Zero® Filter w/ PES membrane	Sterile Filter	To Be Provided in Future Update	Zero® Filter	This product family will be tested.
	PureFlo® Z Series Filters	Sterile Filter	To Be Provided in Future Update	PureFlo® Filter	The Zero® filter consists of a Z Series filter plus C-Flex® 374 tubing and a vent filter. Therefore, the Z Series filters are covered by the extractable data obtained from testing the Zero® filter family.

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Silicone Overmolding	Silicone Overmolding	Overmolding	Refer to product description: Sani-Tech® LIM Sani-Tech® 65 LIM Tygon® 3350 LIM Tygon® 3370 LIM Ultra LIM Ultra 65 LIM PC Silicone ST50 LSR PC Silicone ST65 LSR PC Silicone TYG50 LSR PC Silcone ULT50 LSR PC Silicone ULT65 LSR PC Silicone TYG70 LSR	LIMs/LSR Soup	All Liquid Injected Materials (LIMs) are liquid silicone rubbers (LSR) used to overmold single use assemblies. There are two main grades of LSR materials each of which are purchased at durometers ranging from 50 to 70. As such, the worst case scenario of each LSR grade is the lowest durometer LSR which contains the least amount of additives. To cover the entire range of LSR materials used to manufacture silicone overmolds, the two main LSR materials at 50 durometers will be converted into multi-leg T-reducers where the drop will be plugged with the same LSR material and allow enough space to clamp the ends when performing the extraction. The extractable profile for all silicone overmold materials listed will be the sum of the two LSR materials.

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Pure-Fit® Connectors and Sani-Tech® Rigid Connectors	Smooth Inner Bore (SIB) Connectors	Tubing Connector	PF(A)XXXPVDFAF (A) = style (e.g. T, cross, etc.) XXX = Size in inches	PVDF-SUS Components	A PVDF soup will be created to obtain the extractable profile of SUS components manufactured from PVDF. The soup will consist of the following: • PVDF used to mold Pure-Fit® SIB connectors • PVDF used to mold Sani-Tech® Rigid • PVDF used to mold all components constituting the Pure-Fit® Sterile Connector with the exception of the silicone valve. As the PVDF molded components create the fluid contact path, the silicone valve is considered out of scope for extractable testing.
	Sani-Tech® Rigid Connector	Tubing Connector	KXXXXX-XXX "K" or "T" followed by 5 to 6 alpha or numeric characters then a dash followed by 3 to 4 alpha or numeric characters. KXXXXX "K" or "T" followed by 5 to 7 alpha or numeric characters.	PVDF-SUS Components	
	Pure-Fit® Sterile Connector	Sterile Connector	PFSC250-XXX PFSC375-XXX PFSC500-XXX PFSC750-XXX PFSC1000-XXX Where XXX = IHM, OHM or CAM	PVDF-SUS Components	

	Formulation	Function in Single Use Systems	Part Numbers In Scope	Extractable Report Reference	Rationale for Extractable Report Reference
Pure-Fit® Connectors, Polypropylene Resin and Sani-Tech® Rigid Connectors	Smooth Inner Bore (SIB) Connectors	Tubing Connector	PF(A)XXXPPAF (A) = style (e.g. T, cross, etc.) XXX = Size in inches	PP-SUS Components	A polypropylene soup will be created to obtain the extractable profile of SUS components manufactured from polypropylene. The soup will consist of the following: • Polypropylene used in Clearwater assemblies to manufacture diptubes. • Polypropylene used to mold SIB-PP connectors @ Traverse City • Polypropylene used to overmold assemblies in Clearwater • Polypropylene used to mold Sani-Tech® Rigid connectors in Garden Grove
	Sani-Tech® Rigid Connectors	Sani-Tech® Rigid Connectors	KXXXXX-XXX "K" or "T" followed by 5 to 6 alpha or numeric characters then a dash followed by 3 to 4 alpha or numeric characters. KXXXXX "K" or "T" followed by 5 to 7 alpha or numeric characters.	PP-SUS Components	
	Polypropylene	Overmolding Tubing Diptube	R80-106-000, 30-10008, 30-10013, 30-10014, 30-10115, 30-10175, 30-10482, 30-10488, 30-10519 and 30-10709		
Equflow® Disposable PVDF Flow Tube	PVDF Flow Tube	Disposable parts for flowmeter, connect with tubing	0045 (low flow) 0045 (standard) 0085 0250	PVDF flow tube	This product family will be tested.

NOT IN SCOPE:
Saint-Gobain previously published an extractables test plan communication dated December 21, 2017. With this communication, it outlined all product families within scope of extractables testing per the Biophorum Best Practices Guide. Saint-Gobain has since updated its extractables test strategy and will not actively promote the following products for new Single Use Systems that require extractable data:

- C-Flex® 082 braided tubing
- SaniPure® BDF Tubing
- Pure-Fit® SPT-60L Tubing

Since publishing this test strategy (Revision 0), an additional product is being added to the NOT IN SCOPE section that was previously published as IN SCOPE: Pure-Fit® SPT-60L tubing has been replaced by Sani-Tech® SPT-60L tubing as being IN SCOPE. Only product branded as Sani-Tech SPT-60L shall contain an extractables profile as outlined herein and detailed in the Saint-Gobain extractables protocol. The Pure-Fit® SPT-60L tubing will only have the legacy data and has been added to this section as not in scope. Please note that as change control occurs in the future, Pure-Fit® SPT-60L qualification testing would no longer include an extractables profile.

Therefore, no additional extractable testing will be performed on these product families in the future. The current use of these product families has been substantiated using the historical extractable data on file and summarized in Table 2

Table 2: Extractable Data for Products NOT IN SCOPE*

Product	70% EtOH @70ºC for 24 hours		DI Water @ 70ºC for 24 hours	
	Gamma Irradiated	Autoclave Conditions	Gamma Irradiated	Autoclave Conditions
C-Flex® 082 Braided Tubing	√	Not Performed	√	Not Performed
SaniPure® BDF Tubing	Not Performed	√	Not Performed	√
Pure-Fit® SPT-60L Tubing	√	Not Performed	√	Not Performed

*Extractable test conditions do not follow recommendations within the Biophorum Best Practices Guide or the upcoming USP <665>. Summary of extractable test conditions and results can be made available upon request.

Section 4: Saint-Gobain Test Strategy Executive Summary

2019 / 2020 Test Plan:

- One unique lot (2nd unique lot is discussed under Ongoing Surveillance section below)
- 3 solvents (DI water, low pH and high pH)
- Biophorum Best Practices Guide test intervals for bags, filters, connectors identified herein

Tubing commonly assembled to the storage bag will undergo the 70 days @ 40°C time point. One extractable study contained C-Flex® 374 on the Saint-Gobain storage bag. A 2nd study will be conducted in 2021 to include silicone tubing. The specific product families attached to the storage bag will be outlined in the extractables report.

2020 / 2021 Test Plan:

- One unique lot (2nd unique lot is discussed under Ongoing Surveillance section below)
- 1 solvent (50% EtOH)
- Test intervals for bags, filters, connectors identified herein as outlined in the Biophorum Best Practices Guide

Tubing commonly assembled to the storage bag will undergo the 70 days @ 40°C time point. One extractable study contained C-Flex® 374 on the Saint-Gobain storage bag. A 2nd study will be conducted with silicone tubing in conjunction with the Saint-Gobain storage bag. The specific product families attached to the storage bag will be outlined in the extractables report.

Ongoing Surveillance / Testing Program / Change Control Commitment:

- Extractable testing will be conducted as required when change control necessitates repeating the analysis.
- Saint-Gobain is collaborating with Biophorum to determine if age of data will drive repeat analysis and if so, at what frequency.
- Saint-Gobain is also collaborating with Biophorum to provide a scientific rationale or objective evidence as to the value of testing a 2nd lot since it is not a requirement within the upcoming USP <665>.

Section 5: Saint-Gobain Protocol Highlights

TABLE 3: TEST STRATEGY: COVERAGE, POST TREATMENT, TIME INTERVALS, INTENDED USE						
Product Family	**Testing Coverage**	**Post Treatment Intended Use**		**Test Intervals**		
C-Flex®		**Gamma Test Condition**	**Autoclave Test Condition**	**24h @ 40ºC**	**21 Days @ 40ºC**	**70 Days @ 40ºC**
C-Flex® 374	C-Flex® 374 C-Flex® 376	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Test as part of the Bioprocess Bag Assembly
C-Flex® 082	C-Flex® 050 C-Flex® 051 C-Flex® 082	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Not in Scope
C-Flex® 072	C-Flex® 001 C-Flex® 072 C-Flex® 376	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Not in Scope
Silicone Tubing						
Sani-Tech® STHT-C	STHT-C STHT-65	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Test as part of the Bioprocess Bag Assembly
Sani-Tech® Ultra C	Ultra C Ultra 65	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Test as part of the Bioprocess Bag Assembly
Pure-Fit® SPT-50	SPT-50 SPT-60	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Test as part of the Bioprocess Bag Assembly
Sani-Tech® SPT-60L	SPT-60L	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Test as part of the Bioprocess Bag Assembly
Sani-Tech® STHT-R	STHT-R Tygon® 3370IB	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Not Intended Use
Tygon® 3350	Tygon® 3350 Tygon® 3370IB	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope	Not in Scope

TABLE 3 (Cont'd): TEST STRATEGY: COVERAGE, POST TREATMENT, TIME INTERVALS, INTENDED USE						
	Testing Coverage	**Gamma Test Condition**	**Autoclave Test Condition**	**24h @ 40°C**	**21 Days @ 40°C**	**70 days @ 40°C**
TPE Tubing						
PharMed® BPT	PharMed®	40 – 55 kGy	60 mins @ 125°C	In Scope	In Scope	Not in Scope
PhamaPure®	PharmaPure®	40 – 55 kGy	60 mins @ 125°C	In Scope	In Scope	Not in Scope
FEP Tubing						
Pharmafluor® FEP	PCAMGXXXXX PH100XXXXXX PHFE6XXXXXX PH6303XXXXX PCFE6XXXXXX	Not Intended Use	60 mins @ 125°C	Not In Scope	In Scope	Not Intended Use
PVC Tubing						
Tygon ND-100-65	Tygon® ND-100-65 Tygon® ND-100-80	Not In Scope	Will be tested in conjunction with VueLife AC bag			
Storage Bags						
Bioprocess Bags (Plymouth)	All sizes	40 – 55 kGy	Not Intended Use	In Scope	In Scope	In Scope
VueLife® AC Bags w/ ND-100-65 Tubing	VueLife® Bags VueLife® AC Bags Kryosure® Bags	Not Intended Use	60 mins @ 125°C	In Scope	In Scope	In Scope
Silicone Overmolds						
LIM #1 overmold	LIM #1 overmold w/n LIMs soup	40 – 55 kGy	60 mins @ 125°C	In Scope	In Scope	Not Required
LIM #2 Overmold	LIM #2 Overmold w/n LIMs soup	40 – 55 kGy	60 mins @ 125°C	In Scope	In Scope	Not Required

TABLE 3 (Cont'd): TEST STRATEGY: COVERAGE, POST TREATMENT, TIME INTERVALS, INTENDED USE					
Product Family	**Testing Coverage**	**Gamma Test Condition**	**Autoclave Test Condition**	**24h @ 40ºC**	**21 Days @ 40ºC**
Connectors					
Pure-Fit® SIBs @PVDF w/n PVDF Soup	PVDF Connectors Sani-Tech® Rigid Connectors	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope
Pure-Fit® SIBs @PP w/n PP Soup	PP Connectors PP Overmolding PP Tubing Sani-Tech® Rigid Diptube	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope
Flowmeters					
Equflow® PVDF Flow Tube	Equflow® PVDF Flow Tube	40 – 55 kGy	60 mins @ 125ºC	In Scope	In Scope
Filters	**Testing Coverage**	**Gamma Test Condition**	**Autoclave Test Condition**	**24h @ 40ºC**	**7 days @ 40ºC**
Zero® Filter	Zero Filter PureFlo® Z Series filters	40 – 55 kGy	Not Intended Use	In Scope	In Scope
PureFlo® Z Series filters	PureFlo® Z Series filters	Covered by Zero® Filter	60 mins @ 125ºC	In Scope	In Scope

TABLE 4: TEST PLAN PER SOLVENT				
Product Family	**Low pH[1]**	**High pH[1]**	**DI Water[2]**	**50% EtOH[3]**
C-Flex® Tubing				
C-Flex® 374	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
C-Flex® 082	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
C-Flex® 072	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
Silicone Tubing				
Sani-Tech® STHT-C	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
Sani-Tech® Ultra C	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
Pure-Fit® SPT-50	In Scope (2022)	In Scope (2022)	In Scope (2022)	In Scope (2022)
Sani-Tech® SPT-60L	In Scope (2022)	In Scope (2022)	In Scope (2022)	In Scope (2022)
Sani-Tech® STHT-R	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
Tygon® 3350	In Scope (2020)	In Scope (2020)	In Scope (2020)	In Scope (2020)

1 High pH conditions will follow the upcoming USP <665> of pH = 10, Low pH will follow the Biophorum Best Practices Guide since interchangeable with USP <665> low pH; pH will be adjusted if needed based on chemical compatibility.

2 Extractable data available @ 70°C for 24 hours. Testing will be performed at 40°C for time intervals outlined in this table.

3 Extractable data available @ 70°C for 24 hours using 70% EtOH and DI water. Testing will be performed using 50% EtOH at 40°C for time intervals outlined in this table.

4 Updated protocol no longer includes these solvents. As such, they have been removed from the remainder of the document.

Product Family	Low pH[1]	High pH[1]	DI Water[2]	50% EtOH[3]
TPE Tubing				
Pharmed BPT®	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2021)
Phamapure®	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
Pharmafluor® FEP Tubing	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2021)
Silicone Overmolds				
LIM #1 overmold w/n LIMs Soup	In Scope (2020)	In Scope (2020)	In Scope (2020)	In Scope (2022)
LIM #2 Overmold w/n LIMs Soup	In Scope (2020)	In Scope (2020)	In Scope (2020)	In Scope (2022)
Connectors				
Pure-Fit® PFSIBs w/n PVDF Soup	In Scope (2020)	In Scope (2020)	In Scope (2020)	In Scope (2022)
Pure-Fit® PFSIBs w/n PP Soup	In Scope (2020)	In Scope (2020)	In Scope (2020)	In Scope (2022)
Flowmeters				
Equflow® PVDF Flow Tube	In Scope (2022)	In Scope (2022)	In Scope (2022)	In Scope (2022)

1 High pH conditions will follow the upcoming USP <665>of pH = 10, Low pH will follow the Biophorum Best Practices Guide since interchangeable with USP <665> low pH; pH will be adjusted if needed based on chemical compatibility.

2 Extractable data available @ 70°C for 24 hours. Testing will be performed at 40°C for the time intervals outlined in this table.

3 Extractable data available @ 70°C for 24 hours using 70% EtOH and DI water. Testing will be performed using 50% EtOH at 40°C.

Product Family	Low pH[1]	High pH[1]	DI Water[2]	50% EtOH[3]
Filters				
Zero® Filter	In Scope (2022)	In Scope (2022)	In Scope (2022)	In Scope (2022)
PureFlo® Z Series Filter	In Scope (2021)	In Scope (2021)	In Scope (2021)	In Scope (2021)
Storage Bags				
Plymouth Storage Bags	In Scope (2019)	In Scope (2019)	In Scope (2019)	In Scope (2020)
Vuelife AC Bags w/ ND-100-65 tube set	In Scope (2021)	In Scope (2021)	In Scope (2021)	In Scope (2021)

1 High pH conditions will follow the upcoming USP <665> of pH = 10; Low pH will follow the Biophorum Best Practices Guide since interchangeable with USP <665> low pH; pH will be adjusted if needed based on chemical compatibility

2 Extractable data available @ 70°C for 24 hours. Testing will be performed at 40°C

3 Extractable data available @ 70°C for 24 hours using 70% EtOH and DI water. Testing will be performed using 50% EtOH at 40°C.

Section 6: Timelines

Table 5: Timeline for Extractables Test Report Publications per Test Plan (Aqueous Solvents)

	Extractable Data Source	Publication Date (EOM = End of Month)
Group 1	12 mil Bioprocess Bag (Plymouth Bag)	Gamma – COMPLETE
	Sani-Tech® STHT-C Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	Sani-Tech® STHT-R Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	C-Flex® 374 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	Sani-Tech® Ultra C Tubing	Gamma – COMPLETE Autoclave – COMPLETE
Group 2	PharmaPure® Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	C-Flex® 082 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	PharmaFluor® FEP Tubing	Autoclave – COMPLETE
	Pure-Fit® SPT-50 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
Group 3	C-Flex® 072 Tubing	Gamma – COMPLETE Autoclave - COMPLETE
	Tygon® 3350 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	LIMs/LSR Soup	Gamma – COMPLETE Autoclave –COMPLETE
	PP Soup	Gamma - COMPLETE Autoclave – COMPLETE
	PharMed® BPT Tubing	Gamma - COMPLETE Autoclave – COMPLETE
Group 4	PVDF Soup	Gamma - COMPLETE Autoclave – COMPLETE
	Zero® Filter	Gamma - December 2022
	Sani-Tech® SPT-60L Tubing	Gamma – December 2022 Autoclave – December 2022
	Pure-Fit® SPT-50 Tubing	Gamma – December 2022 Autoclave – December 2022
	Equflow® Flow Tube	Gamma – April 2022 Autoclave – April 2022
	PureFlo® Z Series Filters	Autoclave – December 2022

Table 6: Timeline for Extractable Test Report Publications per Test Plan (Organic Solvents)

	Extractable Data Source	Publication Date (EOM)
Group 5	12 mil Bioprocess Bag (Plymouth Bag)	Gamma– COMPLETE
	Sani-Tech® STHT-C Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	Tygon® 3350 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	C-Flex® 374 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	C-Flex® 082 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
Group 6	Sani-Tech® STHT-R Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	Sani-Tech® Ultra C Tubing	Gamma – March 2021 Autoclave –March 2021
	PharMed® BPT Tubing	Gamma – COMPLETE Autoclave –COMPLETE
	PharmaPure® Tubing	Gamma – COMPLETE Autoclave – COMPLETE
Group 7	C-Flex® 072 Tubing	Gamma – COMPLETE Autoclave – COMPLETE
	Vuelife AC Bag w/ ND-100-65 tube set	Autoclave – COMPLETE
	PP Soup	Gamma – COMPLETE Autoclave –COMPLETE
	LIMs Soup	Gamma – COMPLETE Autoclave –COMPLETE
Group 8	PharmaFluor® FEP Tubing	Autoclave – COMPLETE
	PVDF Soup	Gamma – COMPLETE Autoclave –COMPLETE
	Zero® Filter	Gamma - December 2022
	Sani-Tech® SPT-60L Tubing	Gamma – December 2022 Autoclave – December 2022
	Pure-Fit® SPT-50 Tubing	Gamma – December 2022 Autoclave – December 2022
	Equflow® Flow Tube	Gamma – April 2022 Autoclave – April 2022
	PureFlo® Z Series Filters	Autoclave – December 2022

Section 7: Change History and Approvals

7.1 Revision Information

Revision	Revision Date	Page(s) Affected	Revision Description
0	26 April 2019	All	Original Issue
1	01 Nov 2019	1,2, 6-26	Removed FEP cell / gene therapy bags out of testing scope due to pending review of proposal to FDA to accept FEP film as GRAAS. Removed requirement to repeat testing based on age of data solely. Removed requirement to test 2nd lot. Replaced with statement to collaborate with BPOG on both topics to determine if data expires and whether 2nd lot testing is required. Updated tables to reflect which tubing is undergoing 70d test interval as part of the bioprocess bag. Added External Distribution to the title page. Corrected reference to the extractable protocol. Remove PS80 and 5M NaCl as solvents. Removed time zero interval. Added PFSC to be in scope as part of PVDF Soup. Separated SPT-50 and SPT-60 into its own test family. Added Pure-Fit® SPT-60L to the Out of Scope Section. Added Sani-Tech® SPT-60L to the In Scope section. Adjusted test schedule and report due dates. Updated gamma range target. Fixed time points required for connectors. Added part numbers for the Sani-Tech® Rigid Connectors and PP Soup. Added more part numbers to the LSR / LIMs Soup. Added 2020 due date for performing 50% EtOH test plan. Updated test strategy for 70 day time point.
2	20 April 2020	4, 20, 22 - 24	Update aqueous test plan status. Update the 50% EtOH test plan and include target completion dates for the next year. Add C-Flex® R70-003-000 to the test plan since it is also used in SUS assemblies. Removed R70-051-000 from the test strategy as it not used in any single use systems. Corrected the use of R70-050-000 in single use systems.

3	13 July 2020	22 – 24	Update test completion table to reflect completion of reports year to date and change the Tygon 3350 - 50% EtOH report due dates from July 2020 to March 2021. The samples submitted contained ink. Ink is not present when tubing is converted into a single use assembly. 50% EtOH removed all ink. Testing aborted since not representative.
4	29 Sept 2020	7, 9, 18, 22 - 24	Add in reference to VueLife bag assembly with ND-100-80 tube set extractables report. Add in VueLife AC bag with ND-100-65 tube set, ND-100-65 and ND-100-80 tubing into this test strategy to support CGT business. Update timeline to reflect status.
5	11 Jan 2021	1, 8, 14-16,18, 20, 21 and 24	Add in one additional part number family for PharmaFluor tubing. Update BPOG protocol to Biophorum Best Practices Guide. Replace BPOG with Biophorum to reflect name change. Update Table 6 timeline. Add R70-377-000 C-Flex® resin to the C-Flex® product family rationale section. Updated NOT IN SCOPE section to differentiate Sani-Tech® SPT-60L from Pure-Fit® SPT-60L.
6	21 Jan 2021	8, 19	Corrected test strategy for ND-100-65 PVC tubing.
7	26 April 2022	11, 14, 20-25	Update the test strategy, test plan for filter, SPT-50 tubing, SPT-60L tubing and PVDF flow tube. Update test status.

7.2 Approval Signatures

Prepared By	Signature / Date
Haiyan Hong Analytical Services & QC Manager, Life Sciences	Hong, Haiyan Digitally signed by Hong, Haiyan Date: 2022.04.28 20:18:38 +08'00'
Approved By	**Signature / Date**
Allison Vereb BPS Quality Director	Allison Vereb Digitally signed by Allison Vereb Date: 2022.04.28 08:41:50 -04'00'
Narendar Yeshwanth R&D Vice President, Life Sciences	Narendar, Yeshwanth Digitally signed by Narendar, Yeshwanth Date: 2022.05.05 13:02:23 -04'00'
Aaron Updegrove Marketing Director, Bioprocess Solutions	Updegrove, Aaron Digitally signed by Updegrove, Aaron Date: 2022.04.28 10:50:16 -05'00'