An investigation into the potential for challenge fluid carryover in the vapour phase, post aerosol challenge integrity testing using the Valairdata 4.

Product Support - Technical Information - New Developments

Parker

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Contents

Parker Bioscience Filtration

Setting the standard

Parker brings extensive experience through our scientists, engineers and sales representatives to the process of offering specific filtration systems to meet the needs of your production process. Support services are available covering a wide range of activities including scale-up advice from laboratory through pilot scales to production systems, validation support on-site technical support, design and manufacturing of housings and filtration products.

Committed to quality

Quality is of paramount importance to Parker. As such we have been certified to ISO9001, providing a quality management system that covers the entire organization including R & D, production, warehousing, materials management and customer support. In addition, our manufacturing facilities operate to the principles of cGMP.

Our manufacturing facilities are also certified to ISO14001 Environmental Management Standard and ISO13485 Medical Device requirements.

Validation and product certification

To certify that Parker products meet the required regulatory and quality standards of the industries that we supply, all filters are supplied with a certificate of conformance. These certificates are linked to validation documents for both prefilter and sterilizing grade membrane filter products that define methodologies and data appropriate to each filter type. This information typically includes:

- Technical specifications.
- Biological safety testing information; USP <88> Class VI - 121C Plastics and equivalents.
- Extractable testing including 21CFR211.72 and 210.3(b), 6 for fibre release.
- Purified water filtration quality including TOC, bacterial endotoxins, conductivity and particle release.
- Chemical compatibility guidance information.
- Thermal stability.
- Correlation of an appropriate non-destructive integrity test to a defined bacterial challenge.
- EC Food contact safety specification.

Validation support services

Parker has extensive laboratory facilities and trained personnel capable of providing a range of validation services to support manufacturers in meeting their requirements for process validation relating to the use of filtration products.

1. Introduction

The Valairdata integrity test uses an aerosol challenge method based on generation of a defined aerosol from Purity™ FG WO 15 oil. Whilst this oil meets the UK Mineral Hydrocarbons in Food Regulations 1966 (SI No 1073) and FDA Federal Code Regulation 178-3620(a) for food quality white oils, users have expressed interest in levels of oil carry over to the downstream sector of filtration systems during testing. This study was performed to determine the level of any potential challenge fluid (Purity™ FG WO 15 oil) carry over in vapour phase at both ambient and elevated temperature.

HIGH FLOW TETPOR air sterilization filter cartridges were integrity tested, and hydrocarbon carry over downstream determined using flame ionization detection (FID). The following experimental variations were included in the study:

- Cartridge integrity tested and steam sterilized to remove residual challenge fluid prior to FID analysis. FID analysis was conducted on two cartridges at 23°C (73.4°F) and 60°C (140°F), respectively. (Best case scenario.)
- Cartridge integrity tested and carry over determined by FID at 23°C (73.4°F). (Typical situation.)
- Cartridges tested 12 times consecutively and carry over determined by FID at 60°C (140°F). (Worst-case scenario.)

The data showed that in all cases the level of hydrocarbon detected downstream of the test cartridges was the same regardless of cartridge treatment. In addition, the levels detected were the same as background controls and at the level of the sensitivity of detection for the FID system.

These data indicate that the level of carry over of hydrocarbon following Valairdata integrity testing, in the absence of post test steam sterilization and at elevated operating temperature is negligible.

2. Methods

All tests were performed on 5¨ (125mm) HIGH FLOW TETPOR air sterilization cartridges (product code ZCHT-AZ) installed in a 5 ¨HIGH FLOW air vessel (product code ZVA-01A-BTE). Air was supplied to the test rig from the laboratory ring main and a heater was installed in-line immediately prior to the test vessel. Tests were performed at both ambient temperature and with an inlet air temperature of 60°C (140°F).

Immediately after the test vessel a sample port was installed to allow downstream air samples to be analysed by FID. The Flame Ionization Detection Instrument was run for 24 hours to ensure the oven was up to temperature and the instrument fully stable. Meter readings from the instrument were recorded using a flat bed chart recorder and the flow through the rig was measured using a rotameter (Model No. RD068) and set a 600l/min-1 ANR.

Before proceeding with the following tests, the Flame Ionization Detection Instrument was adjusted for zero reading and span using thecalibration gases. Air was passed through the test vessel with the heaters on and the temperature regulated to 60°C (140°F). When temperature stabilization was achieved a background reading of total hydrocarbon vapour was recorded..

Filter test 1	Integrity tested & steam sterilized - FID 60˚C (140˚F)
Filter test 2	Integrity tested & steam sterilized - FID 23˚C (73.4˚F)
Filter test 3	Integrity tested - FID 23˚C (73.4˚F)
Filter test 4	Integrity tested cumulatively - FID 60˚C (140˚F)

Table 1: Summary of filter tests

Integrity testing

Integrity testing was performed using a Valairdata integrity test system. The standard test time of 10 seconds for a 5¨ (125mm) HIGH FLOW TETPOR (ZCHT-AZ) air sterilization filter cartridge was employed.

Steam sterilization

Where applicable cartridges were steamed in-line at 121°C (249.8°F) for 30 minutes followed by flash drying for 10 seconds. Test fluid employed by the Valairdata is Purity™ FG WO 15 oil.

FID

The FID temperature relates to the temperature of the air entering the housing inlet. Higher temperature studies were performed as a worst-case in terms of generating hydrocarbonsin the vapour phase. The specification for the FID analysis is as follows:

Type	AAL FID Serial No. 520-2303
Gases:	Hydrogen Grade 5.0 Purity 99.999% Hydrocarbon Content 0.5ppm Bottle No BD47889-F
	Ultra Zero Air Hydrocarbon Content 0.2ppm
	Methane Standard 9.1ppm certified standard Bottle No. 8562B (140˚F)
Operating settings	Zero suppression - 0.04 @ 0.0 ppm Span calibrate - 6.70 @ 9.1 ppm

Table 2: Summary of FID analysis specification.

3. Results

Results are shown in Table 3. From these data it can be seen that the levels of hydrocarbons detected downstream of the test cartridges are the same regardless of process conditions (inlet air temperature, plus or minus steam sterilization, single or multiple integrity tests) and comparable to the levels seen from background analysis. The levels described are very low and at the limit of detection for the FID system.

Test	FID Reading (ppm CH_4)	Corrected Reading (ppm hydrocarbons)	Temperature (˚C)	(˚F)
Background	2.1	0.14	60	140
Filter test 1	2.2	0.14	23	73.4
Filter test 2	2.2	0.14	60	140
Filter test 3	2.2	0.14	23	73.4
Filter test 4	2.3	0.15	60	140

Table 3:
Hydrocarbon readings downstream of test cartridges following Valairdata integrity testing under a range of conditions.

4. Technical Support Group activities

Parker have a trained team of scientists and engineers available to answer questions regarding the technical capabilities of our products, to assist in the selection and design of appropriate filtration systems and to provide user training programs. The following services can be delivered both on-site and in-house:

- Filterability testing to optimize filter system design
- Advice on the development of integrity testing, steam sterilization and clean-in-place procedures
- Development of validation protocols
- Troubleshooting
- Facility audits to ensure continued optimization of filter use
- Operator training including filtration theory, validation, filter system design and management

For more information on any of the above support services please contact your local Parker representative.

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