Biotech

Validation Guide Addendum

USTR 3378

Kleenpak® HT Sterile Connector Validation Following a European Commission Regulatory Change

Addendum to the following Pall validation guides:

- *USTR 2232a: Kleenpak Connector for Use with 13 mm (½ in.) Nominal Tubing*
- *USTR 2451a: Kleenpak Sterile Connectors with Hose Barb Adapters*
- *USTR 2532: Kleenpak HT Sterile Connectors – Extension of the Autoclave Cycle Sterilization Time*
- *USTR 2568: Kleenpak Sterile Connectors Shelf Life Studies*

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1 Validation Overview

1.1 Introduction

The European Commission environmental restriction of a compound used in the manufacturing of the hydrophobic peel strip in Kleenpak sterile connectors, is effective from July 4th, 2020. The European Commission Regulation 2017/1000: EU REACH Annex XVII amendment restricts the concentration of perfluorooctanoic acid (PFOA) and its salts in articles in all but a limited number of uses, to a concentration of 25 ppb, and the concentration of various PFOA-related substances in such articles to 1000 ppb. At the time of this publication the European Commission are reviewing adding this restriction to the Persistent Organic Pollutants (POPS) Regulation 2019/1021, effective from July 4th, 2020 and removing the proposed REACH restriction.

To minimize the impact of the regulatory change, the existing peel strip material (polyethersulfone membrane on a polyester support fabric) has been retained and the surface chemistry that conveys hydrophobicity has been replaced with a similar chemistry compliant to the above regulations.

This addendum to the existing validation reports for the Kleenpak sterile connectors describes the testing validating the performance of Kleenpak sterile connectors with the revised peel strip including liquid soiling, biological safety, cleanliness and physicochemical tests.

The peel strip of the Kleenpak sterile connector is not intended to be in contact with the process fluid being transferred as it is peeled away prior to fluid transfer. Should the process fluid contact the peel strip, the connector must not be used. As such, the validation of the revised peel strip was limited in scope. The previously published validation guides for the Kleenpak sterile connectors are still valid for all mechanical and functional tests not repeated in this addendum.

The Kleenpak sterile connectors data presented in this report can be used in conjunction with ¼ in., ⅜ in., ⅝ in., and ½ in. diameter hose barb fittings. The Kleenpak sterile connectors part numbers are shown in Table 1 below.

Table 1

Kleenpak sterile connectors part numbers

Part Number	Description
KPCHT02F6	Female connector with 13 mm (½ in.) hose barb
KPCHT02M6	Male connector with 13 mm (½ in.) hose barb
KPCHT02F7	Female connector with 6 mm (¼ in.) hose barb
KPCHT02M7	Male connector with 6 mm (¼ in.) hose barb
KPCHT02F10	Female connector with 9.6 mm (⅜ in.) hose barb
KPCHT02M10	Male connector with 9.6 mm (⅜ in.) hose barb
KPCHT02F11	Female connector with 15.8 mm (⅝ in.) hose barb
KPCHT02M11	Male connector with 15.8 mm (⅝ in.) hose barb

1.2 Summary of Conclusions

1.2.1 Bacterial Soiling Testing

The bacterial soiling test evaluates the ability of the Kleenpak sterile connectors to maintain a sterile fluid path during connection and fluid transfer after the device is intentionally soiled by exposure to *Geobacillus stearothermophilus* at a minimum level of 10^6 CFU/mL.

The soiling test data in this document confirms that the Kleenpak sterile connectors maintain a sterile fluid path before connection and during fluid transfer.

All Kleenpak sterile connectors passed the bacterial soiling test.

1.2.2 Extractables

Extensive extractables testing has been performed on the product contact portion of the Kleenpak sterile connectors as documented in the current validation guide (document number USTR 2232a). Reports from additional extractables testing that was performed in accordance with BPOG extraction guidelines are also available upon request.

Extractables testing of Kleenpak Presto sterile connectors containing the same post-change peel strip material as the Kleenpak HT sterile connectors, can be used to assess the impact of the change, the results of which are included in this addendum.

1.2.3 Biological Safety, Cleanliness and Physicochemical Tests

1.2.3.1 Endotoxin Test, USP < 85>

The purpose of this test is to quantify the bacterial endotoxin level that may be present in the Kleenpak sterile connectors. A total of 12 non-connected parts were tested. The endotoxin level achieved is 0.25 EU/mL.

Results demonstrated that rinse solutions from the Kleenpak sterile connectors meet the requirements of USP <85> endotoxin content.

1.2.3.2 Biological Reactivity Tests, In Vitro, USP <87>

The purpose of this test is to determine the biological reactivity of mammalian cells (mouse fibroblasts) following contact with a fluid extract from the revised peel strip material as per USP <87> (MEM cytotoxicity). The extract fluid was produced from peel strip material samples that had been gamma irradiated (50 kGY) or autoclaved (2 cycles, 75 min, 130 ºC).

Results demonstrate that the revised peel strip material meets the requirements of USP <87>.

1.2.3.3 Biological Reactivity Tests, In Vivo, USP < 88>

The purpose of this test is to determine the biological reactivity of mammalian cells (mouse fibroblasts) following contact with the fluid extract from the revised peel strip material as per USP <88> for Class VI plastics. These tests were conducted using peel strip material samples which had been gamma irradiated at 50 kGy and devices which had been autoclaved (2 cycles, 75 min, 130 ºC).

Results demonstrated that the revised peel strip material meets the requirements of USP <88>.

1.2.3.4 Physicochemical Test as per USP<661>

The purpose of this test is to evaluate the physicochemical suitability of fluid extracts for contact with parenterals. These tests were conducted on fluid extracts from the revised peel strip material which had been gamma irradiated at 50 kGy or autoclaved (2 cycles, 75 min, 130 ºC).

Results demonstrated that the revised peel strip material meets the requirements of USP <661>. Other connector components meet the requirements of USP<661> as demonstrated in the validation guide USTR 2232a.

1.2.3.5 Particle Release Test, USP < 788> Particulate Matter in Injections

This test determined the particulate level present in the Kleenpak sterile connectors. A total of 6 pairs were tested.

Results demonstrated that the rinse solution from the Kleenpak sterile connectors meet the requirements of USP <788>.

Table 2

Summary of USP test results

Test	Result
Endotoxin Test, USP < 85>	Pass
Biological Reactivity Tests, *in vitro*, USP <87>	Pass
Biological Reactivity Tests, *in vivo*, USP < 88>	Pass
Physicochemical Test, USP < 661>	Pass
Particle Release Test, USP < 788>	Pass

1.2.4 Shelf Life Studies

Shelf life studies were conducted on Kleenpak sterile connectors to evaluate any potential effects of a 1 year storage time.

Samples of Kleenpak sterile connectors were subjected to gamma irradiation and accelerated storage conditions to simulate 1 year of storage. Connectors were subjected to bacterial liquid soil testing, endotoxin testing per USP <85> and particulate testing per USP <788>.

The results indicated that the functionality of the Kleenpak sterile connector remained intact after 1 year of storage.

Shelf life studies for a 3-year post gamma claim and a 5-year claim, for devices not sterilized prior to storage, are currently in progress. Results will be available once complete. Please contact Pall for the latest information.

2 Functional Tests

2.1 Bacterial Soiling Test

The purpose of the bacterial liquid soiling test is to evaluate the ability of autoclaved or gamma sterilized Kleenpak sterile connectors to maintain a sterile fluid path during connection and fluid transfer after the device is intentionally soiled by exposure to a carboxy methyl cellulose (CMC) solution inoculated with *G. stearothermophilus* (ATCC♦ 7953).

2.1.1 Test Method

A total of 60 Kleenpak sterile connector pairs (60 male and 60 female) were used for the test work. 40 pairs were pre-sterilized via gamma irradiation using 50 kGy, of which 20 pairs were frozen at -80 °C for thirty (30) days and thawed before testing. 20 pairs were pre-sterilized via autoclave using one (1) 75-minute autoclave cycle at 130 ºC.

During the functional test, the male and female connectors were soiled with a minimum challenge level of 10^6 CFU of *G. stearothermophilus* spores per connector. The soiling was accomplished by submerging each male and female connector just up to the flange in a spore suspension of *G. stearothermophilus* in a carboxy methyl cellulose (CMC) solution for a minimum of 30 seconds. The soiled connectors were air dried at ambient temperature in a laminar flow hood for a minimum of 12 hours.

To verify the spore titer in the suspension, a 5mL sample was taken, plated on Tryptic Soy Agar and incubated at 55-60 °C for 2 days.

To demonstrate that the connector soiling did not impact the ability of the Kleenpak sterile connector to provide a sterile pathway, the following procedure was followed for each of the tests.

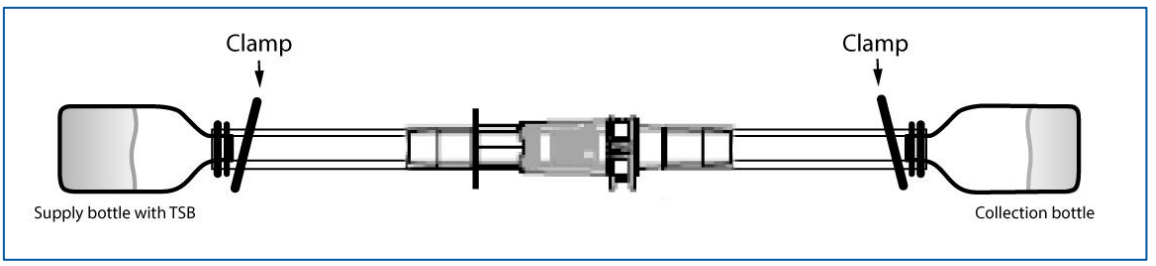
The glass vessel connected to the male connector was first filled with sterile Tryptic Soy Broth (TSB). The male and female Kleenpak sterile connectors were then connected and actuated by removing the peel strip. The clamp on the tubing between the male connector and glass vessel was opened and the TSB was transferred through the Kleenpak sterile connector to the empty glass collection vessel by gravity and incubated for 2 days at 55-60 °C.

Lack of turbidity post the 2-day incubation period indicated absence of any visually detectable microbial growth.

Positive and negative controls were performed as part of the soiling tests. A negative control was achieved by eliminating the inoculation of the male and female connectors with the spore suspension. As a positive control, the protective strip was removed prior to connection and the tip of the plunger on the male connector was inoculated with spore suspension. Positive controls were confirmed by gram staining.

Figure 1

Assembly connected by Kleenpak HT sterile connector for transfer of Tryptic Soy Broth



2.1.2 Results

Table 3

Liquid soiling test results of connected Kleenpak Presto sterile connectors at contamination level 1.0 x 10^6 CFU/mL of B. diminuta

	Batch 1 (Ten Pairs)	Negative Control (1 Pair)	Positive Control (1 Pair)
Gamma irradiated at 50 ± 5 kGy	No growth	No growth	Turbid growth
Autoclaved at 130 °C for 1 x 75-minute cycle	No growth	No growth	Turbid growth
Gamma irradiated at 50 kGy and frozen at -80 °C for 30 days	No growth	No growth	Turbid growth

2.1.3 Conclusion

A total of 60 Kleenpak sterile connector pairs (60 male, 60 female) were actuated and used for the test work. No bacterial growth was detected in the samples collected after the transfer through the Kleenpak sterile connector units previously contaminated by a minimum challenge level 1.0 x 10^6 CFU/mL of *G. stearothermophilus*.

The input verification tests indicated that the inoculation step described in the liquid soiling test procedure ensured enough spores adhered to each Kleenpak sterile connector to pass the acceptance criteria of ≥1.00 x 10^6 CFU per connector.

Negative controls did not show any growth, the positive controls demonstrated a confluent growth as expected. The soiling test demonstrated that the Kleenpak sterile connectors can maintain a sterile pathway even in worst case bacterial challenging conditions.

The Kleenpak sterile connector assemblies met the test requirements of the bacterial soiling.

3 Extractables

Extractables testing of Kleenpak Presto sterile connectors containing the same post-change peel strip material as the Kleenpak HT sterile connector, can be used to assess the impact of the change as described below.

The purpose of this test is to quantify and characterize the extractables from the Kleenpak Presto sterile connectors in an extraction solvent of 50% v/v ethanol aqueous solution according to the recommendations of the BPOG (BioPhorum Operations Group) Extractables Working Group.

3.1 Test Methods

Extractables tests were performed on 24 connected Kleenpak Presto sterile connector pairs subjected to the following pre-treatment: a total of 24 connected individual connector parts were irradiated at 50 kGy; a total of 24 connected individual connector parts were submitted to 1 autoclave cycle for 75 minutes at 130 °C.

Table 4

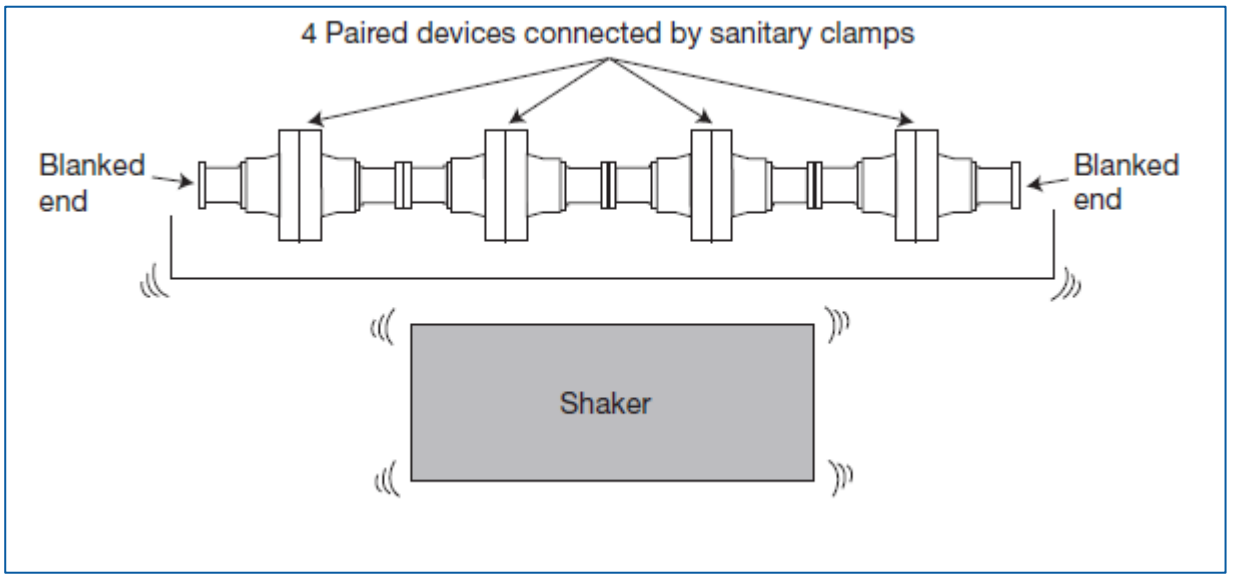
Extraction conditions with 50% v/v ethanol aqueous solution

Extraction Conditions		
30 min at 25° C	24 hours at 40° ± 2.5° C	7 days at 40 ± 2.5 ° C

Four pairs of Kleenpak Presto sterile connectors were connected in series (Figure 2). The interior assembly was flooded with extraction solvent (3.31 cm^2/mL) and extracted dynamically in duplicate according to the conditions outlined in Table 4. Extracted samples were analyzed by Headspace GC/MS, Direct Injection GC/MS, LC/PDA/MS and ICP/MS.

Figure 2

Extractables test setup of four Kleenpak Presto sterile connector pairs in series



3.2 Results

Results of the tests performed to quantify and identify extractables from Kleenpak Presto sterile connectors having been subjected to gamma irradiation at 50 kGy or to one 75-minute autoclave cycle at 130 °C, are given in Table 5.

Table 5

Summary of organic extractables from Kleenpak Presto sterile connector

		Worst-Case Amount (µg/cm²)						Worst-Case Amount	Worst-Case Total Daily Intake	PDE or Risk Index
		Autoclaved			Gamma Irradiated					
Compound	**CAS**	**½ h**	**24 h**	**7 days**	**½ h**	**24 h**	**7 days**	**(µg/cm²)**	**(µg/day)**	**(µg/day)**
Hexamethylene diacrylate	13048-33-4	-	13.136	18.972	-	0.485	0.905	18.972	1.572	5320
Cyclohexyl propionate	N/A	-	3.754	7.520	-	-	-	7.520	0.623	560[a]
Triethyl borate	150-46-9	-	-	-	-	-	2.028	2.028	0.168	N/A
PEG n=3 monoethyl ether	112-50-5	-	-	-	-	-	1.396	1.396	0.116	N/A
5-Hexenyl propionate	N/A	-	0.436	1.232	-	-	-	1.232	0.102	525[a]
2,2-Dimethoxy-2-phenylacetophenone	24650-42-8	-	0.367	0.661	-	-	-	0.661	0.055	672[a]
a Borate ester	N/A	-	0.411	-	-	-	0.642	0.642	0.053	N/A
Unknown (mass ion 229.0)	N/A	-	0.441	0.586	-	-	-	0.586	0.049	N/A
1,1-Diethoxyethane	105-57-7	-	-	-	-	-	0.539	0.539	0.045	3500
Benzil	134-81-6	-	0.347	0.524	-	-	-	0.524	0.043	1750[a]
Unknown (mass ion 231.1)	N/A	-	-	0.478	-	-	-	0.478	0.040	N/A
1H,1H,2H,2H-Perfluorooctan-1-ol	647-42-7	-	-	-	-	0.415	0.476	0.476	0.039	N/A
Unknown (mass ions 245.0, 267.0)	N/A	-	-	-	-	-	0.413	0.413	0.034	N/A
Cyclohexyl acrylate	3066-71-5	-	-	-	-	-	0.375	0.375	0.031	N/A
2,4-Di-*tert*-butylphenol	96-76-4	-	-	0.358	-	-	-	0.358	0.030	175
Trimethylhydroxysilane	1066-40-6	-	-	0.343	-	0.343	0.343	0.343	0.028	11200
Tetrahydrofuran	109-99-9	-	0.343	0.343	-	-	-	0.343	0.028	7200[c]
Siloxane related (-[O-Si(CH_2)]-, mass ions 223.2, 371.3)	N/A	-	-	0.312	-	-	0.252	0.312	0.026	700[b]
Methyl ethyl ketone	78-93-3	-	-	-	-	0.307	0.307	0.307	0.025	50000[c]
Siloxane related (-[O-Si(CH_2)]-, mass ions 223.0, 556.1)	N/A	-	-	0.288	-	-	0.287	0.288	0.024	700[b]

Table 5 Notes:

"-" indicates values is below 0.25 mg/cm^2. For compounds detected at < 0.25 µg/cm^2 and details, please contact Pall Corporation.

Total Daily Intake (TDI) was calculated based on a model worst-case process conditions (5 L process volume using 2 assembled connectors and a 10 mL drug product daily dosage).

TDI (Hexamethylene diacrylate) = 18.972 µg/cm^2 x 41.42 cm^2/connector pair x 1 / 5000 mL x 10 mL/day = 1.572 µg/day

Unless otherwise noted, toxicology information is taken from Jenke and Carlson, PDA J Pharm Sci and Tech 2014, 68, 407 – 455.

a. *PDE values from Pall Internal Toxicological Report. For more details, please contact Pall Corporation*

b. *Risk Index of Octamethylcyclotetrasiloxane (D4) was used as surrogate for the siloxane related compounds since it is considered the most toxic REACH related siloxane.*

c. *PDE values are taken from International Conference on Harmonization (ICH) Q3C: Impurities: Guideline for Residual Solvents. www.ich.org.*

3.3 Conclusion

Consistent with BPOG recommendations, 50% v/v ethanol was selected as the most relevant, industry-standard solvent to evaluate the extractables that could be generated by the Kleenpak Presto sterile connector.

The study was conducted on 4 pairs of Kleenpak Presto sterile connectors connected in series which were previously gamma irradiated (50 kGy) or autoclaved (1 cycle, 75 min, 130 ºC). Three different extractions were performed at ambient temperature (25 °C) for time 0 (≤30 mins) and at 40 ± 2.5 °C for 24 hours and 7 days.

The extracts were analyzed using a variety of analytical techniques to detect various compounds that might be present.

4 Biological Safety, Cleanliness and Physicochemical Tests

4.1 Endotoxin Test, USP <85>

The purpose of this test was to quantify the bacterial endotoxin level that may be present in Kleenpak sterile connector.

4.1.1 Test Method

A total of twelve (12) Kleenpak sterile connectors (6 male, 6 female) were tested for endotoxin levels as per USP <85>. The connectors were sterilized by autoclaving at 121 °C for a minimum of 20 minutes and aliquot soak water samples were tested using Limulus Amoebocyte Lysate (LAL) reagent per the current USP Bacterial Endotoxins test (<85>). The sensitivity of the reagent is 0.125 EU/mL.

4.1.2 Results

Table 5

Kleenpak sterile connector (½ in. hose barb) endotoxin level

Sample Batch and Size	Quantity Tested	Single Devices or Pairs
921301M	6	Single devices
921303F	6	Single devices

All results were < 0.25 EU/mL.

4.1.3 Conclusion

Rinse solutions from both gamma-irradiated and non-sterilized Kleenpak sterile connectors meet acceptance criteria for endotoxin content when tested in accordance with USP <85>.

4.2 Biological Reactivity Tests, *In Vitro*, USP <87>

The purpose of this test is to determine the biological reactivity of mammalian cells (mouse fibroblasts) following contact with a fluid extract from the revised peel strip material as per USP <87> (MEM cytotoxicity).

4.2.1 Test Method

Tests were performed as per USP <87>, MEM Elution Method. The samples to be tested were gamma irradiated to 50 kGy, - or autoclaved (2 cycles, 75 min, 130 ºC), and then totally immersed in the cell culture for 24 hours at 37 ºC in a 5% CO_2 incubator.

The extracts were then examined to determine any biological reactivity.

4.2.2 Results

Results demonstrated that the Kleenpak sterile connector with revised peel strip material meets the specifications requirements of the USP <87>.

4.2.3 Conclusion

The Kleenpak sterile connector revised peel strip material meets the USP <87> requirements.

4.3 Biological Reactivity Tests, USP <88>

The purpose of this test is to determine the biological reactivity of mammalian cells (mouse fibroblasts) following contact with the fluid extract from the revised peel strip material as per USP <88> for Class VI plastics. connector, as per USP <88> for Class VI plastics.

4.3.1 Test Method

Tests include USP Biological Reactivity Tests, *in vivo* for Class VI Plastics (121 ºC) as described in the United States Pharmacopoeia Chapter <88>. These tests were conducted using peel strip material samples which had been gamma irradiated at 50 kGy and devices which had been autoclaved (2 cycles, 75 min, 130 ºC).

The Biological Reactivity Tests *in vivo* for Class VI-121 ºC Plastics as described in the United States Pharmacopoeia Chapter <88> include:

- Injection of extracts of plastic materials
- Implantation of the solid material into animal tissue.

The four extraction media listed in the USP simulate parenteral solutions and body fluids include:

- Sodium Chloride Injection
- 1 in 20 Solution of Alcohol in Sodium Chloride Injection
- Polyethylene Glycol 400
- Vegetable Oil (sesame or cottonseed oil)

USP <88> states that extracts may be prepared at one of three standard conditions: 50 ºC for 72 hours, 70 ºC for 24 hours, or 121 ºC for 1 hour. The most stringent condition not resulting in physical changes in the plastic is recommended; therefore, the fluid contact material was extracted at 121 °C for 1 hour. The extracts were then used in the following tests to determine the biological effects they have:

4.3.1.1 Systemic Injection Tests

A systemic injection test is performed to evaluate systemic biological responses of animals to plastics, polymers and biomaterials by a single dose injection. The Sodium Chloride Injection and Alcohol Sodium Chloride Injection extracts are injected intravenously. The Polyethylene Glycol 400 and Vegetable Oil extracts are injected intraperitoneally.

4.3.1.2 Intracutaneous Tests

An intracutaneous test is performed to evaluate the local biological response to a single injection of an extract to produce tissue irritation. All four of the extracts listed above were used for these tests.

4.3.1.3 Implantation Tests

An implantation test is also performed to evaluate animal response in case of direct contact with sample materials.

4.3.2 Results

The Kleenpak sterile connector the revised peel strip material passed the USP <88> tests as described above.

4.3.3 Conclusion

The Kleenpak sterile connector revised peel strip material meets the USP <88> requirements.

4.4 Physicochemical Test as per USP <661>

The purpose of these tests is to evaluate the physicochemical suitability of Kleenpak sterile connector revised peel strip material for contact with parenterals.

4.4.1 Test Method

Plastic devices that are intended for packaging products for parenteral use must meet the requirements of Physicochemical Testing-Plastics found in the current USP. These tests are designed to measure the properties of impurities extracted from plastics when leached with extraction medium over a specified period and temperature. Irradiated (50 kGy) or autoclaved (2 cycles, 75 min, 130 ºC) samples of peel strip material were extracted at 70 ºC for 24 hours in purified water. Samples of the liquids were then tested for the following under USP <661> guidelines:

- Buffering Capacity - measures the alkalinity and acidity of the extracts.
- Non-Volatile Residue (NVR) - measures organic/inorganic residues soluble in extraction media.
- Residue on Ignition - performed when the NVR is greater than 5 milligrams.
- Heavy Metals - detects the presence of metals such as lead, tin, and zinc.

4.4.2 Results

The Kleenpak sterile connector revised peel strip material meets acceptance criteria for all three (3) tests. Residue on ignition was not performed as NVR residue was lower than 5 mg.

4.4.3 Conclusion

Results demonstrated that the revised peel strip material meets the requirements of USP <661>. Other connector components meet the requirements of USP<661> as demonstrated in the validation guide USTR 2232a.

4.5 Particles Release Test, USP <788> Particulate Matter in Injections

The purpose of this test is to determine the particulate level present in the Kleenpak sterile connector.

4.5.1 Test Method

Six (6) pairs of Kleenpak sterile connectors (3 gamma irradiated at 50 kGy, 3 non-sterilized) were actuated, flushed with 0.2 µm filtered water and the fluid effluent counts of particles and fibers were determined microscopically.

4.5.2 Results

Table 6

Kleenpak sterile connector (½ in. hose barb) particle release results

Batch Details	Single Devices or Pairs	Quantity	Pass/Fail
921301M, 921303F	Pairs	6	Pass

4.5.3 Conclusion

The Kleenpak sterile connectors meet with adequate safety margin the current limits under USP <788>.

5 Shelf Life Studies

5.1 Introduction

Accelerated ageing studies were conducted on Kleenpak sterile connectors representing a one (1) year storage time, post gamma irradiation.

Shelf life studies for a 3-year post gamma claim and a 5-year claim for devices not sterilized prior to storage are currently in progress. Results will be available once complete. Please contact Pall for the latest information.

5.2 Test Method

Testing was undertaken using Kleenpak sterile connectors that had been gamma irradiated (50 kGy) and stored at 50 ºC with 75% relative humidity for 46 days to simulate 1 year of storage. Connectors were subjected to bacterial liquid soil testing, endotoxin testing per USP <85> and particulate testing per USP <788>.

5.3 Results

5.3.1 Bacterial Liquid Soiling Test

All Kleenpak sterile connector samples passed the soiling test with no bacterial growth. The positive control showed bacterial growth and the negative control did not show any bacterial growth.

Table 7

Liquid soiling test results of connected Kleenpak sterile connector (gamma irradiated at 50 kGy and stored at 50° C with 75% relative humidity for 46 days). Contamination level: >1.0 x 10^6 CFU/mL of G. stearothermophilus

	Quantity Tested (Pairs)	Growth Observed
Batch 1	20	None
Negative Control	1	None
Positive Control	1	Turbid Growth

5.3.2 Endotoxin and Particulate Testing

All Kleenpak sterile connector samples passed endotoxin testing per USP <85> and particulate testing per USP <788> after accelerated aging representing one (1) year storage conditions.

Table 8

Endotoxin and particle release test results after accelerated ageing

Test	Quantity Tested	Single Devices or Pairs	Result
Endotoxin Test, USP < 85>	6	Single devices	Pass
Particle Release Test, USP < 788>	3	Pairs	Pass

5.4 Conclusion

Following gamma irradiation and accelerated storage conditions to simulate 1 year of storage, post gamma irradiation, Kleenpak sterile connectors passed bacterial liquid soiling, endotoxin and particulate testing.

The results indicated that the functionality of the Kleenpak sterile connector remained intact after 1 year of storage.

Shelf life studies for a 3-year post gamma claim and a 5-year claim for devices not sterilized prior to storage are currently in progress. Results will be available once complete. Please contact Pall for the latest information.

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