Optimizing contamination control

Supporting your pharmaceutical environmental monitoring program

thermo scientific

A strong environmental monitoring program is crucial to ensuring product quality and patient safety

Environmental monitoring is essential for contamination control in pharmaceutical manufacturing, enabling early detection of risks through continuous monitoring of air quality, surface cleanliness, equipment and personnel. This proactive approach allows swift corrective actions to prevent product contamination and ensure quality standards. Regular monitoring assesses contamination levels, informs adjustments to control measures, ensures regulatory compliance, and enhances patient safety.

Sampling methods

- **Standardized procedures and validated techniques:** Use appropriate test methods for reliable and accurate environmental monitoring results.
- **Air sampling:** Perform with calibrated active air samplers or strategically placed settle plates throughout the cleanroom.
- **Surface and personnel sampling:** Conduct periodically, especially after critical interventions, while minimizing process disruption.
- **Equipment and process sampling:** Use growth media in place of product during simulated processing to assess the sterility of aseptic processes and cleanroom facilities.

Monitoring locations

- **Risk-based selection:** Choose monitoring locations based on risk assessments to represent various processes and environmental conditions.
- **High-risk areas and CCPs:** Focus on high-risk areas prone to contamination and critical control points (CCPs) to prevent and detect contamination.
- **Regular review and adjustment:** Regularly review and adjust monitoring locations based on trend analysis and production process changes to ensure effective contamination control and compliance with quality standards.

Action and alert limits

- **Establish limits:** Define alert and action limits for environmental monitoring to ensure timely responses to deviations and maintain product quality and safety.
- **Alert limits:** Identify potential deviations from normal conditions to catch early signs of issues before they escalate, ensuring proactive problem-solving and preventing contamination or quality issues.
- **Action limits:** Determine thresholds requiring immediate corrective actions to prevent contamination or quality issues from occurring, safeguarding product integrity and consumer safety.

High-quality environmental monitoring plates you can count on

Environmental monitoring plates must provide consistent and robust growth of a wide range of microorganisms to effectively monitor the cleanliness of air, surfaces, and personnel in cleanrooms and other controlled environments. High-quality plates reduce the risk of false positives or negatives, thereby enhancing the reliability of contamination control measures.

Explore our range of high-quality environmental monitoring plates and learn how we can support your environmental monitoring program to ensure accurate and reliable detection of microbial contaminants.

Grade A & B cleanrooms including isolators

Thermo Scientific™ Triple Wrap Plates

- Tryptone soya agar (TSA) media with and without neutralizers
- Available in both 55 mm contact plates and 90 mm settle plates
- 2D (GS1-matrix) barcodes as standard

Grade C and D cleanroom-appropriate

Thermo Scientific™ Oxoid™ general plates

- Tryptone soya agar (TSA) media with and without neutralizers
  - Available in 55 mm contact and 90 mm settle plates
- Sabouraud dextrose with neutralizers
  - Available in 90 mm settle plates

Thermo Scientific™ Triple Wrap Plates
Better for *your* environment. Better for *our* environment.

Triple-wrapped plates are ideal for environmental monitoring in sterile and aseptic pharmaceutical settings because they provide enhanced sterility assurance. Our pharmacopoeia harmonized Thermo Scientific™ Triple Wrap Plates are designed to meet your needs and are now shipped with zero styrofoam to support your facility's green initiatives.

Better sustainability

- Reduced waste with styrofoam-free shipper packaging
- Practical storage temperature (2-25 °C) with no refrigeration required

Isolator compatible

- Deeper fill (30 g) settle plates to reduce the risk of desiccation
- Three protective wraps including a VHP impervious layer

Full traceability

- Available with 2D (GS1-matrix) barcoding for sampling accuracy

Three protective wraps including a VHP™ impervious layer

2D (GS1-matrix) barcodes for full traceability

VHP exposure indicator to ensure media integrity

Gamma-irradiation indicator for sterility assurance

Confidence in your aseptic process simulation is confidence in your contamination control strategy

Aseptic process simulations, or media fills, are a critical component of the overall environmental monitoring program. They involve using a growth medium in place of the actual product to simulate the aseptic filling process, ensuring that the manufacturing environment, procedures, and personnel can maintain sterility. These simulations help detect potential contamination risks, validate aseptic techniques, and demonstrate compliance with regulatory requirements.

Developing a robust media fill protocol necessitates careful consideration of various factors

Timing and frequency

- Validation of new lines
- Verification of new equipment or process changes
- And, every 6 months during normal operations

Volumes and batch sizes

- Enough to coat all internal surfaces of container
- Minimum of 5,000 – 10,000 units
  - If <5,000 the total units should equal a full production batch

Simulation conditions

- Reflect normal operating conditions as closely as possible
- “Worst case” condition challenges need to be selected

Quality culture media is at the core of effective media fills

The quality of media used in media fills is paramount as it directly impacts the reliability and accuracy of the simulation. Additionally, cold filterable media reduces preparation time by facilitating quick and easy dissolution at lower temperatures, eliminating the need for the heating and cooling steps often necessary with traditional media. This streamlined process optimizes media preparation, leading to overall time savings in pharmaceutical production.

Explore how our Thermo Scientific™ cold filterable media can enhance the reliability and accuracy of your simulations, mitigating contamination risks and ensuring pharmaceutical integrity.

Designed for efficiency

- Ultrafiltered for fast and consistent solubility
- No heating required to dissolve into liquid
- Excellent solubility reduces risk of blockages

Pharma grade media

- Pharmacopoeia (USP/EP) compliant
- BSE & mycoplasma free
- γ-irradiated for sterility assurance and reduced risk of false positives

Flexible formats to suit your needs

Available as:

Animal Origin (AO)

- Sourced from World Organization for Animal Health (OIE) designated BSE negligible countries

Animal Origin Free (AOF)

- Eliminates risk of BSE* and TSE** contamination

*Bovine Spongiform Encephalopathy (BSE)
**Transmissible Spongiform Encephalopathy (TSE)

Available in:

Dehydrated Culture Media (DCM)

- Large single lots up to 600 kg
- 500 g, 2.5 kg, 5 kg, 25 kg sizes

Bioprocess Containers (BPC)

- Plug and play with universal connectors
- 1 L, 10 L, 20 L sizes

Product information:
Triple Wrap Environmental Monitoring Plates

55 mm Contact Plates with neutralizers

For surface and personnel monitoring

90 mm Settle Plates

Available with and without neutralizers
For air and finger dab sampling

Grade A and B cleanrooms including isolators

Product description	Format	Storage temperature	Shelf life	Product code	Country of manufacture
Triple Wrap Sterile TSA with neutralizers	55 mm contact plates (15 g fill) 100 plates (10 packs of 2 x 5 plates)	2-25 °C	Total: 301 days Minimum: 184 days	PO4011D	Scotland
	90 mm settle plates (30 g fill) 100 plates (10 packs of 2 x 5 plates)	2-25 °C	Total: 301 days Minimum: 184 days	PO4001B	Scotland
Triple Wrap Sterile TSA only	90 mm settle plates (30 g fill) 100 plates (10 packs of 2 x 5 plates)	2-25 °C	Total: 301 days Minimum: 184 days	PO4000B	Scotland

For more information on environmental monitoring solutions, visit **thermofisher.com/triplewrap**

Product information:
General environmental monitoring plates

Grade C and D cleanroom appropriate

Product description	Format	Storage temperature	Shelf life	Product code	Country of manufacture
TSA + Tween + Lecithin irradiated	55 mm contact plates 10 plates (1 pack of 2 x 5 plates)	2-25 °C	Total: 98 days	PO0479D	Germany
Pro-Tect TSA + neutralizers irradiated	55 mm contact plates 10 plates (1 pack of 2 x 5 plates)	2-12 °C	Total: 98 days	PO0678D	Germany
Pro-Tect TSA + neutralizers irradiated	90 mm settle plates 10 plates (1 pack of 2 x 5 plates)	2-25 °C	Total: 98 days	PO0746B	Scotland
Tryptone soya agar irradiated	90 mm settle plates 10 plates (1 pack of 2 x 5 plates)	2-25 °C	Total: 98 days	PO0821B	Scotland
Tryptone soya agar irradiated	90 mm settle plates 10 plates (1 pack of 2 x 5 plates)	2-25 °C	Total: 112 days	PO5012B	Germany
TSA Contact with disinhibitor plus irradiated	55 mm contact plates 20 plates (2 packs of 2 x 5 plates)	2-25 °C	Total: 84 days	PO5171D	Germany
SAB DEX + Tween + Lec C/P irradiated	90 mm contact plates 20 plates (2 packs of 2 x 5 plates)	2-12 °C	Total: 98 days	PO0734D	Scotland

Product information: Media fills

Product description	Format	Storage temperature	Shelf life	Product code
Tryptone Soya Broth (Animal Origin)				
Cold filterable Tryptone Soya Broth	Dehydrated media (500 g)	2-25 °C	Total: 60 months Minimum: 24 months	CM1065B
	Dehydrated media (2.5 kg)	2-25 °C	Total: 60 months Minimum: 24 months	CM1065R
	Dehydrated media (5 kg)	2-25 °C	Total: 60 months Minimum: 24 months	CM1065T
	Dehydrated media (25 kg)	2-25 °C	Total: 60 months Minimum: 24 months	CM1065K
Cold filterable Tryptone Soya Broth BPC	Bioprocess container (1 L)	2-25 °C	Total: 18 months Minimum: 6 months	BP1065A
	Bioprocess container (10 L)	2-25 °C	Total: 18 months Minimum: 6 months	BP1065C
	Bioprocess container (20 L)	2-25 °C	Total: 18 months Minimum: 6 months	BP1065E
Vegetable Peptone (Animal Origin Free)				
Cold filterable Vegetable Peptone Broth	Dehydrated media (500 g)	2-25 °C	Total: 60 months Minimum: 24 months	VG0104B
	Dehydrated media (5 kg)	2-25 °C	Total: 60 months Minimum: 24 months	VG0104T
Cold filterable Vegetable Peptone Broth BPC	Bioprocess container (1 L)	2-25 °C	Total: 18 months Minimum: 6 months	BP0104A
	Bioprocess container (10 L)	2-25 °C	Total: 18 months Minimum: 6 months	BP0104C
	Bioprocess container (20 L)	2-25 °C	Total: 18 months Minimum: 6 months	BP0104E

For more information on media fill solutions, visit **thermofisher.com/mediafills**

Product information: Quality control organisms

Complete your workflows with our ISO 17034 accredited and fully characterized ATCC® Licensed Derivative strains of Thermo Scientific™ Quanti-Cult Plus™ quality control microorganisms for growth promotion testing.

- ATCC derived for use at passage 2
- <100 colony forming units (CFU) per inoculum
- Practical storage temperature (2-8 °C)

Organism	Format	Order quantity	Shelf life	Product code
Staphylococcus aureus ATCC® 6538™	Quanti-Cult Plus	100 tests per kit	18 months	R4717016
Bacillus spizizenii ATCC® 6633™	Quanti-Cult Plus	100 tests per kit	18 months	R4711221
Pseudomonas paraeruginosa ATCC® 9027™	Quanti-Cult Plus	100 tests per kit	12 months	R4715210
Clostridium sporogenes ATCC® 11437™	Quanti-Cult Plus	100 tests per kit	18 months	R4711703
Candida albicans ATCC® 10231™	Quanti-Cult Plus	100 tests per kit	18 months	R4711503
Aspergillus brasiliensis ATCC® 16404™	Quanti-Cult Plus	100 tests per kit	18 months	R4711100

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For more information on our full environmental monitoring portfolio, visit **thermofisher.com/environmentalmonitoring**

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