Biotech

Validation Guide Addendum

USTR 3379

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

Addendum to the following Pall validation guide:

- *USTR 3130b: Kleenpak Presto Sterile Connector*

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1 Validation Overview

The European Commission environmental restriction of a compound used in the manufacturing of the hydrophobic peel strip used in Kleenpak Presto 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 report for the Kleenpak Presto sterile connectors (document number USTR 3130b) describes the validation of the performance of Kleenpak Presto sterile connectors with the revised peel strip including liquid soiling, biological safety, cleanliness and physicochemical tests.

The peel strip of the Kleenpak Presto 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. Therefore, the validation of the revised peel strip was limited in scope. The previously published validation guide for the Kleenpak Presto sterile connectors (USTR 3130b) is still valid for all mechanical and functional tests, therefore they are not repeated in this addendum.

The Kleenpak Presto sterile connectors' data in this report can be used in conjunction with ¼ in., ⅜ in., ⅝ in., ½ in., and ¾ in. diameter hose barb fittings and ½ in. sanitary fitting.

Table 1

Kleenpak Presto sterile connector part numbers

Part Number	Size
PSC1G07	¼ in. hose barb
PSC1G10	⅜ in. hose barb
PSC1G11	⅝ in. hose barb
PSC1G06	½ in. hose barb
PSC1G08	½ in. sanitary connection
PSC1G05	¾ in. hose barb

1.1 Summary of Tests

1.1.1 Bacterial Soiling Testing

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

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

All Kleenpak Presto sterile connectors passed the bacterial soiling test.

1.1.2 Extractables

The purpose of this test is to quantify and characterize the extractables from the device in a chosen solvent.

The study was carried out on Kleenpak Presto sterile connectors that have been irradiated at 50 kGy or autoclaved (1 cycle, 75 minutes, 130 °C).

Analysis of the extracts showed that the extractable level in the test contact fluid was extremely low. Bis-phenol A was not detected in any samples.

1.1.3 Endotoxin Test, USP <85>

This test quantified the bacterial endotoxin level that may be present in the Kleenpak Presto sterile connector. A total of 4 non-connected parts were tested.

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

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

This test determined 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 or autoclaved.

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

1.1.5 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 ± 5 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>.

1.1.6 Physicochemical Test as per USP <661>

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

Results demonstrated that the revised peel strip material and the Kleenpak Presto sterile connectors meet the requirements of USP <661>.

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

The purpose of this test is to determine the particulate level present in the Kleenpak Presto sterile connector. A total of 6- non-connected parts were tested.

Results demonstrated that the rinse solution from the Kleenpak Presto sterile connectors meet with adequate safety margin the current limits under 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

1.1.8 Shelf Life Studies

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

Samples of Kleenpak Presto 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 Presto 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 Bacterial Liquid Soiling Test

The bacterial liquid soiling test evaluated the ability of a Kleenpak Presto sterile connector to maintain a sterile fluid path during connection and fluid transfer after the device is intentionally soiled by exposure to a CMC solution inoculated with *Brevundimonas diminuta* bacteria (ATCC♦ 19146).

2.1 Test Method

A total of 60 unconnected Kleenpak Presto sterile connectors (30 pairs) were used for the test work. 20 devices were pre-sterilized via gamma irradiation using 50 ± 5 kGy, 20 were pre-sterilized via autoclave using one (1) 75-minute autoclave cycle at 130 ºC. 20 devices were pre-sterilized via gamma irradiation using 50 ± 5 kGy then frozen at -80 °C for thirty (30) days and thawed before testing.

For each set of Kleenpak Presto sterile connectors two 125 mL glass bottles were used. One glass bottle was filled with 25 mL of Tryptic Soy Broth (TSB) and the second was left empty. The open ends were wrapped in autoclave tape. The glass bottles were then autoclaved. After autoclaving, tubing and a pre-sterilized Kleenpak Presto sterile connector were attached to the glass bottles. A closed clamp was installed between the glass bottle and the Kleenpak Presto sterile connector.

The tamper resistant caps were removed from each connector, then the peel strips of each connector were immersed in the CMC/*B. diminuta* liquid (Figure 1). The soiled devices were dried and then connected as per the standard assembly procedure (Figure 2). The clamp between the glass bottle and the Kleenpak Presto sterile connector was opened. The TSB was transferred through the Kleenpak Presto sterile connector assembly under gravity. The TSB material was flushed back and forth several times to ensure that the entire interior of the assembly was exposed. After flushing back and forth, the TSB was collected in one bottle. The glass bottle containing the TSB was then clamped off and placed in an incubator at 30 ± 2 ºC for 2 days.

After the 2-day incubation period the samples were evaluated for bacterial growth by examining for turbidity. For each manufacturing batch one positive and one negative control was used.

As a positive control, the protective peel strip was removed from the connector before soiling of the device with the *B. diminuta*.

As a negative control, the peel strips were not exposed to *B. diminuta*.

Figure 1

Soiling of both ends of Kleenpak Presto sterile connector assemblies prior to connection

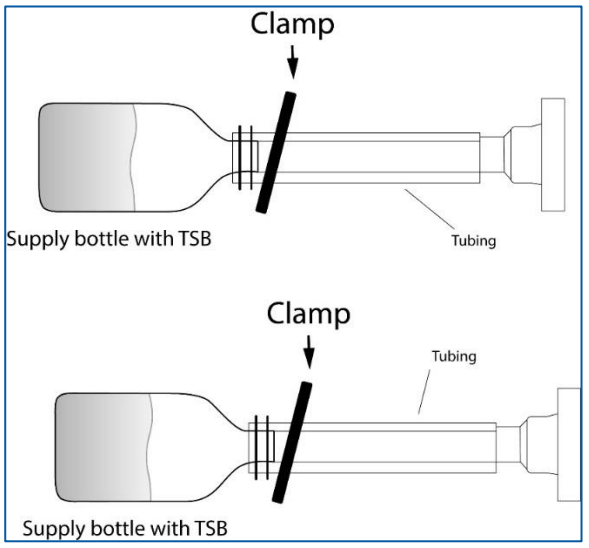
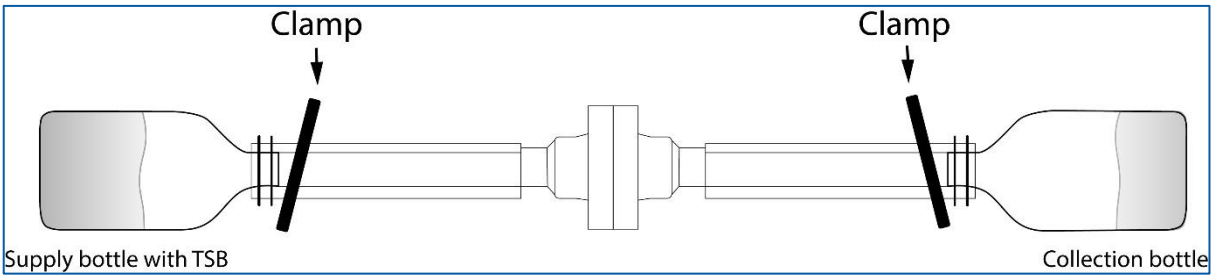


Figure 2

Assembly connected by Kleenpak Presto sterile connector for transfer of TSB



2.2 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

2.3 Conclusion

A total of 60 Kleenpak Presto sterile connectors were tested. No bacterial growth was detected in the samples collected after the transfer through the Kleenpak Presto sterile connector units previously contaminated by a minimum challenge level of 10^6 CFU/mL of *B. diminuta*.

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

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

3 Extractables

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

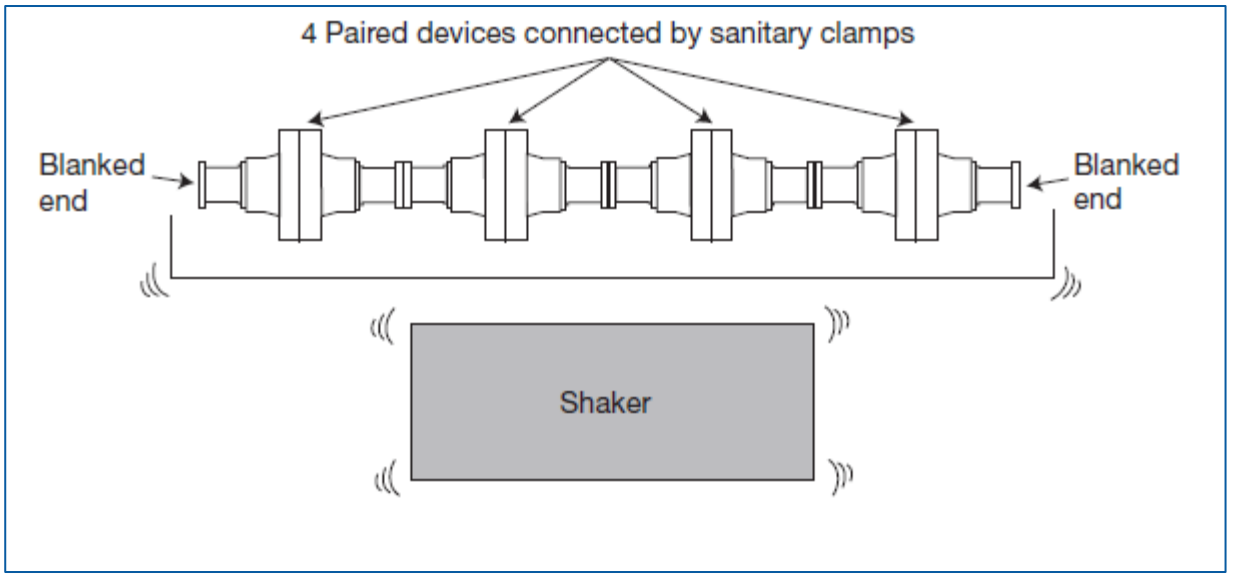
Extraction conditions with 50% v/v ethanol aqueous solution

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 3). 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 3

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)								
		Autoclaved			Gamma Irradiated			Worst-Case Amount	Worst-Case Total Daily Intake	PDE or Risk Index
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.*

Table 6

Summary of elemental impurities from Kleenpak Presto sterile connector

Elements	ICH Q3D Class	Worst Case Amount, µg/cm^2	
		Autoclaved	Gamma Irradiated
Silicon	N/A	0.3502	0.3833

**All ICH Q3D elements and Boron, Sodium, Tungsten, Magnesium, Aluminum, Calcium, Titanium, Manganese, Iron, Zinc, Potassium, and Silicon are below detection limit or reporting threshold (< 20 ppb).*

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. No Bis-phenol A was detected with limit of detection of 0.05 ppm.

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 Presto sterile connector.

4.1.1 Summary of Test Method

Two gamma-irradiated and two non-sterilized Kleenpak Presto sterile connector devices were tested individually for endotoxin level as per USP <85>. Rinse solutions 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

Both samples were gamma sterilized at 50 - kGy. Additionally, two (2) assembled non-sterilized Kleenpak Presto sterile connector devices were tested individually for endotoxin level as per USP <85>.

Table 7

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

Sample Batch and Size	Single Devices or Pairs	Quantity Tested
ID2526	Single devices	4

All results were <0.25 EU/mL.

4.1.3 Conclusion

Rinse solutions from both gamma-irradiated and non-sterilized Kleenpak Presto 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 Summary of Test Method

Tests were performed as per USP <87>, MEM Elution Method. The samples to be tested were gamma irradiated to 50 ± 5 kGy, 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 revised peel strip material meets the specifications requirements of the USP <87>.

4.2.3 Conclusion

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

4.3 Biological Reactivity Tests, *In Vivo*, USP <88>

4.3.1 Introduction

The purpose of this test is to determine the biological response of animals to direct and indirect contact with the materials of construction of Kleenpak Presto sterile connector or injection of extract from the materials of construction of the Kleenpak Presto sterile connector, as per USP <88> for Class VI plastics.

4.3.2 Summary of 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 devices previously gamma irradiated at 50 ± 5 kGy and on the fluid contact material.

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.

Four extracting media listed in the USP simulate parenteral solutions and body fluids. These 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:

4.3.2.1 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.

4.3.2.2 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.

4.3.2.3 Implantation Tests

An implantation test is also performed to evaluate animal response in case of direct contact with Kleenpak Presto sterile connector construction materials.

4.3.3 Results

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

4.3.4 Conclusion

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

4.4 Physicochemical Test as per USP <661>

4.4.1 Introduction

The purpose of these tests is to evaluate the physicochemical suitability of Kleenpak Presto sterile connector for contact with parenterals.

4.4.2 Summary of 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. Autoclaved samples (2 cycles, 75 min, 130 °C) of Kleenpak Presto sterile connectors were extracted at 70 ± 2 °C for 24 hours in purified water. Tests were also conducted on fluid extracts from the revised peel strip material which had been gamma irradiated at 50 kGy.

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. These tests were performed on Kleenpak Presto sterile connector giving a surface area sample equivalent to 120 cm^2 /20 mL as per USP and previously gamma irradiated at 50 ± 5 kGy.

4.4.3 Results

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

4.4.4 Conclusion

Results demonstrated that the revised peel strip material and the Kleenpak Presto sterile connector meet the requirements of USP<661>.

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

4.5.1 Introduction

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

4.5.2 Summary of Test Method

Six Kleenpak Presto sterile connectors (3 gamma irradiated at 50 ± 5 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.

4.5.3 Results

Table 8

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

Batch Details	Single Devices or Pairs	Quantity	Pass/Fail
ID2526	Single devices	6	Pass

4.5.4 Conclusion

The Kleenpak Presto sterile connectors meet the requirements of particulate testing performed as per the requirements of USP <788>.

5 Shelf Life Studies

Accelerated ageing studies were conducted on Kleenpak Presto sterile connectors representing a one year storage time.

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.

Kleenpak Presto sterile connectors had been gamma irradiated (50 ± 5 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>. As this change impacts the peel strip material only, additional tests such as the leak test, the burst test and the extractables test were not repeated for this addendum.

5.1 Results

5.1.1 Bacterial Liquid Soiling Test

All Kleenpak Presto 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 9

Liquid soiling test results of connected Kleenpak Presto sterile connectors gamma irradiated at 50 ± 5 kGy and stored at 50 ºC with 75% relative humidity for 46 days. Contamination level 1.0 x 10^6 CFU/mL of B. diminuta

	Quantity Tested (Pairs)	Growth Observed
Batch 1	10	None
Negative control	1	None
Positive control	1	Turbid growth

5.1.2 Endotoxin and Particulate Testing

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

Table 10

Endotoxin and particle release test results after accelerated ageing

Test	Quantity Tested	Single Devices or Pairs	Result
Endotoxin Test, USP <85>	2	Single devices	Pass
Particle Release Test, USP <788>	3	Single devices	Pass

5.1.3 Conclusion

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

The results indicated that the functionality of the Kleenpak Presto 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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