



Aseptic Media Fill Information Sheet

(Ref. MICLAB 035)

Start Date _____

Reason for Media run:	

Micro To Complete

Machine Number	
Batch number	
Code	
Media type & Lot No. and Expiry Date	
Volume of media prepared & Storage Vessel size	
Time media prepared	
Media Prepared by	
Manufacturing instruction sheet filled up?	
Container & Size	
Volume fill size	
Soup Test required	YES / NO

Production to complete

Machine/Line No.	
Line steamed and date	
Machine Steaming and date	
Holding Tank # & Steaming	



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Production to complete

Full Name of all Sterile Operators. This includes Fitters, Electricians, Cleaners, etc.			
Start Time of Media Run: Shift:			
Finish Time of Media Run: Shift:			
Filter No. & Integrity test results Pre and Post			
Settle/Fallout Plates exposed			
Air sampling conducted			
Personnel Monitoring on exit from media run completed by each operator			
List all the Mould Number details if applicable	Main Mould	Numbers	Size (ml)
	Head Mould	Numbers	Size (ml)



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PRODUCTION TO COMPLETE

Number filled per shift:	Day	Afternoon	Night
	Counter reading:		
Number of Rejects:			
Number of Filled units:			

Intervention List:

The following routine interventions are to be included into the running of a media fills.

The number and types of interventions will vary depending on the process line, however we need to cover off normal daily interventions that take place during the manufacturing of our production batches.

Type of Intervention	Shift	Time	Person responsible
Weight and fill volume adjustments			
Component replenishment			
Filter Change			
Filling needle change			
Operator breaks Personnel leaving the room.			
Component change			
Operator Changes (Need to note maximum number of persons in room)			



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Sterilisation/Product Filter change			
Major Stoppage			
Electrically Adjustments			
Mechanical Adjustments			
Recovery Procedure Stop, Clean, Flush			
Mould head change			
Cleaning of mould and extruder			
Parison and bag adjustments			



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Incubation Details: MICRO TO COMPLETE

Date Incubated at 30°C in Microlab	
Initials of person incubating Media run	

Media Check (as per MICLAB 035) Inspection Results:

Inspected of Media fill containers	Date	Name of Inspectors	Result
7 days			
On the 7 th day inspection ensure that the containers are rotated and re-incubated in a new orientation, from the first incubation period. Yes / No			
15 days			

Environmental Monitoring Results:

Fallout Plates: Include times and shift		Gram-Stain and Identification
Air sample: Include times and shift Contact Plates: Include locations.		



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Personnel Monitoring Results:

Operator name and Sample Date	Finger Dabs:	Hood:	Chest:	Sleeve:	Name of Person Recording Results and Date	Gram-Stain and Identification



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Stasis Media Check as per MICLAB 035

Organism	Date	Inoculum	Bottles	Temp.	Result
<i>S.aureus</i> ATCC 6538			x 2	30°	
<i>C.albicans</i> ATCC 10231			x 2	30°	
<i>B.subtilis</i> ATCC 6633			x 2	30°	
<i>A.niger</i> ATCC 16404			x 2	30°	
<i>E.coli</i> ATCC 8739			x 2	30°	
<i>Environmental</i> <i>Isolate</i>			x 2	30°	

Comments:
