

Standard Operating Procedure

Title: Aseptic Media Fill/'Soup' Test Guidelines

Department	Micro Laboratory	Document no	MICLAB 040
Prepared by:		Date:	Supersedes:
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Document Owner

Microbiology Laboratory Manager

Affected Parties

All Microbiology Laboratory and production colleagues

Purpose

To outline the guidelines in determining when an Aseptic Media Fill and/or a 'Soup' (Integrity) test is required.

Scope

1. It is the responsibility of the Microbiology Manager to set up a yearly schedule of routine Media runs - this is a guide only and can be altered within reason to fit in with Production requirements. To ensure compliance with the GMP Routine media runs for aseptically filled processes (process simulations) are to be conducted at least twice per year per shift and process. For terminally sterilised lines and non-sterile process once per year per shift.
2. It is the responsibility of the Process Team to schedule their routine Media runs in accordance with the yearly schedule set up by the Microbiology Manager.
3. It is the responsibility of the Micro. Lab. staff to chart and check that the required number of Media runs are performed each year.
4. It is the responsibility of the area Production Manager to consult with the Micro. Lab. staff to organise Media runs/'Soup' tests required outside the routine schedule for validation or major/minor changes made.
5. All sterile personnel associated with the process are required to participate in a media run at least once per year.

Definition

Media Fill	Process simulation using bacterial nutrient broth.
BRF	Bioburden Reducing Filter

Related Documents

Form 665	Microbiological Integrity (Soup) Test
Form 670	Aseptic Media Fill Information Sheet
MICLAB 020	Destruction of Biological Waste in the Microbiology Laboratory
MICLAB 035	Aseptic Media Filling and Micro. Integrity Leak (Soup) Testing Procedure
MICLAB 070	Identification of Microorganisms to Genus and Species Level
MICLAB 090	Stock Suspension of Micro Organism

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High Speed Filling Machines are to fill equal to 10,000 units.

Low speed Filling Machines are to fill equal to 5000 units.

1.3.1. Any **design** change to product path - 3 media runs.

1.3.2. “Like-for-like” changes to validated processes from the primary sterilising filter to completed primary container i.e. product path - no media run required.

Container Integrity Test (‘Soup’ Test)

This test is designed to confirm/assure the container integrity produced by the equipment.

1.4. **Initial Validation of new process**

- 1 ‘Soup’ test

1.5. **New Moulds**

- 1 ‘Soup’ test

1.6. **Any Change -**

Considered likely to affect the break-open section or shoulder of plastic ampoule:

Cutting out/stress on base or side of container - 1 ‘Soup’ test.

Any Mould repairs – 20 racks to be tested for ‘Blue dye’ Integrity test.

A ‘Soup’ test performed on:

1.7. **Aseptically filled product:**

An aseptically filled product container is required to have a media fill conducted with a full 15-day incubation prior to the ‘Soup’ test.

However, if there is enough history to support the process, then you are able to conduct the ‘Soup’ test without first incubating the containers for the full 15-day incubation period.

Allowing both the Media run and ‘Soup’ test to be run in parallel.

It is required to incubate at least 1000 units for a validated ‘Soup’ test.

1.8. **Terminally Sterilised product:**

A terminally sterilised product container does not require the media to be incubated for the initial 15 days if it is sterilised using the appropriate Sterilisation cycle prior to the ‘Soup’ test.

It is required to incubate at least 1000 units for a validated ‘Soup’ test.

NOTE: Additional Media runs or ‘Soup’ Tests may be conducted with the agreement of Production and QA.

Guideline Table for Media Fill or ‘Soup’ Test

Initial Validation	Routine Revalidation	Revalidation - Changes (per Change Control SOP G.1.3.)
Media Runs Three (3) Media Runs per shift	Media Runs Two (2) runs per year per shift on any validated moulds size for aseptically filled lines.	Mould Repairs 20 racks to be tested for “Blue Dye” Integrity test.
‘Soup’ Test To be performed on every mould size	For terminally sterilised lines and non-sterile process once per year per shift on any validated moulds size	New Mould Design 1 Media Run and ‘Soup’ Test required. New Mould (current design) 1 Media Run and ‘Soup’ Test required. A <u>design</u> change to the Product path must be regarded as requiring initial validation, i.e. 3 media runs. Note: General Maintenance – i.e. Cleaning of moulds and “Like-for-Like” changes to the Product path require no media runs or ‘Soup’ tests. Visual inspection after cleaning is to be conducted before the moulds are replaced back on line. Once placed back on line all start up tests and Blue Dye testing of all containers is required, record in Work Order and machine logbook.