

Method Title: Aseptic Media Filling and Micro. Integrity Leak (Soup) Testing Procedure

LabLog id: 338

Date of Preparation: 20-Oct-2019	Revised Method Id: N/A	Revision No.: N/A
Created by: Phil Risher LabLog user id: 142	Reviewed by: Kirby Buxton LabLog user id: 145 Timestamp: 10/20/2019 4:11:02 PM +00:00	Approved by: Kimberley Odonnell LabLog user id: 146 Timestamp: Oct 20 19 - 16:07:29 +00

Related Documents

Form 665: Microbiological Integrity (Soup) Test

MICLAB 020: Destruction of Biological Waste in the Microbiology Laboratory

EHS Statement

All care must be taken when preparing media fills with HOT water. Rubber gloves are to be worn when using HOT water.

Procedure

1- A representative from the Microbiology Laboratory team is to attend the scheduled meeting the week prior to a media run being performed on a process. At this meeting they will outline the purpose of the media run, the type and size of product container to be used and hence the volume of medium required (determining a minimum number of units to be filled with sufficient medium), the volume required is dependent on the process to be evaluated. They will go over the Intervention matrix to predetermine what routine interventions and non- routine interventions need to be conducted during the media run.

2- The filled units received by the Microbiology Laboratory are to be placed into the 30C (1.5) Hot room. The Microbiology Laboratory personnel are to inspect the containers for evidence of microbial growth after 7 and 15 days incubation. During the 7day inspection, shake the contents of the container to ensure that the media has come in contact with all internal surfaces of the container. Store back into either shippers or buckets in a different orientation to the first incubation period.

3- Record all additional information onto the “Aseptic Media Fill Information Section” (see below) and in the media fill Manufacturing Instruction sheets, which were initiated at the manufacture of the medium used for the media run.

4- If any containers show evidence of microbial growth raise a DR. Inform Microbiology Manager, Production

Manager and review the possibility of off line dye testing to confirm container integral. Then open the container and streak (for individual colonies) the contaminated broth onto a Nutrient Agar plate and incubate at 30°C (1.5°C) for 24 hours.

Aseptic Media Fill Information Section

Record all additional information here

Observations: