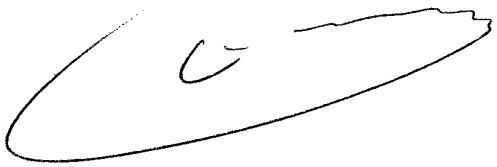
armfield

Trials Report
FT83 Sterility Tests

Report Number: **CAM: 31673**
Date: **June 2006**

John Maybury PhD (Biochemical Engineering)
Senior Development Engineer

Ted Sansom B.Eng. C.Eng. MIEE.
Technical Director



Introduction

The FT83 is designed to fill containers in a sterile environment with product that has been UHT treated by an Armfield FT74 or FT94 system, thus producing aseptic packaged product. The FT83 utilises a HEPA filtration system that produces air filtered to Federal Standard 209e – Class 100.

A number of trials have taken place to establish the sterility performance of FT83, and these are summarised in this report.

The trials have been performed using the standard Media Fill Test (MFT) as used to validate aseptic filling and processing systems in the pharmaceutical and food industries. A standard general growth medium was used, soybean casein digest medium (Oxoid tryptone soya broth (TSB) CM129). This medium has been developed specifically for sterility testing and the validation of aseptic media filling procedures. This particular media is recommended by Annex B of ISO 11137. Contamination is indicated by broth turbidity. If samples remain clear following incubation under defined conditions then they are declared to be sterile.

Method

For the trials, the FT83 pipework and filling nozzle were sterilised by pressurised hot water from the UHT equipment at a minimum temperature of 121°C for 20 minutes. This was performed under control of the FT83 in accordance with the standard operating procedures. The cabinet internal surfaces were sterilised by a 70% ethanol hand spray, as were the operator's latex gloves.

After the pipework was sterilised, the cooling water was switched on, cooling the flow to the FT83, whilst maintaining UHT temperatures in the heating section. The product was then changed from water to TSB again maintaining UHT temperatures. Pre-sterilised (gamma irradiated) screw top plastic containers (Fisher Scientific, FB51513) were then filled with the UHT treated TSB using the FT83, the containers only being opened inside the FT83 working area. The containers were then incubated under the conditions described below.

For the trials with larger numbers of containers, additional containers were introduced into the chamber during the trial and filled containers removed from the chamber.

Results

	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5
Date	25-11-05	15-12-05	25-05-06	31-05-06	31-05-06
No. samples	25	58	600	200	200
Equipment	FT94X + Tubular Heat Exchanger	FT94X + Plate Heat Exchanger	FT74X + FT74-45 + Tubular Heat Exchanger	FT74X + FT74-45 + Tubular Heat Exchanger	FT74X + FT74-45 + Plate Heat Exchanger
Operator	EES	JPM	JPM	JPM	JPM
Incubation Period	3 months	3 months	14 days	14 days	14 days
Incubation Temperature	Room Temp	Room Temp	30 °C	30 °C	30 °C
No. Contaminated	0	0	0	0	0
Percentage Sterile	100%	100%	100 %	100 %	100 %

Verification of Method

Two simple 'controls' were introduced to verify the test method.

On Trial 3 one sample was deliberately opened after 5 days incubation and contaminated. This sample showed growth after two more days incubation.

At the end of trial 4, the process temperature was allowed to drop below the UHT limit to 40°C. During this time 11 samples were filled and after incubation all 11 showed microbial growth.

Discussion

In total 1083 samples have been taken, using four different sets of heat exchanger equipment and two different operators. All these samples were sterile and none were contaminated.

A defect ratio of better than 0.1 % is therefore established.

The requirements for aseptic filling as defined by ISO 11137 are for a defect ratio of better than 1 micro-organism in 10^6 samples. To prove this in a statistically valid method would require processing and analysis of several million samples and so is not realistic. This is a fundamental limitation of validating any aseptic system. Because of this difficulty, the normal criterion for evaluating Aseptic filling systems is to use Media Fill Tests and to declare an "action" level at 0.1%. i.e. a defect ratio above this requires further action and trials. A defect ratio below this means no action is required and the process can be assumed aseptic. This criterion is encompassed into ISO 13408-1, Aseptic Processing of Health Care Products.

Under this criterion, the FT83 filling process can be classified as aseptic.

Conclusion

The Armfield FT83 can form part of an aseptic processing system and produce sterile packaged samples.