ELDON JAMES

Validation Guide

Polypropylene Copolymer

ELDON JAMES

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1. VALIDATION GUIDE OVERVIEW

1.1 Introduction

The information provided in this validation document is intended to be used for informational purposes only. The information is provided on a without prejudice basis and should not be viewed as giving technical advice, instruction, or otherwise. The information is furnished free of charge and is based on supplier knowledge and understanding. Eldon James Corporation makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of any compound under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications. Products are manufactured in compliance with ISO 9001:2015 & ISO 13485:2016 Standards. Products are controlled and inspected in accordance with our applicable product specifications and standard operating procedures.

All Eldon James polypropylene fittings, adapters, and connectors are injection molded PVC- free, DEHP/BPA-free, are manufactured according to GMP and meet USP Class VI requirements. This material is an animal derivative free polypropylene formulated for biomedical and bio process applications. It meets FDA requirements 21 CFR 177.1520(a)(3)(i) and (c)3.1a. PP material has a Drug Master File listing (#7478) and is RoHS compliant and can be used in food, bio process and medical device applications. The polypropylene is radiation stable and is resistant to solvents, chemicals, water and other inorganic environments. It resists most strong mineral acids and bases (however, it is subject to attack by oxidizing agents). It is temperature stable from -23 °C to 66 °C (-9°F to 150°F) and can be sterilized by autoclave, ethylene oxide or e-beam.

This Validation Summary is intended to provide users of the polypropylene fittings, adapters, and connectors with the information necessary to assess the suitability of these products for use in their intended application.

1.2 Scope

All Eldon James polypropylene fittings, adapters, and connectors are injection molded PVC- free, DEHP/BPA-free, are manufactured according to GMP and meet USP Class VI requirements. This material is an animal derivative free polypropylene formulated for biomedical and bio process applications. It meets FDA requirements 21 CFR 177.1520(a)(3)(i) and (c)3.1a. PP material has a Drug Master File listing (#7478) and is RoHS compliant and can be used in food, bio process and medical device applications. The polypropylene is radiation stable and is resistant to solvents, chemicals, water and other inorganic environments. It resists most strong mineral acids and bases (however, it is subject to attack by oxidizing agents). It is temperature stable from -23°C to 66°C (-9°F to 150°F) and can be sterilized by autoclave, ethylene oxide or e-beam.

This Validation Summary is intended to provide users of the polypropylene fittings, adapters, and connectors with the information necessary to assess the suitability of these products for use in their intended application.

1.3 Effective Date

The information contained within this document is current as of October 2023.

1.4 Country of Origin

Polypropylene fittings are manufactured in the U.S.A.

1.5 Product Manufacturer

Polypropylene fittings are manufactured by:

Eldon James Corporation
3486 Precision Drive
Fort Collins, CO 80528

Eldon James Corporation
3420 Precision Drive
Fort Collins CO 80528

1.6 Manufacturing Environment

Polypropylene fittings are manufactured in both non-cleanroom and ISO Class 7 cleanroom environments within a facility certified to both ISO 9001:2015 and ISO 13485:2016. Cleanroom manufactured product is designated with a QC suffix.

1.7 Materials of Construction

Eldon James considers certain information regarding the manufacture of our products to be confidential trade secrets, such as, product raw materials and formulations.

1.8 Summary of Material Specifications

Attribute	Nominal Value		Test Method
	English	(SI)	
Specific Gravity	0.902	0.900 g/cm^3	ASTM D792
Tensile Strength (yield)	4060 psi	28.0MPa	ASTM D638
Tensile Elongation (break)	>700%	>700%	ASTM D638
Notched Izod Impact (73°F, 23°C)	1.1 ft lb/in	60J/m	ASTM D256
Rockwell Hardness (R-Scale)	90	90	ASTM D785
Deflection Temperature Under Load (66psi – 0.45MPa unannealed)	194°F	90.0°C	ASTM D648

2. REGULATORY INFORMATION

2.1 Regulatory Summary

2.1.1 Food Contact Status (USA)

This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.1a. According to our information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact, except for cooking, under conditions of use C through H as listed in 21 CFR 176.170(c), Table 2.

2.1.2 California Proposition 65 (PROP65) (Safe Drinking Water and Toxic Enforcement Act of 1986)

Based on available information this product does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels, which would be subject to Proposition 65.

2.1.3 US Pharmacopeia USP

USP <88> is a series of three tests that evaluate biological reactivity of animals to polymeric material: systemic toxicity, intracutaneous reactivity and implantation.

USP <88> / ISO 10993-5

These products have been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, *In Vivo*). USP Class VI and ISO 10993, following conclusions from test laboratory:

- Meets requirements of the guidelines for the Biological Test for Plastics, Class VI - USP 32, NF 27, 2009. <88> Biological Reactivity Tests, *In Vivo.*
- Considered non-cytotoxic and meets the requirements of the L929 MEM Elution Test ISO 10993-5, 1999 guidelines.

USP <161> / <661> / <85>

These products meet the requirements of the Transfusion and Infusion Assemblies and Similar Medical Devices (USP<161>), Physicochemical (USP<661> and Endotoxin (USP<85>) testing have also been performed.

2.1.4 Substance Reviews

As with almost all polypropylenes, including these products, antioxidants (preservatives) are used to some degree to protect the polymer during conversion/processing. A phenolic antioxidant (phenyl group containing) is used in the formulation. This product is not intentionally manufactured or formulated with the following substances or compounds; however, we do not analyze for these substances or compounds.

2-Mercaptobenzothiazole (MBT)	Not Present
Aflatoxin-like compounds	Not Present
Aldehydes	Not Present
Alkylphenols (nonylor	Not Present
Asbestos	Not Present
Azoxy compounds	Not Present
Bis(2-ethylhexyl) Adipate (DEHA)	Not Present
Bisphenol A (BPA)	Not Present
Bisphenol compounds, incl. but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ	Not Present
Bisphenol S (BPS)	Not Present
Brominated	Not Present
Butylated	Not Present
Butylated Hydroxyanisole (BHA)	Not Present
Butylated Hydroxytoluene (BHT)	Not Present
compounds	Not Present
Dibutyl-tin (DBT)	Not Present
Dimethyl Fumarate (DMF)	Not Present
Dioxins	Not Present
Dioxins and similar compounds	Not Present
Endocrine Disruptors (proven by the industry)	Not Present
Epoxy Resin	Not Present
Formaldehyde	Not Present
Halogenated (Brominated or chlorinated) or phosphorous based flame retardants	Not Present
Hydroxytoluene (BHT)	Not Present
Isocyanate	Not Present
Materials Considered Pyretic (Pyrogens)	Not Present
Melamine	Not Present
Monobutyl-tin (MBT) or any other	Not Present
Natural rubber latex, dry natural rubber, or synthetic latex	Not Present
Nitrosamines	Not Present
Nitroso compounds	Not Present
Novolac Glycidyl Ethers (NOGE)	Not Present
octyl-) or Alkylphenol ethoxylates (nonyl- or octyl-)	Not Present

Organic phosphates	Not Present
Organo-tin compounds	Not Present
Parabens	Not Present
Perfluorooctane	Not Present
Perfluorooctane Sulfonate (PFOS)	Not Present
Perfluorooctanoic Acid (PFOA)	Not Present
Phosphite (TNPP)	Not Present
Phthalates / Phthalate esters	Not Present
Plasticizers	Not Present
Polybrominated Biphenyls (PBB's)	Not Present
Polybrominated Diphenyl Ethers (PBDE's)	Not Present
Polybrominated Diphenyl Ethers (PBDEs)	Not Present
Polybrominated Terphenyls (PBT's)	Not Present
Polybrominated Terphenyls (PBTs)	Not Present
Polychlorinated Biphenyls (PCB's)	Not Present
Polychlorinated Biphenyls (PCBs)	Not Present
Polychlorinated Terphenyls (PCT's)	Not Present
Polycyclic aromatic hydrocarbon (PAH)	Not Present
Polycyclic Aromatic Hydrocarbons (PAH)	Not Present
Polyurethane	Not Present
Polyvinyl Chloride (PVC)	Not Present
Polyvinylidene Chloride (PVDC)	Not Present
Sulfonate (PFOS)	Not Present
Tributyl-tin (TBT)	Not Present
Triclosan	Not Present
Tris-nonylphenol	Not Present
Tris-nonylphenol Phosphite (TNPP)	Not Present
Vinylidene chloride	Not Present

2.1.5 European Union Standards

Food Contact Status (EU)

Polypropylene fittings do not meet the requirements of EU Regulation 10/2011 for food contact as the material resin contains an additive not included in Annex 1.

2.1.6 Allergens

This material does not intentionally use allergens - as defined by FDA as Milk,

Eggs, Fish, Crustaceans, Wheat, Soy, Peanuts, Tree Nuts - in the formulation of this product. This product does not intentionally use any of the following substances in the formulation of this product: natural rubber latex, dry natural rubber, synthetic latex, rubber that contains natural rubber.

2.1.7 REACH 235 Substances of Very High Concern (SVHC) June 14th, 2023

The raw material manufacturer does not believe any of the chemicals as per the EU Candidate List of Substances of Very High Concern (SVHC) are present in our polypropylene products at levels greater than 0.1%. Testing has indicated that some of our polypropylene products may contain trace residues (<8 ppm) of Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), and Bis (2-ethylhexyl) phthalate (DEHP). Benzyl butyl phthalate (BBP) was below the detection limit of the instrument used to test.

2.1.8 Restriction of Hazardous Substances (RoHS) EU Directive 2015/863/EU (RoHS 3 Directive)

The resin manufacturer does not intentionally use (suggest to add: or add heavy metals) Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's), or Polybrominated Diphenyl Ethers (PBDE's) or phthalates (DEHP, BBP, DBP, or DIBP)to any of the polypropylene products. Testing has indicated that some of our polypropylene products may contain trace catalyst residues (<8 ppm) of Dibutyl phthalate, Diisobutyl phthalate, and/or Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test. This product conforms to the RoHS 3 Directive (2015/863/EU) and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates.

2.1.9 Heavy Metals (ELV Directive 2000/53/EC) Coalition of Northeastern Governors (CONEG)

The raw material supplier does not use cadmium, chromium, lead, or mercury in the manufacture or formulation of this product. In addition, this product meets the CONEG limitation of 100 ppm for the total incidental content of cadmium, chromium, lead, and mercury.

2.1.10 HALAL

This product has no animal fats or ingredients derived from animal or fermentation products; therefore, it will comply with the dietary laws of Halal; however, it is not Halal certified.

2.1.11 Conflict Materials (Dodd-Frank Wall Street Reform and Consumer Protection Act)

This product is not intentionally manufactured or formulated with the listed conflict Materials as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; tin, tantalum, tungsten, or gold.

- Columbite-Tantalite – refined into Tantalum (Ta) (CAS# 7440-25-7)
- Cassiterite – refined into Tin (Sn) (CAS# 7440-31-5)

- Wolframite refined into Tungsten (W) (CAS# 7440-33-7)
- Gold (Au) (CAS# 7440-57-5)

We are disclosing the above information, to the best of our knowledge based upon data from our raw material supplier. We believe this information to be accurate and reliable as of the effective date of this Regulatory Data Sheet.

2.1.12 Ozone-Depleting Chemicals (ODCs)

This material does not use Class I or Class II ODCs listed in the Resolution 1005/2009/EC in the manufacture or formulation of this product.

2.1.13 Phthalates

Although phthalates are not intentionally added in the formulation of this product, there are phthalates in the final resin as a result of catalyst residues. Analytical testing has been performed on several grades with specific phthalates determined to be in concentrations less than 5 ppm. Dibutyl phthalate, Diisobutyl phthalate, and Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test.

2.1.14 Persistent Organic Pollutants (POPs)

All Eldon James products manufactured with Flexelene 135C are free of Persistent Organic Pollutants (POPs) as listed in Annex I, Part A of the EU regulation on POPs. We do not intentionally add any of these substances to our products and take necessary measures to ensure the absence of POPs in our manufacturing processes.

2.1.15 Per- and Polyfluoroalkyl Substances (PFAS) and Perfluorchemicals (PFCs)

Based on the information provided to us by our raw material supplier and review of their product formulation it has been determined that this product do not contain any known sources of the following substance(s):

- Per- and Polyfluoroalkyl substances (PFAS) including:

  - Perfluorooctanoic acid (PFOA), CAS No. 335-67-1
  - Perfluorooctane sulfonate (PFOS), CAS 1763-23-1

- Perfluorochemicals (PFCs)

2.1.16 European Directive (94/62/EC) Packaging and Packaging Waste EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)

EU Directive 202/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product. This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste. This product is recyclable according to the

recycle code 5.

2.1.17 European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)

The resin manufacturer does not use 2,2-bis(4-hydroxyphenyl) propane bis (2,3- epoxypropyl) ether (BADGE), bus(hydroxyphenyl)methane bus(2,3-epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this product.

2.1.18 Plant Derived Components

This product may contain one or more additives(s)/substances(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

2.1.19 Toxic Substances Control Act (TSCA)

13R9A is not intentionally formulated with any of the following compounds (TSCA section 6(h)):

- Decabromodiphenyl ether (DecaBDE)
- Phenol, isopropylated phosphate (3:1) (PIP (3:1))
- 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)
- Hexachlorobutadiene (HCBD)
- Pentachlorothiophenol (PCTP)

2.1.20 Animal Derivative Content & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Based on the information provided to us by our raw material suppliers, review of their product composition, this product is not intentionally manufactured or formulation with tallow or any other animal derived materials or associated with Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE) infectivity.

2.1.21 Kosher

The raw materials used in the manufacture of this product are derived from non-animal sources. There is no animal fat, no animal derived materials, grain derived, or fermentation products used in this product. The product is not certified as kosher but will comply with kosher dietary laws. Therefore, this product can be used with kosher products without compromising the status of the products.

2.1.22 Materials from Genetically Modified Organisms

Resin manufacturer utilizes a component produced from material of unknown genetic origin in its formulation.

2.1.23 Medical Device Regulation (EU) 2017/745

Polypropylene does not intentionally use any substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR 1A/1B/2) or endocrine disrupting substances (EDS) in amounts over 0.1%w/w (weight-by-

weight)

2.1.24 Sterilization Methods

Gamma	25-50 kGY – Some discoloration may occur at the higher doses. No significant effect on physical properties.
EtO	No issues. Can be safely used.
Autoclave	Limited to 121° C with no stress on part.

2.1.25 Shelf Life and Expiration Date

Eldon James has tight controls on inventory, so finished products are manufactured and sold quickly. Consequently, raw materials are stored for a relatively short time before use in the manufacturing process. Eldon James Polypropylene fittings have a minimum shelf life of 10 years; provided the fittings are stored in dry conditions at temperatures below 50°C (122°F) and protected from UV and nitrous oxide exposure. Improper storage conditions can initiate premature degradation of color, odor, and physical properties. Each individual condition and application should be tested by the customer to determine the limits of each product, material, and use.

3. PERFORMANCE TESTING

3.1 Biological Safety, Particulates and Physio-Chemical Tests

CLASS VI TESTING, USP <88> / ISO 10993

This is a series of three tests that evaluate biological reactivity of animals to polymeric material: systemic toxicity, intracutaneous reactivity and implantation. The Systemic Injection Test and the Intracutaneous test are designed to determine the systemic and local, respectively, biological responses of animals to plastics and other polymers by the single dose injection of specific extracts prepared from a sample. The Implantation Test is designed to evaluate the reaction of living tissue to the plastic and other polymers by the implantation of the sample itself into animal tissue. Eldon James have received the following conclusions from an outside test laboratory on these products:

General Procedure:

The test article was prepared at a ratio of 60cm2: 20mL and extracted at 121°C for one hour.

Test date	February 2009		
Test Article	Polypropylene fitting	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test - USP	**Extract Conditions**	121°C for 1 hour

General Procedure:

The extraction conditions were performed as stated above. The test article extracts, and corresponding blanks were injected systemically and

intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP. The animals were observed for signs of toxicity and skin reactivity post treatment. In addition, the test article was implanted into rabbit muscle for 7 days and observed macroscopically for signs reaction.

Results:

USP Systemic Toxicity Study in the mouse. The test article was extracted as above and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extracts.
USP Intracutaneous Toxicity Study in the Rabbit. The test article was extracted as above and injected into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extracts.
USP Muscle Implantation Study in the Rabbit. The macroscopic reaction of the test article, implanted into rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

Conclusion:

The test article meets the requirements of the guidelines for the Biological Test for Plastics Class VI in that it meets the requirements of the guidelines for the Biological Test for Plastics, Class VI, USP <88> Biological Reactivity Tests, *In Vivo.*

ENDOTOXIN

Test date	09/June/2015		
Test Article	Polypropylene fitting	**Vehicles**	Water for Injection
Study	LAL	**Extract Conditions**	37 +/- 1°C for 24 +/- 2 hours

Method:

1 gram of sample was covered with 10mL of Water for Injection and placed in a 37°C shaker incubator for between 40-60 minutes.
Individual 0.1 mL portions of the test and control solutions were placed in sterile microplate wells and incubated at 37°C for 10 minutes in a Kinetic-Chromogenic Reader. Individual 0.1 mL portions of lysate, reconstituted per manufacturer's current directions, were then added to each well and testing was initiated. The concentration of the endotoxin was determined spectrophotometrically. A Positive Product Control solution (inhibition/enhancement control) was simultaneously prepared and tested to evaluate any possible interference by the test article on the lysate/endotoxin reaction. All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

Test Acceptance Criteria:

Type of Product	Current FDA Requirements*	Current USP Requirement
Medical Device	Less than or equal to 0.5 EU/mL	Less than or equal to 20.0 EU/device
Medical Device Contacting Cerebrospinal Fluid	Less than or equal to 0.06 EU/mL	Less than or equal to 2.15 EU/device
Water for Injection	Not applicable	Less than or equal to 0.25 EU/mL

*Based on an extract volume of 40 mL / device

Results:

Test article Extract Dilution:	1
Positive Product Control Percent Recovery:	83% (between 50% and 200% is acceptable)
Test article extract:	<0.00500 EU/mL (Total Concentration) <0.0500 EU/g

References:

Association for the Advancement of Medical Instrumentation (AAMI) ST72: Bacterial Endotoxins - Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing (2011). United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <85>, Bacterial Endotoxins Test (2015). United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <161>, Transfusion and Infusion Assemblies and Similar Medical Devices (2015).

CYTOTOXICITY / ISO 10993-5

This test is a common cytotoxicity assessment designed to assess the toxicity to cells of leachable components of the material. The material is extracted in cell culture media (Minimum Essential Medium, or "MEM") at 37°C for 24 hours. Negative control reagent control and positive controls were similarly prepared. Extracts are placed in contact with triplicate monolayers of L-929 mouse fibroblast cells. Cells are incubated in a controlled environment (37°C in the presence of 5% CO_2) for 48 hours after which they are examined microscopically for abnormal cell morphology and cellular degeneration.

Test date	04/08/2011		
Test Article	Polypropylene fitting	**Vehicles**	Serum-Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test - ISO	**Extract Conditions**	37 +/- 1°C for 24 +/- 2 hours

References:

The study was conducted based on the following references: ISO 10993-5, 2009, Biological Evaluation of Medical devices – Part 5: Tests for *In Vitro* Cytotoxicity. USP 32, NF27, General Chapter <87>, Biological Reactivity Tests, In Vitro (2009) ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity

General Procedure:

The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control and negative control articles together with reagent control were prepared to verify the proper functioning of the test system. The test extracts were not centrifuged, filtered, or otherwise altered prior to dosing. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37 +/- 1 °C, in a humidified atmosphere containing 5 +/- 1% carbon dioxide. Biological reactivity (Cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity) as below.

Grade	Reactivity	Conditions of all cultures
0	None	Discreate intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no excessive cell lysis, not more than 50% growth inhibition observed.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed.
4	Severe	Nearly complete or complete destruction of the cell layers.

The test article met the requirements of the test if the negative control extracts must have had a reactivity of none (Grade0) and the positive control must have been a grade 3 or 4. None of the cultures exposed to the test article showed greater than a Mild reactivity (Grade2).

Results:

No signs of reactivity (Grade0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48-hour observations. Severe signs of reactivity (Grade4) were observed for the positive control article extract at the 48-hour observation.

Conclusion:

The test article is considered non-cytotoxic and meets the requirements of the L929 MEM Elution Test ISO 10993-5, 1999 guidelines.

Note:
Although the above information was provided, only actual testing of the final medical device product will positively establish this status for your final product. Please note that meeting Class VI criteria is only the base starting point. The ultimate suitability for use in a medical device application would depend on the specifics of the final product, its specific end use application and meeting the USP or ISO testing criteria required for that specific end use application.

As Eldon James does not control the conditions under which our products are used in our customer's products, we are not able to warrant that the customer's products meet FDA or other regulatory requirements.

LEACHABLES AND EXTRACTABLES

Materials Tested

ITEM	DESCRIPTION
12000-00	FITTING, SANITARY TO HOSE BARB, PP, 3/4" SANITARY TO 3/8" BARB
11672-15	FITTING, BARBED REDUCER, PP, 3/4 X 3/8
11672-02	FITTING, REDUCER, 1/4 IN HB X 1/8 IN HB, PP
11811-03	STRAIGHT CONNECTOR 1/8", PP
11973-03	FITTING, BARBED CROSS, PP, 1/4"
12015-05	FITTING, TEE CONNECTOR, 1/4" HB X 3, PP
11673-01	PLUG, HOSE BARB, PP, 1/8"
11672-04	FITTING, BARBED REDUCER, PP, 3/8" X 1/8"

11673-04	PLUG, HOSE BARB, PP, 1/4
12015-02	FITTING, BARBED TEE, PP, 1/8"
12022-00	FITTING, SeriesLock™ QUICK CONNECT, IN LINE BARBED, PP, MALE, 3/4" BARB
12023-00	FITTING, SeriesLock™ QUICK CONNECT, IN LINE BARBED, PP, FEMALE, 3/4" BARB

An extractables study was performed to identify and to estimate the amounts of compounds that may be extracted from an assembly upon contact with model solvents. Prior to extraction, the fitting assembly was sterilized using Gamma irradiation. During the sterilization process the delivered dose was monitored:
Minimum delivered dose: 27.7 kGy Maximum delivered dose: 36.3 kGy
Each sample was analyzed by direct injection gas chromatography mass spectrometry (GC/MS) to screen for semi-volatile organic compounds and by headspace GC/MS to screen for volatile organic compounds. Liquid chromatography with ultraviolet and mass spectrometry detection (LC/UV/MS) was used to screen for non-volatile organic compounds. An elemental analysis was performed using inductively-coupled plasma optical emission spectroscopy (ICP-OES).

Extraction Solvents:

Sample ID	Solvent
Fittings Assembly	Water at pH3
	Water at pH10
	1/1 Ethanol/Water
	Water

For each solvent above, the assembly was filled with 4200ml (approximately half-full) of solvent and stored at 40ºC for 21 days, with agitation.
After the storage period, the sample extracts were transferred into glass containers for analysis by GC/MS and LC/UV/MS and polypropylene containers for analysis by ICP-OES. Control solutions for each solvent and condition were prepared in the same manner as the sample preparations.

The solutions to be analyzed by GC/MS and LC/UV/MS were then stored at 2°C to 8°C until analysis, and the solutions to be analyzed by ICP-OES were stored at ambient conditions until analysis.

Direct Injection GC/MS

The water at pH3, water at pH10, and water extracts and controls were exchanged to a 10 µg/mL phenanthrene-d10 solution in methylene chloride by combining 2.0 mL of each extract or control with 2.0 mL of a methylene chloride extraction solution. Each solution was vortex- mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes. A portion of each mixture's methylene chloride layer was transferred into a vial for analysis.
The 1/1 ethanol/water extracts and controls were exchanged twice to a 10 µg/mL phenanthrene-d10 solution in methylene chloride by combining 3.0 mL of each extract or control with two 1.5-mL aliquots of the 10 µg/mL phenanthrene-d10 solution. The first aliquot was combined with the extract or control and vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes before transferring the methylene chloride layer to a 3-mL volumetric flask. Then the second aliquot was combined with the extract or control and vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes before transferring the methylene chloride layer to the same

volumetric flask as the first aliquot. As the ethanol made the volume greater than 3 mL, each solution was evaporated with nitrogen to less than 3 mL and was then brought back to volume with methylene chloride. A portion of each solution was transferred into a vial for analysis.
Mass spectra were compared to reference spectra found in the Wiley2010/NIST2011 (W10/N11) database and a proprietary Eurofins database to determine plausible identities. When confident matches to the database were not found, compounds were classified as accurately as possible. The results for the direct injection GC/MS analysis are shown below.

Direct Injection GC/MS Results for Water at pH3 Extracts

Solvent	Tentative Identification	Est. Conc.(µg/mL)	Est. Conc. (µg/assembly)
Water at pH3	NA	< RL	< RL
Water at pH10	NA	< RL	< RL
1/1 Ethanol/Water	1,3-Bis(1,1-dimethylethyl)- benzene	0.2	668.8
	1-Decanol	< 0.1	207.7
	Unknown (Ions: 177, 220, 41)	0.1	298.2
	2,4-Bis(1,1-dimethylethyl)-phenol	2.2	9082.6
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the direct injection GC/MS analysis, no compounds were reportable in the water at pH3, water at pH10, or water extracts of the fittings. Four compounds (1,3-bis(1,1- dimethylethyl)-benzene, 1-decanol, 2,4-bis(1,1dimethylethyl)-phenol, and an unknown) were reportable in the 1/1 ethanol/water extracts of the fittings.

Headspace GC/MS

Internal standards were added to the water at pH3, water at pH10, and water extracts and controls directly by combining 1.0 mL of each extract or control with 4.0 mL of a 1.25 µg/mL 1,4-dichlorobenzene-d4 spiking solution in water in 10 mL headspace vials. This spiking yielded a final concentration of approximately 5 µg/vial. Internal standard was added to the 1/1 ethanol/water extracts and controls directly by combining 0.5 mL of each extract or control with 5.0 mL of a 0.5 µg/mL 1,4-dichlorobenzene- d4 spiking solution in water in 10 mL headspace vials. This spiking yielded a final concentration of approximately 2.5 µg/vial. Mass spectra were compared to reference spectra found in the Wiley2010/NIST2011 (W10/N11) database and a proprietary Eurofins database to determine plausible identities. The results for the headspace GC/MS analysis are shown below.

Headspace GC/MS Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH3	NA	< RL	< RL
Water at pH10	NA	< RL	< RL
1/1 Ethanol/Water	1,3-Bis(1,1-dimethylethyl)- benzene	0.3	1336.1
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the headspace GC/MS analysis, no compounds were reportable in the water at pH3, water at pH10, or water extracts of the fittings. One compound

(1,3-bis(1,1-dimethylethyl)- benzene) was reportable in the 1/1 ethanol/water extract of the fittings.

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH3	NA	< RL	< RL
Water at pH10	Tris (2,4-di-tert butylphenyl) phosphate (Ion 663.4551)	1.3	5291.0
1/1 Ethanol/Water	Bis (2,4-di-tert butylphenyl) phosphate (Ion 475.2971)	0.4	1660.0
	Irganox 245 (Ion 604.3799)	0.3	1216.3
	Dilauryl Thiodipropionate (oxidized) (C30H58O5S) (Ion 531.4082 [M+H]+)	0.5	2053.1
	Tris (2,4-di-tert butylphenyl) phosphate (Ion 663.4549)	0.4	1841.0
Water	NA	< RL	< RL

LC/UV/MS

Each of the extracts and controls was transferred directly into a vial for analysis.

LC/MS MM^+ Results for Extracts

NA = Not applicable; RL = Reporting limit

LC/MS MM^- Results for Extracts

Solvent	Tentative Identification	Est. Conc.(µg/mL)	Est. Conc. (µg/assembly)
Water at pH3	NA	< RL	< RL
Water at pH10	Bis (2,4-di-tert butylphenyl) phosphate (Ion 473.2839)	1.4	6007.5
1/1 Ethanol/Water	Irgafos 168 degradant (C14H23O3P) (Ion 269.1322 [M-H]-)	0.1	577.9
	Bis (2,4-di-tert butylphenyl) phosphate (Ion 473.2840)	3.6	15054.1
	C28H43O5P (Ion 489.2781 [M-H]-), Irganox 245 (Ion 585.3438), and related to Bis (2,4-di-tert butylphenyl) phosphate (Ion 473.2831)	0.2	661.8
Water	Bis (2,4-di-tert butylphenyl) phosphate (Ion 473.2845)	0.4	1690.1

NA = Not applicable; RL = Reporting limit

LC/UV Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH3	NA	< RL	< RL
Water at pH10	Bis (2,4-di-tert butylphenyl) phosphate	0.4	1677.3
1/1 Ethanol/Water	Unknown	1.8	7668.8

	Bis (2,4-di-tert butylphenyl) phosphate	1.1	4479.1
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the LC/UV/MS analysis, no compounds were reportable in the water at pH3 extract of the fittings. Several Irgafos 168 degradants and a few unknown compounds were reportable in the water at pH10, 1/1 ethanol/water, and water extracts.

ICP-OES

System suitability standards were prepared from purchased stock standards. Two standards were prepared at approximately 1 µg/mL in the 5% nitric acid / 5% hydrochloric acid matrix and contained all reported elements. One standard was used for system calibration while the other was used as a check standard. A sensitivity solution was prepared at approximately 0.1 µg/mL in the 5% nitric acid / 5% hydrochloric acid matrix and contained all reported elements.
In addition, an internal standard containing 3 µg/mL yttrium was prepared in the 5% nitric acid/ 5% hydrochloric acid matrix. This internal standard was mixed with each standard and sample online by the instrument in order to eliminate issues associated with the differences in physical properties between the standard and sample solutions, such as viscosity, which can affect the mobility of the test solutions passing into the spray chamber and through the ICP-OES system.
Each water at pH3, water at pH10, and water extract and control were prepared by adding 0.5 mL of nitric acid and 0.5 mL of hydrochloric acid to a digestion vessel containing the extract or control. The solutions were then brought to a volume of 10.0 mL, each with the appropriate extract or control. For the preparation of the 1/1 ethanol/water extracts and controls, 10 mL of each was evaporated to near dryness and then reconstituted with an equivalent volume of 5% nitric acid / 5% hydrochloric acid.

The following elements were evaluated:

1.	Ag	11.	Hg	21.	Ru
2.	Al	12.	Ir	22.	Sb
3.	As	13.	Li	23.	Se
4.	Au	14.	Mo	24.	Sn
5.	Ba	15.	Ni	25.	Ti
6.	Cd	16.	Os	26.	Tl
7.	Co	17.	Pb	27.	V
8.	Cr	18.	Pd	28.	W
9.	Cu	19.	Pt	29.	Zn
10.	Fe	20.	Rh	30.	Zr

Reportable results for a given element in a sample were calculated by subtracting the concentration of the element in the associated control from the concentration of the element in the sample. The concentration the reporting limit corresponded to in-sample as a result of any dilutions performed during sample preparation are shown below.

ICP-OES Results for Extracts

Solvent	Element	Corrected Est. Conc. (µg/mL)	Corrected Est. Conc. (µg/assembly)
Water at pH3	NA	< RL	< RL
Water at pH10	NA	< RL	< RL

1/1 Ethanol/Water	NA	< RL	< RL
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

Note: Spectral interference was observed in the water at pH10 extract and control solutions for As, Hg, Ir, Pb, Sb, Se, and Tl. Note: Cr was detected in the water at pH10 extract and control solutions above the reporting limit (but was not reportable due to control correction). This response is likely due to the presence of P in the extraction solvent because P is known to interfere with Cr at the analyzed wavelength.

In the ICP-OES analysis, no elements were reportable in the extracts of the fittings.

Conclusion:

In the direct injection GC/MS analysis, no compounds were reportable in the water at pH3, water at pH10, or water extracts of the fittings. Four compounds (1,3-bis(1,1-dimethylethyl)- benzene, 1-decanol, 2,4-bis(1,1dimethylethyl)-phenol, and an unknown) were reportable in the 1/1 ethanol/water extracts of the fittings. In the headspace GC/MS analysis, no compounds were reportable in the water at pH3, water at pH10, or water extracts of the fittings. One compound (1,3-bis(1,1-dimethylethyl)- benzene) was reportable in the 1/1 ethanol/water extract of the fittings. In the LC/UV/MS analysis, no compounds were reportable in the water at pH3 extract of the fittings. Several Irgafos 168 degradants and a few unknown compounds were reportable in the water at pH10, 1/1 ethanol/water, and water extracts. In the ICP-OES analysis, no elements were reportable in the extracts of the fittings.

Shelf Life Testing:

Eldon James contracted with a third party to expose samples to accelerated aging and testing. Accelerated aging conditions provided a real time, product age of ten (10) years (T=10). After aging, the samples where tested and compared to newly produced samples to indicate that the product did not change with time. Conditions for all test samples were done at 60 degrees C and no more than 20% RH for a time equivalent to ten (10) years real time aging. (323 days).

Test Results:

Two functional tests were completed to assess the performance of a newly produced tube (T=0) and a tube manufactured and accelerated aged for an equivalent real-time period of ten (10) years (T=10). Tests completed included leak testing and pull testing from a barb fitting.

Leak Testing was completed by pressurizing the tubing/fitting assembly and measuring the air loss from the pressurized cavity. In both cases, T=0 and T=10, the pressure loss otherwise known as leak decay was well below the required test criteria. The only difference between time test points was the time at which the measurement was taken directly after the initial pressurization. The T=0 testing was measured directly after pressurization and the T=10 testing was completed after fifteen (15) seconds to account for tubing stretch. It was determined that during the initial testing, the tube stabilizes dimensionally with the added internal pressure and needs to stabilize prior to a measurement being taken. Both tests, however, are considered within specification and performed as intended. Additionally, if measured at times greater than 30 seconds, the tube has had sufficient time to dimensionally stabilize, and the leak decay values go to zero as no leaks are present. See the chart below for test results.

DESCRIPTION	LEAK TESTING (T=0Yrs)	LEAK TESTING (T=10Yrs)
ACCEPTANCE CRITERIA	9 mL/min Maximum	
SAMPLE SIZE (N)	73	
UNIT OF MEASURE	L/min	
Test Time	After Pressurization	After 15sec Post Pressurization
MIN	0.006	0.001
MAX	0.008	0.001
AVE	0.0069	0.001
S.D.	0.0005	0.000
# PASSED / # TESTED	73/73	73/73

A functional pull test was completed to assess the performance of a newly produced molded luer fitting (T=0) and a luer fitting manufactured and accelerated aged for an equivalent real-time period of ten (10) years (T=10). The linear forecast trending of the study points to age as not being a factor in the Eldon James PP fitting product.

Pull Testing was completed using standard barb fittings manufactured by Eldon James. Each connection was pulled to structural failure at a rate of 20in/min per ASTM guidelines for materials with softer durometers and greater elongation potential. Both time points, T=0 and T=10, passed the testing criteria. See the chart below for test results.

DESCRIPTION	PULL TESTING (T=0Yrs)	PULL TESTING (T=10Yrs)
ACCEPTANCE CRITERIA	4 Lbf Minimum	
SAMPLE SIZE (N)	73	
UNIT OF MEASURE	Lbf	
MIN	9.0	5.18
MAX	11.0	9.32
AVE	10.0	6.70
S.D.	0.365	0.839
# PASSED / # TESTED	73/73	73/73

Dimensional analysis of the T=10 aged product was completed to assess the dimensional stability of the tubing. Both tubing inner diameter and outer diameter were measured for all test samples. All samples passed the critical dimension criteria set forth by the design drawings. See chart below for the dimensional results.

DESCRIPTION	DIMENSION Inner Diameter	Outer Diameter
ACCEPTANCE CRITERIA	.047 ± .003	. 110 ± .003
SAMPLE SIZE (N)	73	73
UNIT OF MEASURE	In	In
MIN	.044	.107
MAX	.047	.110
AVE	.046	.109
S.D.	.0006	.00061
# PASSED / # TESTED	73/73	73/73

Dimensional analysis of the T=10 aged product was completed to assess the dimensional stability of the molded luer fittings. Various dimensions were measured for all test samples. All samples passed the critical dimension criteria set forth by the design drawings. See chart below for the dimensional results.

DESCRIPTION	DIMENSION Thru Hole	Barb Length	Length	Outer Diameter
ACCEPTANCE CRITERIA	.041 ± .018	.092 ± .018	.585 ± .023	. 445 ± .023
SAMPLE SIZE (N)	73	73	73	73
UNIT OF MEASURE	In	In	In	In
MIN	.041	.088	.583	.440
MAX	.044	.095	.588	.444
AVE	.042	.090	.585	.442
S.D.	.0009	.0014	.0014	.0005
# PASSED / # TESTED	73/73	73/73	73/73	73/73

Conclusion:

All tests were conducted in accordance with the methodology set forth in the testing protocol and test results indicate that the established acceptance criteria were met.
Eldon James' Flexelene™ FX polymer and EJ polypropylene fittings have passed ten (10) year accelerated aging and as such should have a shelf-life of ten (10) years AFTER processing into product configurations.