TECHNICAL OVERVIEW CLEANROOM GARMENTS

MICRONCLEAN INDIA

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EXECUTIVE SUMMARY

Cleanroom garments play a critical role in cleanroom contamination control; they are designed to contain contamination generated by the greatest source of contamination in a cleanroom – the people.

Micronclean has extensive experience in the UK of delivering high quality, value for money cleanroom garments service and has built a brand new facility in Bangalore to introduce world class cleanroom garments services and practices that are unparalleled in India.

This is achieved through knowledge of cleanroom garment technology, as well as expertise and innovation in cleanroom garment performance and optimisation of laundering and sterilisation cycles. Micronclean offers cleanroom garments via a rental service. Through this service model, Micronclean oversees and manages all aspects of cleanroom garment provision including selection of garment materials, garment design and construction and the laundry and sterilisation cycles.

High performing cleanroom garments must meet varying requirements. They must have high barrier properties to successfully retain contamination generated by the wearer. They must be durable to ensure they can withstand the stresses of use and repeat decontamination and sterilisation cycles. They must offer wearer comfort to increase the chance that the wearer will don and use the garments correctly. Finally, the garment system (including materials and garment designs) must work optimally as a whole in real cleanroom conditions.

Various guidelines are available that describe the considerations to be made in designing, selecting and using cleanroom garments. Further, standard test methods are available to demonstrate the performance of cleanroom garments against critical parameters.

By performing extensive studies of cleanroom garment performance, Micronclean is able to select the best materials, garments designs and garment construction methods to work with, and is able to optimise its laundry and sterilisation processes to ensure that a high performing garment is delivered to the customer throughout a garment rental contract. Micronclean is also able to establish the safe useful life of a cleanroom garment and design its contracts to ensure that customers receive high quality and good value for money.

This document presents data from three studies these being:

- Data is presented from such studies performed by Micronclean UK.
- A preliminary study performed by Micronclean India with conditions simulating those planned for the Micronclean India factory.
- An extensive comparative garment study performed by Micronclean India at their plant in Bangalore.

In all three cases the Micronclean fabric is shown to perform well and in the final extensive test it is shown to outperform competitor products that are on the market in India.



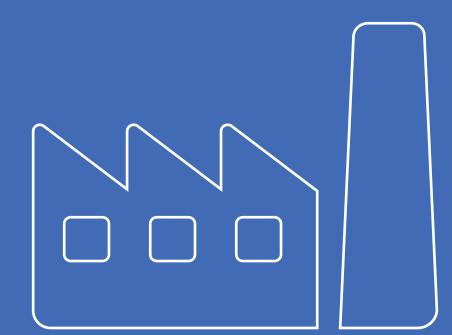
EXECUTIVE SUMMARY



Everything you see in the image is available direct from Micronclean in India.



MICRONCLEAN OVERVIEW



MICRONCLEAN OVERVIEW

Micronclean is a UK company with a history dating back over 100 years. The company has been involved with the provision of textile rental and laundry services throughout its history. Over the last 40 years Micronclean has specialised in the provision of cleanroom garments to various industries including pharmaceutical, biotechnology, microelectronics, aerospace and defence.

Micronclean is the UK market leader in provision of cleanroom garment rental and laundry services. Micronclean has the privilege of providing cleanroom garments to over 65% of aseptic pharmaceutical / biotechnology production facilities in the UK.

Micronclean is known for its expertise in a number of aspects of cleanroom garment provision:

- · Cleanroom garment technology fabric, garment design
- Cleanroom garment decontamination and sterilisation laundry design, validation and process control
- Development of IT solutions to provide market-leading tracking and traceability for cleanroom garments



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PURPOSE

Micronclean defines its company aims in its Purpose:

"At Micronclean our passion is to be the first to develop new technological solutions that change the shape of the markets we serve, creating quality and efficiency for our customers."





SKIEs

Micronclean aspires to fulfil its Purpose through its core values – SKIEs:



STEWARDSHIP

We strive to leave more than we started with by creating lasting business structures that are enduring and act as a base for future, sustainable development. Stewardship enables us to do this and it is the management system by which we capture and embed our values and ethos into everyone and everything that we do.

Pride is at the core of our business; we do all we can to ensure everyone with the company feels, an integral part of something important and good, that we have helped to create. A high ethical integrity is at our heart and we aim to work with sincerity and honesty, treating everyone in a respectful and fair manner.



KNOWLEDGE

The foundation of our ability to serve our customers with Excellence and Innovation. Knowledge is the life blood of our business forming the backdrop against which all our activities are played out.

We aim to drive knowledge into our business by an openness of information and by consistently delivering training.

We strive to be experts in our business activities, allowing us the power and flexibility to exceed customer expectations. Being the best is aspirational and is achieved by a thirst for knowledge and betterment.



INNOVATION

Investment in change to create a better future for ourselves and our customers. It is the primary strategic choice of our company to position ourselves as the technological market leader. It is our investment in innovation that supports this and drives us into new markets. Innovation is core to what we do and defines our business. It ensures that we focus on 'how we can be the best'.

Our company strives to develop a management culture that encourages innovation and creative ideas from across the company. This enables all of us to feel a part of this process and allows innovation to become an intrinsic part of how we all think in our roles.



EXCELLENCE

The business process to continually improve the quality and cost base of our products and services. The key to achieving Excellence is a remorseless focus on being the best so that we can delight our customers and surpass their expectations. We achieve Excellence through the tight control of quality and the maintenance of an efficient cost base.

We achieve Excellence by simplifying our processes so that they are more logical and easily understood, then we train our staff to fully understand these systems. We are a company where any mistake is grasped as an opportunity for improvement. Creating an atmosphere where we are encouraged to bring forward mistakes enables us to learn from them and to make the changes that make us better than we were.



MICRONCLEAN INDIA

Micronclean India has brought Micronclean's expertise in cleanroom garment provision to India. With the backing of technical expertise and experience from the UK, Micronclean India has established a state-of-the-art cleanroom laundry facility in Bangalore.



Figure 2 - Micronclean India facility, Bangalore

From this facility, Micronclean India offers a market-leading cleanroom garment rental and laundry service. The service incorporates the latest technology, including:

• Cleanroom garments manufactured from advanced cleanroom fabrics and with optimised garment designs, maximising barrier performance, durability and wearer comfort. Garments have assured performance throughout their useful life.

• A modern GMP Grade B cleanroom laundry with barrier washing machines, cleanroom dryers and steam sterilisers. All processes are validated to achieve assurance of quality. Key process parameters are continuously monitored and controlled. Process data is reported in the form of batch certificates to demonstrate batch conformance.



MICRONCLEAN INDIA

• Garments are packaged using high quality materials. Sealing of primary packaging – the critical sterility barrier – is validated. Packaged, sterilised garments have a validated shelf-life. The garment batch number and expiry date are clearly marked on each pack.

• Garments receive total inspection on receipt at the Micronclean laundry. Defects are identified and, wherever practical and economically viable, Micronclean performs validated repairs according to repair criteria agreed with the customer.

• Each garment is tagged with a radio frequency transponder. This, coupled with Micronclean's proprietary software (Protrack), allows Micronclean to track each individual garment. A complete garment history is assembled for each individual garment including customer details, processing history and batch data, repair history, as well as the last known location. This data can be interrogated as required, for example during a regulatory audit, to demonstrate garment fitness for use.

• Logistics are provided to ensure efficient stock management of garments at a customer's site. Regular deliveries ensure availability of sterile garments and efficient collection of used garments.

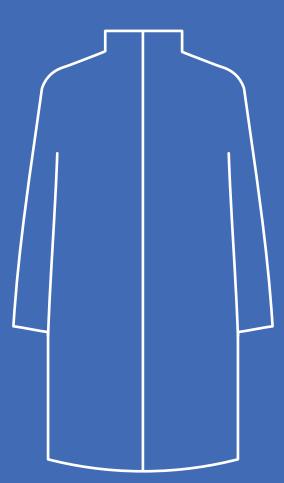
• Protrack assembles contract-level data to facilitate the effective management of the cleanroom garment rental service. This allows Micronclean's service team to work with customers to ensure contracts are structured and optimised, as necessary, to ensure continuity of supply and cost efficiency.





CLEANROOM GARMENTS

INTRODUCTION



INTRODUCTION – CLEANROOM GARMENTS

This section provides an overview of the purpose and function of cleanroom garments, a comparison between a cleanroom garment rental service and alternative approaches to cleanroom garment provision, and an introduction to cleanroom garment technology and assessment of cleanroom garment performance through life.

THE ROLE OF CLEANROOM GARMENTS

Cleanroom garments must fulfil several important requirements:

1. Cleanroom garments must act as an effective contamination control measure, containing viable and non-viable particulate released from the wearer thus preventing cleanroom contamination.

2. Cleanroom garments must not themselves generate particulate or fibre contamination.

3. Cleanroom garments must be durable to ensure that it will not become easily damaged during use therefore presenting a contamination risk.

4. Cleanroom garments must be comfortable and practical for the wearer to allow the wearer to easily comply with cleanroom garment policies.

5. Cleanroom garments must be a cost-effective contamination control solution for the specified manufacturing operation.

6. The environmental impact of cleanroom garments must be as low as possible throughout its life cycle (from fabric and garment manufacture, through garment processing and use, to end of life).

Micronclean takes these requirements seriously. With several decades of experience, Micronclean has developed and optimised a number of aspects fundamental to delivering high quality cleanroom garments that perform consistently, including:

- Material and component selection
- Garment design
- Garment manufacture
- Garment laundering and sterilisation





ASSURED CLEANROOM GARMENT PERFORMANCE

It is not enough to determine the performance of cleanroom garments in the 'as new' state. Cleanroom garments endure significant stresses from repeat cycles of use, decontamination and sterilisation. These activities cause wear and tear and therefore cause inevitable deterioration in performance of cleanroom garments.

Micronclean has performed extensive studies to measure the performance of its cleanroom garments through life. The studies involved a comparison of market leading materials and components, optimised garment designs, and laundering and sterilisation using Micronclean's validated processes.

These studies have allowed Micronclean to select the best materials and garment designs, but also provide evidence of performance. Micronclean can provide to customers assurance of cleanroom garment performance throughout life in the form of quantitative data which can help form the basis of your garment qualification for Annex 1.

Through its garment rental service Micronclean retains complete control of the materials, garments and the laundry and sterilisation cycles and can therefore manage risks associated with changes, including repeating studies as necessary.

By overseeing all aspects of cleanroom garment provision, and by extensively studying garment performance, Micronclean can deliver assurance of consistently high quality and value for money. For this reason, cleanroom garment rental from a specialist provider is considered best practice and has become the leading model of cleanroom garment provision in Europe, USA and other leading markets. The alternative approaches carry challenging risks:

• Garment Purchase and On Premise Laundry

The garment manufacturer might provide performance data for garments as new. However, as the manufacturer cannot plan for all potential decontamination/sterilisation cycles, it is impractical for garment manufacturers to conduct through life studies. The user might therefore experience reduction in cleanroom garment performance over time, which presents a significant risk to cleanroom contamination.

There are also risks from changes. The garment manufacturer might change a material or component that is not compatible with the laundry / sterilisation process, or the laundry might change the laundry/ sterilisation process resulting in incompatibility with garments. This might result in contamination risks, issues with usability, or unforeseen escalation in costs.

As well as contamination risks, premature degradation of cleanroom garments can result in unforeseen costs and therefore poor value for money.

• Disposable Garments

The materials and manufacturing methods used in production of disposable cleanroom garments are necessarily low in cost. Compromises are necessarily made in performance, durability or comfort in order to achieve an appropriate price point. The pursuit of low manufacturing costs can lead to risks in quality and consistency of products.

Non-woven materials naturally strike a poorer balance between barrier performance and wearer comfort. Although non-woven fabrics typically have very high barrier performance (e.g. particle filtration performance is excellent), this is combined with very low air permeability rates. This leads to two issues. Firstly, garments are less breathable and therefore less comfortable to wear. This reduces the likelihood that wearers will consistently comply with gowning policies. Secondly, as the wearer moves, compressed air within the garment will be expelled from garment closures (e.g. cuffs, neck) rather than through the fabric. This 'pumping effect' presents a risk of cleanroom contamination, with contaminated air escaping from the suit rather than being filtered through the suit.



Cleanliness of disposable cleanroom garments is a further challenge. The act of manufacturing fabrics and then cutting and sewing these into garments inherently generates large amounts of particle and fibre contamination. Consideration must therefore be given of how to minimise contamination of garments during manufacture or, for high grade cleanroom applications, how to decontaminate garments (e.g. by laundering) prior to supply for use. Many disposable garments available on the market are not fit for use in cleanrooms due to the level of particle and fibre contamination.

Regarding life cycle, disposable garments present several key challenges. Overall, disposable garments have a greater environmental impact¹. Further, use of disposable garments present significant risks and costs associated with supply chain, logistics, stock control and waste management.

Micronclean believes that the cleanroom garment rental model delivers the greatest possible quality assurance and value for money to cleanroom operators.

CLEANROOM GARMENT PERFORMANCE – GUIDANCE AND TEST METHODS

From a practical and technical perspective, there are several internationally used guidance documents that describe good practice approaches to the design and use of cleanroom garments.

EU GMP Annex 1 describes the requirements for the manufacture of sterile medicines, including outlining the requirement cleanroom garments to be qualified as part of an integrated contamination control strategy.

ISO 14644-5: Operations includes a section and informative annex on the function, properties and practical considerations relating to cleanroom garments.

USP 797 outlines basic requirements for cleanroom garments in pharmaceutical compounding environments.

These documents are good sources of useful introductory information and indications for further reading. However, none of them intend to tackle cleanroom garment technology in any depth. For more detailed information and guidance the American Institute of Environmental Sciences and Technology (IEST) – Contamination Control Division has developed and published what is considered a recommended practice document – IEST RP CC 003. This document is considered to be the leading guideline on cleanroom garment technology and covers the key considerations for garment systems to be used in cleanrooms and controlled environments. Guidance is offered on the specification, design, construction, maintenance and use of cleanroom garments. Further, several test methods are described and referenced that can be used to measure the performance of cleanroom barrier fabrics and of cleanroom garment systems. This document is a good starting point for anyone wishing to learn about cleanroom garment technology.

Micronclean utilises these guidelines to assess cleanroom garment performance, and to design and plan its throughlife cleanroom garment performance studies. In the following pages the key test methods incorporated in these studies are described. The test methods are divided into five groups – (i) barrier properties, (ii) durability, (iii) comfort, (iv) particle and fibre contamination, and (v) garment system performance.

¹ See - Vozzola E., Overcash M. & Griffing E. Life Cycle Assessment of Reusable and Disposable Cleanroom Coveralls. PDA J Pharm Sci Technol. 2018. 72(3). pp.236-248. (<u>https://www.ncbi.nlm.nih.gov/pubmed/29444994</u>)



BARRIER PROPERTIES

Assessment of barrier properties provide an indication as to how a fabric will perform in the containment of contamination released from the wearer. Test methods are available to both directly and indirectly assess the barrier properties of a fabric.

PORE SIZE

Pore size is a key physical property of a fabric associated with adequately containing contamination released by the wearer and breathability. In a woven fabric, the pore is the space between the yarns. The pore size is controlled by the construction of the yarn, and the tightness and consistency of the weave.

In simple terms, the smaller the pore size the increased barrier efficiency (i.e. greater containment of contamination) of the fabric. However, this comes with compromise in breathability and therefore decreased 15 of 40 comfort and increased risk of the 'pumping effect'. Having said this, it is also true to say that fabrics can – through their three-dimensional structure – achieve a 'depth filtration' effect. Weave patterns such as twills create fabric pores that are convoluted, meaning the path for a particle through the fabric is more complex, thus increasing the chance of particle impaction within the fabric and thus increasing particle filtration efficiency.

IEST RP CC 003 refers to a British Standard – BS 3321, commonly referred to as the 'bubble point' method (this method is similar to the method used in the assessment of pore size in membrane filters).

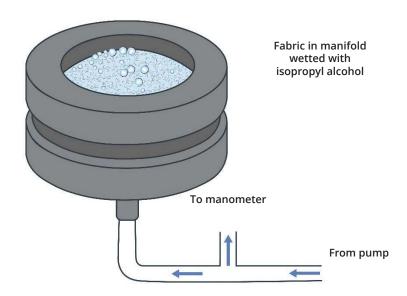


Figure 3 - Bubble point test apparatus to determine fabric pore size

Figure 3 shows a typical apparatus set up for the bubble point test method. The method involves placing the specimen fabric in a manifold, covering the fabric with a solvent of known surface tension (typically isopropyl alcohol), and applying increasing air pressure to the underside of the wetted fabric until bubbles emerge from the fabric. The air pressure is proportional to the pore diameter.

As an indication, everyday polycotton fabrics (e.g. those used in shirts and blouses) have a pore size of 50 to 100µm, whereas a cleanroom fabric would typically have a pore size of 5 to 15µm.



PARTICLE FILTRATION EFFICIENCY

Particle filtration efficiency is a direct measurement of how well a cleanroom fabric contains particulate contamination. IEST RP CC 003 describes a particle penetration test whereby contaminated air is passed through a cleanroom fabric in controlled conditions and the amount of particle retention by the fabric is measured by comparing the particle concentration in the upstream and downstream air. The test can be conducted at different particle sizes and different exposure times to achieve a more complete assessment of how a fabric might perform in typical use conditions.

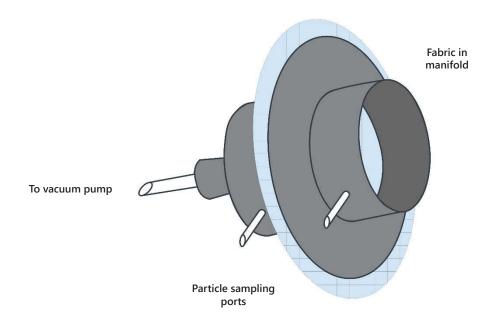


Figure 4 - Test apparatus to determine particle filtration efficiency of fabric

Figure 4 shows a typical apparatus set up for the particle filtration efficiency test method.

Several laboratories have developed test methods according to the guidance in IEST RP CC 003. The methods involve preparation of contaminated air using silicon oxide particles of differing sizes.

A high quality cleanroom fabric would typically be expected to achieve a particle filtration efficiency of >80% for particles greater than 0.5μ m in size, and >90% for particles greater than 5.0μ m in size.



DURABILITY

Assessment of durability is important to ensure that a fabric will withstand normal wear and tear expected in the repeat cycles of garment use, laundering and sterilisation. A durable fabric will ensure low risk of garment breach during use, while increased durability can also result in longer life and therefore better value for money of cleanroom garments.

TENSILE STRENGTH

A tensile strength test measures the force required to break the fabric. Typically a 'grab test' is used for fabrics, such as ISO 13934-2 or ASTM D5034.

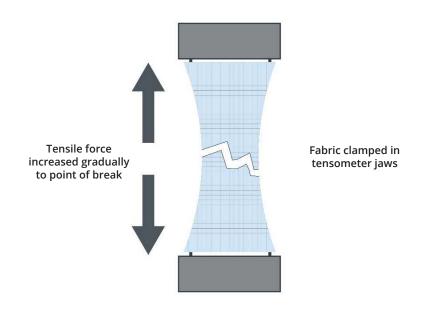


Figure 5 - Test apparatus to measure tensile strength of fabric

Figure 5 shows a typical apparatus set up for a fabric tensile strength test. A piece of fabric is gripped in the jaws of a tensometer or universal test machine and an increasing tensile force is applied until the point at which the fabric breaks.

The tensile strength of a fabric is a useful indicator of a fabric's capability to withstand the rigours of repeat use, laundering and sterilisation, and a garment's likelihood of breach during use.



It is important to measure the tensile strength of a fabric through repeat laundering and sterilisation cycles as these processes can significantly degrade fabric strength. Poor fabric strength increases the risk of fabric breach during use and increases the cost of garment maintenance (e.g. more frequent repairs).

ABRASION RESISTANCE

An abrasion resistance test measures a fabric's durability to rubbing and scuffing action. Standard test methods such as ISO 12947-1 and ASTM D3884 are commonly used.

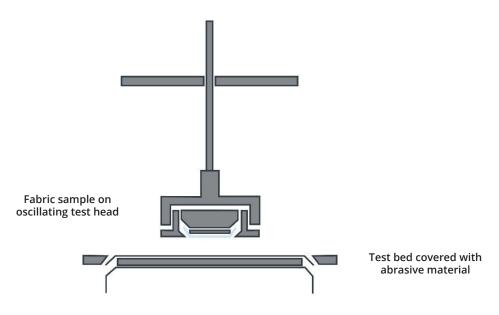


Figure 6 - Test apparatus to measure abrasion resistance of fabric

Figure 6 shows a typical apparatus set up for a fabric abrasion resistance test. Typically, an abrasion test will involve moving a sample of fabric over a standardised abrasive surface (e.g. sandpaper) in an oscillating pattern and counting the number of cycles the fabric can withstand before showing signs of breakdown.

The abrasion resistance of a fabric is a useful indicator of how well the fabric will stand up to the stresses of repeat use. A low resistance to abrasion can indicate risks of rapid fabric degradation through use, which can lead to premature garment replacement and therefore unforeseen costs.



COMFORT

In order to perform its function, cleanroom garments must be donned and worn according to strict procedures. There is a risk that contamination from the wearer will be released into the cleanroom in greater, and unacceptable, quantities if their cleanroom garments are not worn and fastened correctly. Cleanroom garment comfort is therefore an important factor. If cleanroom garments are more comfortable then there is a greater chance they will be worn correctly.

AIR PERMEABILITY

Air permeability is a measure of how freely air can pass through a fabric; this is sometimes referred to as 'breathability'. Standard test methods such as ASTM D737 are typically used. Breathability is important from a wearer comfort perspective as the more breathable the fabric, the quicker the temperature of the air inside the garment can equilibrate with the air outside the garment. Further, air permeability is critical from a contamination control perspective. The ideal cleanroom fabric is breathable with a small pore size; air can freely pass through the fabric and particulate will be filtered from the air as it passes through due to the small pores. A fabric with low air permeability increases the risk of 'pumping action'; as the wearer moves contaminated air within the garment is compressed. This contaminated air cannot easily pass through the fabric and will tend to escape from closures (e.g. cuffs, neck) in the garment carrying with it contamination and thus contaminating the cleanroom.

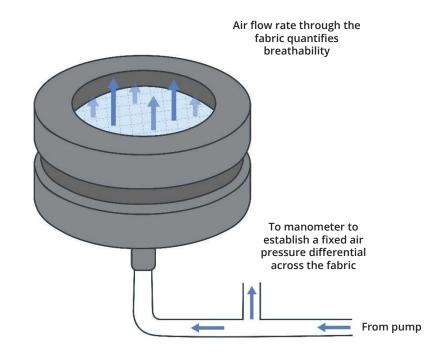


Figure 7 - Test apparatus to measure air permeability (or 'breathability') of fabric

Figure 7 shows a typical apparatus set up for a fabric air permeability test. An air permeability test is conducted at a fixed air pressure differential across the fabric. Air flow rate is measured at the exhaust side, and this quantifies the air permeability of the fabric. Air permeability is typically expressed as volume of air that can pass through a fabric per surface area of fabric per unit of time (e.g. litres / square metre / second).



Cleanroom fabrics, due to their small pore size, are less breathable than everyday fabrics. As an indication, everyday polycotton fabrics (e.g. those used in shirts and blouses) might have air permeability of 150 to 200 litres/ m²/s, whereas a cleanroom fabric would typically have air permeability of 25 to 50 litres/m²/s. However, cleanroom fabrics, depending on their construction, can vary significantly in breathability. For reference, due to their construction (extremely small pore size and / or polymeric film lamination), non-woven materials used in cleanroom garments have much lower air permeability and therefore typically offer poorer comfort to the wearer and significantly increase the risk of 'pumping action'.

There is no specific rule regarding what level of breathability will lead to a comfortable garment. Many other factors influence operator comfort in a cleanroom (cleanroom garment design, primary garment attributes, cleanroom temperature and humidity, cleanroom air flow, physicality of work, etc.). However, the difference in breathability between cleanroom fabrics can provide a useful indication as to their relative contribution to achieving comfort for the wearer.

WATER VAPOUR TRANSMISSION

Water vapour transmission is a measurement of the free movement of moisture across a fabric. This is another important factor in the comfort of the wearer of a cleanroom garment. As the wearer perspires, they will be more comfortable the quicker that moisture can evaporate and escape through the fabric. Standard test methods such as ASTM E96 are typically used.

Cleanroom fabrics have lower water vapour transmission rates (10 to 20g/m²/24hr) than everyday polycotton fabrics (30 to 50g/m²/24hr). For reference, due to their construction (extremely small pore size and / or polymeric film lamination), non-woven materials used in cleanroom garments have much lower water vapour transmission and therefore typically offer poorer comfort to the wearer.

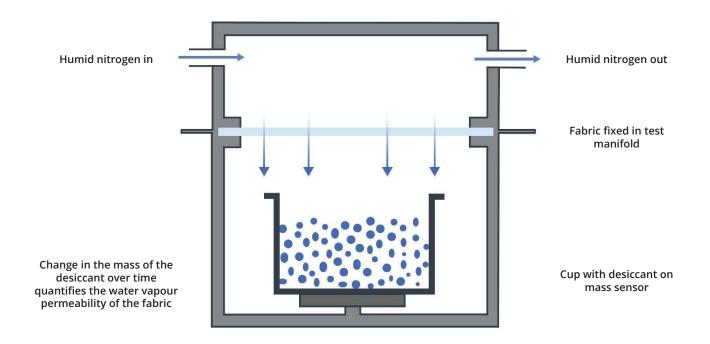


Figure 8 - Test apparatus to measure water vapour permeability of fabric



Figure 8 shows a typical shows a typical apparatus set up for a fabric water vapour permeability test. A fabric sample is held in a test manifold. In the space below the fabric a cup of desiccant is places on a mass sensor. Humid nitrogen is supplied to the space above the fabric at a set rate. Water vapour passing across the fabric over time will be absorbed by the desiccant, thus changing its mass. The degree of mass change quantifies the water vapour permeability of the fabric. Water vapour transmission is typically expressed as mass of moisture moving across the fabric per surface area of fabric per unit of time (e.g. grams / square metre / 24hr).

As with air permeability, there is no specific rule regarding what level of water vapour transmission will lead to a comfortable garment. Many other factors influence operator comfort in a cleanroom (cleanroom garment design, primary garment attributes, cleanroom temperature and humidity, cleanroom air flow, physicality of work, etc.). However, the difference in water vapour transmission between cleanroom fabrics can provide a useful indication as to their relative contribution to achieving comfort for the wearer.

PARTICLE AND FIBRE CONTAMINATION

As well as containing contamination from the wearer, cleanroom garments must not generate contamination during use. To achieve this, cleanroom garments incorporate a number of key features including specialist yarns and garment construction methods. Further, cleanroom garments must be successfully decontaminated of particulate matter before they are first used (i.e. to remove particulate from garment manufacture) and after each use (i.e. to remove the particulate contamination collected by the garment during use). This decontamination is achieved using a cleanroom laundry with validated processes that can remove contamination from garments and prevent recontamination of garments prior to packaging.

Two standardised test methods are primarily used. They are intended to measure the amount of particulate matter releasable from the surface of a cleanroom garment in its 'ready for use' state. Both methods are outlined below with notes to describe their use cases.

HELMKE DRUM

IEST RP CC 003 describes a method involving tumbling a garment inside a rotating drum; the test is therefore sometimes referred to as the 'rotating drum method'. This action is intended to simulate particle shedding from the garment during use. As the garment tumbles inside the test drum, an electronic particle counter is used to sample the air within the drum to quantify the particulate matter released by the garment.



Figure 9 - Diagramatic representation of Helmke Drum test for garment particulate contamination



Figure 9 provides a diagramatic representation of the Helmke Drum test to quantify garment particulate contamination. The test is performed in cleanroom conditions to prevent contamination of the garment prior to and during the test. The test machine consists of a stainless steel drum with an electronic particle counter, which samples air from a fixed position in the centre top part of the drum interior. A garment is folded in a standardised way and then placed within the test drum. The drum door is closed, then the garment is set to rotate at a fixed frequency. As the drum rotates the garment inside tumbles, and this action releases particulate contamination from the surface of the garment. The particle counter is set to run to quantify the particulate contamination being released.

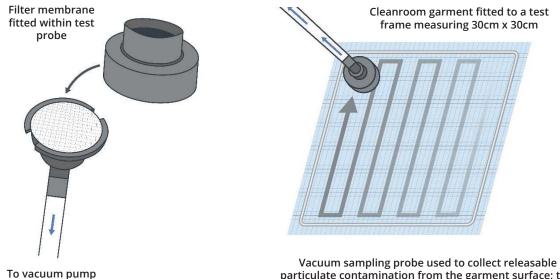
The test method samples particulate of 0.3µm and larger or 0.5µm and larger. Due to the higher rates of deposition of larger particulate matter in the air sampling line, the method is not appropriate for measuring particulate of 5.0µm and larger, nor fibres. The method is therefore especially suited to application in assessing the cleanliness of garments intended for use in the microelectronics and photonics industries.

The method can be used for both woven materials (reusable garments) and non-woven materials (disposable garments) as well as cleanroom wipes.

ASTM F51

ASTM F51 describes a standard test method whereby releasable particulate is vacuumed from the surface of a cleanroom garment and impinged on a filter membrane. The filter is then visually inspected under the microscope to count the recovered particles and fibres. Two optional methods are described; (i) the 5-point method whereby five small, discrete areas of the garment are sampled, and (ii) the frame method whereby a larger, 300mm x 300mm area of fabric is samples. The 5-point method is best suited for smaller items (e.g. headwear or footwear) or for garments where a high particulate level is expected. The frame method is best suited for larger items (e.g. coveralls or coats) especially where a low particulate level is expected and therefore a larger samples size contributes to greater result accuracy.

For cleanroom coveralls intended for use in high grade cleanrooms, the frame method is most widely used.



particulate contamination from the garment surface; test area sampled using 8 overlapping passes in 60 seconds

Figure 10 - Diagramatic representation of ASTM F51 test for garment particulate contamination

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Figure 10 provides a diagramatic representation of the ASTM F51 test to quantify garment particulate contamination. The test is performed in cleanroom conditions to prevent contamination of the garment prior to and during the test. The test apparatus consists of a stainless steel test frame measuring 30cm x 30cm and a sampling probe attached to a vacuum line. A garment is laid over and fitted to the test frame. A filter membrane is fitted within the sampling probe and the vacuum pump switched on. The surface of the garment is sampled over a total of 60 seconds in 8 overlapping passes. Releasable particulate contamination from the surface of the garment is impinged on the filter membrane. The filter membrane is then inspected using an optical microscope and the particles and fibres are counted.

The test method samples particulate of 5.0µm and larger and fibres (particles greater than 100µm in length). These particles are more likely to be biologically active or be relevant to human physiology. The method is therefore suited to application to assess the cleanliness of garments intended for use in the pharmaceutical and biotechnology industries.

The method can be used for woven (reusable garment) materials only. Non-woven (disposable garment) materials have insufficient air permeability to achieve the necessary vacuum-driven air flow through the fabric.

GARMENT SYSTEM PERFORMANCE

All of the above test methods measure fabric performance. The performance of a cleanroom fabric plays a critical role in the performance of a cleanroom garment system. However, cleanroom garment system performance is also significantly influenced by other key factors including garment construction; garment design; accuracy of donning and use by the wearer; and use of undergarments, which provide a coarse filtration of contamination from the wearer while themselves not producing contamination.

Assessing the performance of an entire garment system is therefore an important tool in ensuring cleanroom garments are fit for purpose.

BODY BOX

IEST RP CC 003 describes a method by which the contamination control performance of the whole garment system can be assessed. The test is commonly referred to as the 'body box' method; it measures particle dispersion – both viable and non-viable – from a garment system in simulated use conditions.

A person is asked to don cleanroom garments, enter a clean air booth, and then perform standardised action with a metronome. While the actions are being performed, an electronic particle counter and microbiological active air sampler are used to sample airborne contamination at close to floor level in the booth.

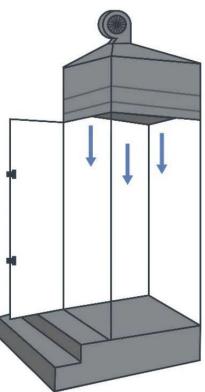


Figure 11 - Diagrammatic representation of a Body Box test apparatus



CLEANROOM GARMENTS

Figure 11 shows a typical Body Box test apparatus. The test is conducted in cleanroom conditions to prevent extraneous contamination impacting the test results. The test apparatus consists of a booth fed with cleanroom air and, at the base of the booth, an electronic particle counter and microbiological active air sample. A person is asked to aseptically don a set of cleanroom garments. They then enter the Body Box and the door is closed. The person is asked to perform standardised exercises to the beat of a metronome. Simultaneously the particle counter and active air sampler are used to sample the air in the booth to quantify the particulate contamination and viable particulate contamination being released from the person into the air.

The test method does not produce absolute results. For example, the rate of particulate dispersion from the person is an uncontrolled variable as different people shed particulate contamination from their skin at significantly varying rates.

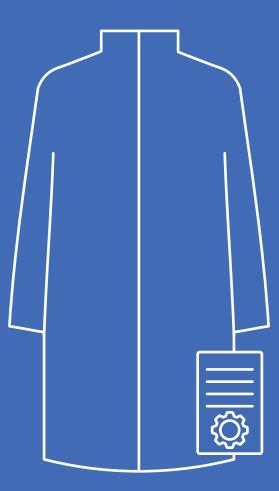
The method is however useful in measuring the relative contamination control performance of different cleanroom garment systems, for example several garment systems of the same design but incorporating different fabrics (to test relative differences between fabric options), or several garment systems of different designs but incorporating the same fabric (to test relative differences between garment design options). Comparison tests are best performed using the same test subject (i.e. person) and in close time proximity to minimise the influence of uncontrolled variables on the results.

The test has also helped to establish the significance of other important cleanroom garment system factors, such as of good garment decontamination practice prior to use, the contamination control benefits of using clean, low linting primary garments, and of proper maintenance of cleanroom garments (e.g. repair of even small areas of fabric or garment damage).



GARMENTS STUDY AND EXPERIENCE

MICRONCLEAN UK





MICRONCLEAN UK - GARMENT STUDY AND EXPERIENCE

By performing extensive studies of cleanroom garment performance, Micronclean is able to select the best materials, garment designs and garment construction methods to work with, and is able to optimise its laundry and sterilisation processes to ensure that a high-performing garment is delivered to the customer throughout a garment rental contract. Micronclean is also able to establish the safe useful life of a cleanroom garment and design its contracts to ensure that customers receive high quality and good value for money.

In this section, data from a UK cleanroom garment study is presented demonstrating the important insight gained. The studies show that market-leading fabrics do not all perform equally. Despite approximately equal performance when new, some fabrics significantly outperform others when tested throughout life, offering higher performance levels, greater garment life, and better value for money.

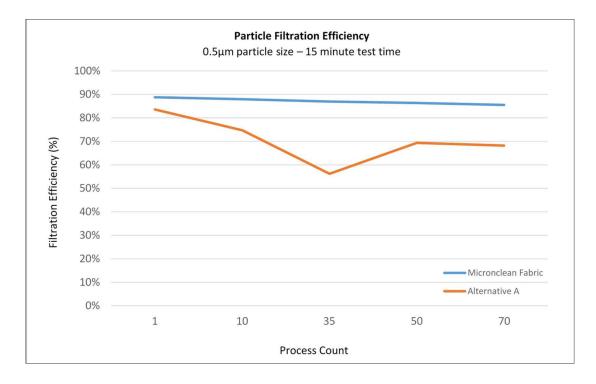
In the subsequent sections Micronclean India - Preliminary Garment Study and Micronclean India - Extensive Garment Study the effect of steam sterilisation on garments is explored.

The study presented in this section involved exposing cleanroom garments of the same design but in two different fabrics to repeat cycles of Micronclean's standard UK laundry and sterilisation (gamma irradiation) processes. The fabrics were exposed to a maximum of 70 process cycles. At planned cycle intervals garments were removed from the study for analysis.

The two fabrics in the study were (i) 'Micronclean Fabric' – the fabric that Micronclean uses in its garments, and (ii) 'Alternative A' – another market-leading cleanroom fabric.

Results are shown for various key cleanroom fabric performance characteristics across the spectrum of barrier properties, durability and comfort.





PARTICLE FILTRATION EFFICIENCY

Figure 12 - Graph to show fabric particle filtration efficiency through life

In this test the particle filtration efficiency of the fabrics was measured. Test conditions were a particle size of 0.5µm, and a test time of 15 minutes. Results are expressed in percentage particle filtration efficiency.

As can be seen in **Figure 12**, the two fabrics begin with broadly equal levels of particle filtration efficiency in the region of 85 to 90%. As the number of process cycles increases, the particle filtration efficiency of both fabrics decreases. Micronclean Fabric shows a decrease from 90% to 85%. However, Alternative A shows a much more significant decrease from 85% to 70%. Throughout the study Micronclean fabric outperforms Alternative A, offering a superior contribution to the contamination control performance of the cleanroom garment system.

This highlights that a cleanroom fabric should not be selected based on 'as new' performance data only. What appear to be similar fabrics in the 'as new' state offer the user significantly different levels of performance over the course of garment life.

FABRIC PORE SIZE

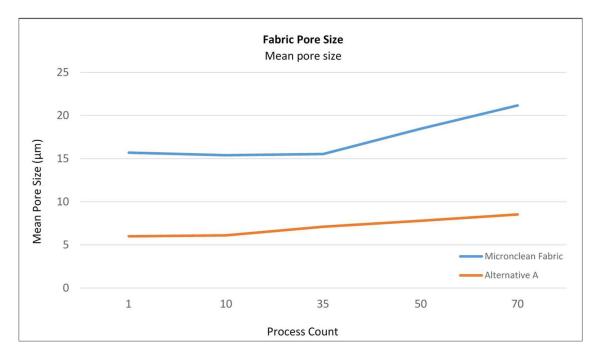


Figure 13 - Graph to show fabric pore size through life

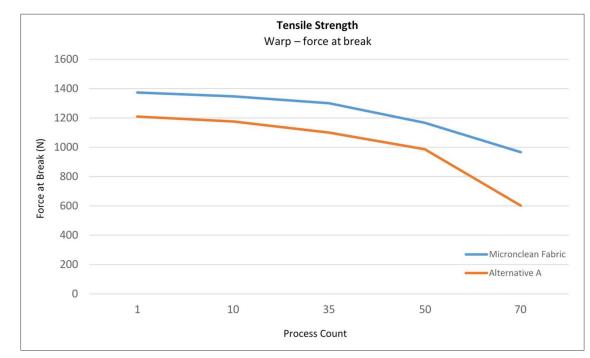
In this test the pore size of the fabrics was measured. Results are expressed in micrometres.

As can be seen in **Figure 13**, the two fabrics have significantly different pore sizes. Micronclean Fabric begins with a pore size of 15µm, which increases somewhat to 21µm by the end of the study. Alternative A begins with a pore size of 6µm, which increases slightly to 8µm by the end of the study.

Micronclean Fabric therefore appears to achieve improved particle filtration efficiency despite having a larger pore size. This is likely due to the 'depth filtration' effect achieved by a twill weave fabric, the pores being complex in shape and therefore increasing the chance of particle impaction as a particle passes through the fabric. The larger pore size should contribute to a more breathable, and therefore more comfortable, cleanroom garment. Although Alternative A has a smaller pore size, it is not able to achieve the same particle filtration efficiency as Micronclean Fabric.

This highlights that reasonable assumptions, for example larger pore size leads to poorer particle filtration efficiency, do not hold true in all cases. The overall performance of a cleanroom fabric and cleanroom garment system can only be established through extensive studies.





TENSILE STRENGTH

Figure 14 - Graph to show fabric tensile strength through life

In this test the tensile strength (force required to break the fabric) of the fabrics was measured. Results are expressed in Newtons at the point of break.

As can be seen in **Figure 14**, the two fabrics have significantly different tensile strength. Micronclean Fabric begins with a strength of 1400N and, through repeat processing, this reduces to 1000N by the end of the study. Alternative A has a starting strength of 1200N and shows a more significant decrease to 600N at the end of the study.

The results demonstrate the significant effect that repeat laundering and sterilisation (in particular irradiation) has on the polyester fabrics used to manufacture cleanroom garments. However, not all fabrics degrade in the same way. The results suggest that Micronclean Fabric will be more durable than Alternative A. At 70 process cycles Alternative A might not be able to withstand the stresses of use, while Micronclean Fabric remains significantly stronger.

ABRASION RESISTANCE

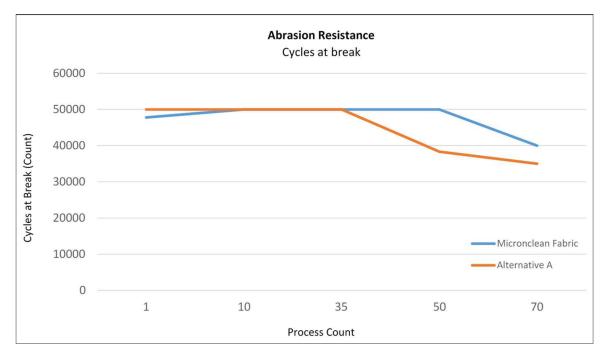


Figure 15 - Graph to show fabric abrasion resistance through life

In this test the abrasion resistance (cycles required before the fabric shows signs of breakage) of the fabrics was measured. Results are expressed in count of cycles at the point of break. Tests ran to a maximum of 50,000 cycles in each case, which for a cleanroom fabric is considered highly resistant to abrasion.

As can be seen in **Figure 15**, both Micronclean Fabric and Alternative A consistently withstand 50,000 cycles up to a process count of 35. After 70 cycles, Micronclean Fabric shows a reduction in abrasion resistance to 40,000 cycles. However, Alternative A shows an earlier and more significant reduction in abrasion resistance, which reduces to 35,000 cycles at a process count of 70.

Like the observations for tensile strength, and due to the same degradation mode, he results demonstrate the effect that repeat laundering and sterilisation (in particular irradiation) has on the polyester fabrics used to manufacture cleanroom garments. The results suggest that Micronclean Fabric remains more durable than Alternative A. At 70 process cycles Alternative A is more prone than Micronclean Fabric to damage by the stresses of use.



AIR PERMEABILITY

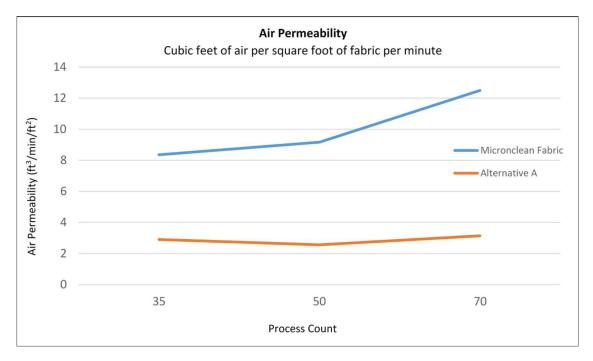


Figure 16 - Graph to show fabric air permeability through life

In this test the air permeability of the fabrics was measured. Results are expressed in cubic feet of air per square foot of fabric per minute.

As can be seen in **Figure 16**, and consistent with the assumptions that might be derived from the relative pore sizes of the two fabrics, Micronclean Fabric demonstrates a higher levels of air permeability in the 'as new' state (8ft³/ft²/min) throughout the study up to 70 process cycles (12ft³/ft²/min). Alternative A begins with a significantly lower air permeability (3ft³/ft²/min – less than half of that of Micronclean Fabric), and approximately maintains the same level up to a process count of 70.

The results suggest that the two fabrics might contribute very differently to the comfort of a cleanroom garment system. Micronclean Fabrics has significantly higher breathability than Alternative A. A cleanroom garment system manufactured from Micronclean Fabric should therefore offer significantly greater comfort to the wearer. This increases the chance that the wearer will don and use the garments correctly, and therefore contributes positively to a successful cleanroom contamination control strategy.

DISCUSSION

By conducting these studies, encompassing a range of cleanroom garments and with its controlled cleanroom laundering and sterilisation processes, Micronclean is able to select the best materials, garment designs and garment construction methods to work with. Further, Micronclean can optimise its laundry and sterilisation processes to ensure that a high-performing garment is delivered to the customer throughout a garment rental contract.

The studies also provide data that support the establishment of a safe useful life for cleanroom garments. This allows Micronclean to design cleanroom garment rental service contracts to ensure that customers receive high quality and high performing garments throughout a contact term, as well as good value for money.

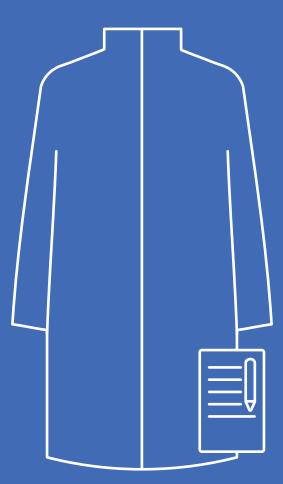
In the study presented, Micronclean Fabric was shown to offer superior performance to another market-leading cleanroom fabric – Alternative A – in several areas. Importantly, Micronclean Fabric retains excellent particle filtration efficiency up to 70 process cycles. This is fundamental to its performance in cleanroom contamination control. Coupled with this, Micronclean Fabric offers super breathability, and therefore greater comfort to the wearer; not only will the garment perform well, but it is more likely that it will be donned and worn correctly by the wearer. Further, Micronclean Fabric retains greater durability – both in terms of tensile strength and abrasion resistance – with repeat laundering and sterilisation cycles, leading to reduced risk of damage through use and therefore better value for money through reduced frequency of garment repairs and replacements.

This UK study assessed the impact of repeat cycles of laundering and sterilisation by gamma irradiation. The Micronclean India cleanroom garment rental service will instead employ steam sterilisation. Steam sterilisation presents different challenges to cleanroom garments; the ageing effects caused can be expected to be different when compared with gamma irradiation and therefore cleanroom garment performance may change in different ways throughout garment life. The following sections explore this in more detail.



PRELIMINARY GARMENTS STUDY

MICRONCLEAN INDIA



MICRONCLEAN INDIA | PRELIMINARY GARMENT STUDY

MICRONCLEAN INDIA - PRELIMINARY GARMENT STUDY

As noted in the previous section, the Micronclean India cleanroom garment rental service will use steam sterilisation. The impact of the moist heat under pressure involved in steam sterilisation is known to have different ageing effects on cleanroom garments when compared with gamma irradiation. Further, although the laundering processes of Micronclean UK and Micronclean India will be broadly similar, the small differences in laundry machine configuration and process recipes also present a risk that cleanroom garments will age differently.

Micronclean has therefore investigated the performance of different cleanroom garments through repeat cycles of the laundering and sterilisation processes used in India.

This section presents data from a preliminary study conducted in the UK with simulations of the laundering and sterilisation cycles planned for Micronclean India. This study was performed to provide preliminary performance data for Micronclean's cleanroom garments when exposed to repeat cycles of laundering and steam sterilisation. The data also informs the design and scope of the extensive study to be carried our at the Micronclean India factory.

The data presented below shows a comparison in the performance of Micronclean Fabric when exposed to repeat cycles of laundering and steam sterilisation ('Autoclave') compared with equivalent garments exposed to repeat cycles of laundering and sterilisation by gamma irradiation ('Irradiation').



MICRONCLEAN INDIA | PRELIMINARY GARMENT STUDY

BARRIER PROPERTIES

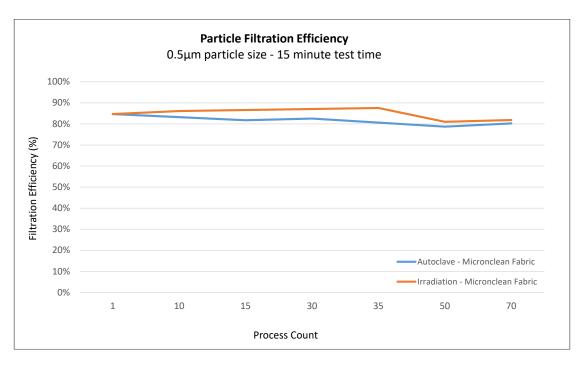


Figure 17 - Graph to show fabric particle filtration efficiency through life

In this test the particle filtration efficiency of Micronclean Fabric was compared for the two study conditions. The test was conducted with a particle size of 0.5µm, and a test time of 15 minutes. Results are expressed in percentage particle filtration efficiency.

Figure 17 shows that Micronclean Fabric achieves approximately equivalent levels of particle filtration efficiency in the two study conditions. At the start of the study, the fabric shows a particle filtration efficiency of 85% in both conditions.

This provides reassuring evidence that the barrier properties of Micronclean Fabric remain excellent when sterilised by gamma irradiation and when sterilised by steam.

MICRONCLEAN INDIA | PRELIMINARY GARMENT STUDY

DURABILITY

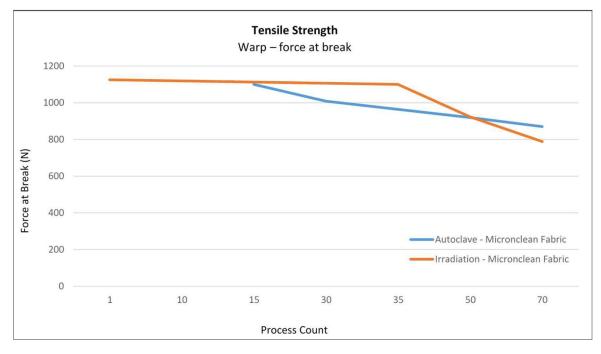


Figure 18 - Graph to show fabric tensile strength through life

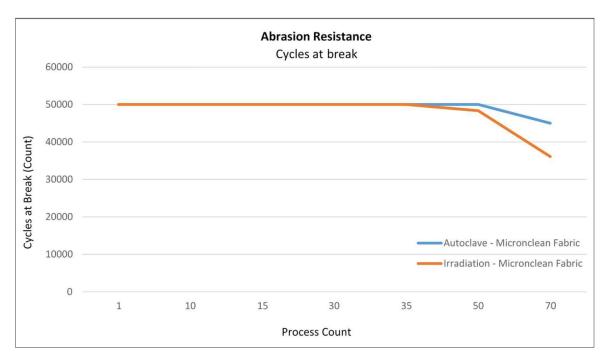


Figure 19 - Graph to show fabric abrasion resistance through life



MICRONCLEAN INDIA | PRELIMINARY GARMENT STUDY

Figure 18 compares the tensile strength (force required to break the fabric) of Micronclean Fabric in the two study conditions. Results are expressed in Newtons at the point of break.

In both study conditions, Micronclean Fabric begins with a tensile strength of approximately 1100N. Fabric in the Autoclave study condition shows signs of reducing tensile strength earlier, starting at a process count of 15. However, the rate of reduction of tensile strength in the Autoclave condition is slower. Comparatively, fabric in the Irradiation study condition shows a reduction in tensile strength from a process count of 35, but then loses tensile strength more rapidly with further processes. At 70 process cycles, fabric in the Autoclave study condition retains higher tensile strength (900N) when compared to fabric in the Irradiation study condition (800N). At a process count of 70, both fabrics retain a good level of tensile strength.

Figure 19 compares the abrasion resistance (cycles required before the fabric shows signs of breakage) of Micronclean Fabric in the two study conditions. Results are expressed in count of cycles at the point of break. Tests ran to a maximum of 50,000 cycles in each case, which for a cleanroom fabric is considered highly resistant to abrasion.

In both study conditions, Micronclean Fabric begins with excellent abrasion resistance (>50,000 cycles), and this is retained until at least 35 process cycles. Fabric in both conditions demonstrates a slight reduction in abrasion resistance after 35 cycles. However, the rate of reduction in abrasion resistance in the Autoclave condition is slower. At 70 process cycles, fabric in the Autoclave study condition retains higher abrasion resistance (45,000 cycles) when compared to fabric in the Irradiation study condition (37,000 cycles). At a process count of 70, both fabrics retain a good level of abrasion resistance.



MICRONCLEAN INDIA | PRELIMINARY GARMENT STUDY

DISCUSSION

This preliminary study simulated the laundering and sterilisation cycles planned for Micronclean India. The effect of these processes on the performance of Micronclean Fabric was compared with the equivalent effect of the UK processes (similar laundering and sterilisation by gamma irradiation).

This study provided preliminary performance data for Micronclean Fabric in the conditions expected in the Micronclean India cleanroom garment rental service.

Investigation of barrier properties demonstrated that Micronclean Fabric achieved comparable, excellent levels of particle filtration efficiency when exposed to 70 processes in each study condition. This provides reassuring evidence that Micronclean Fabric is compatible with steam sterilisation and will perform equivalently from a contamination control perspective in these conditions.

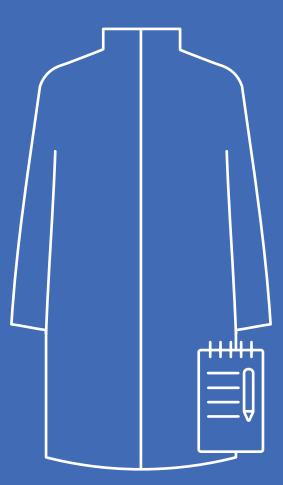
Investigation of durability showed that Micronclean Fabric demonstrates comparable or better levels of robustness (tensile strength and abrasion resistance) when exposed to 70 cycles of laundering and steam sterilisation than it does when exposed to 70 cycles of laundering and sterilisation by gamma irradiation. This suggests that steam sterilisation is less physically damaging to Micronclean Fabric, and therefore that greater garment life might be achieved in Micronclean India. This would offer lower risk of garment damage during use and greater value for money to customers.

An extensive study is required to fully establish these findings, and it is important that this study is conducted in the actual process machinery and actual process recipes that will be incorporated in the Micronclean India cleanroom garment rental service. The next section outlines the results from this study.



EXTENSIVE GARMENTS STUDY

MICRONCLEAN INDIA



MICRONCLEAN INDIA – EXTENSIVE GARMENT STUDY

The preliminary study presented in the previous section provided performance data for Micronclean Fabric in a simulation of the conditions expected in the Micronclean India cleanroom garment rental service. It provided reassuring evidence that Micronclean Fabric is compatible with the planned processes and will perform well through life. However, an extensive study was required to reinforce the preliminary findings. This study was performed in the actual process machinery using actual process recipes of the Micronclean India factory during the plants commissioning phase.

AIM

The study aimed to provide data to confirm the best cleanroom garment materials to offer customers in India. The study also provided data to inform the determination of safe useful life of cleanroom garments offered by Micronclean India.

SCOPE

The study was performed in actual processing conditions in the Micronclean India factory, using the actual process machinery and actual process recipes. Fabrics under test were exposed to 120 process cycles of wash, dry and steam sterilisation.

The study included garments manufactured from Micronclean India's own cleanroom fabric ('MCI Source') and fabrics from two leading competitors in India ('Alternative Source A' and 'Alternative Source B').

The study assessed performance of cleanroom garments against a number of key parameters including cleanroom barrier properties (particle filtration efficiency and pore size) and durability (tensile strength). At set numbers of process cycles, samples of fabric were withdrawn from the study for analysis.

RESULTS

The results of the study are detailed in the following sections.



PARTICLE FILTRATION EFFICIENCY

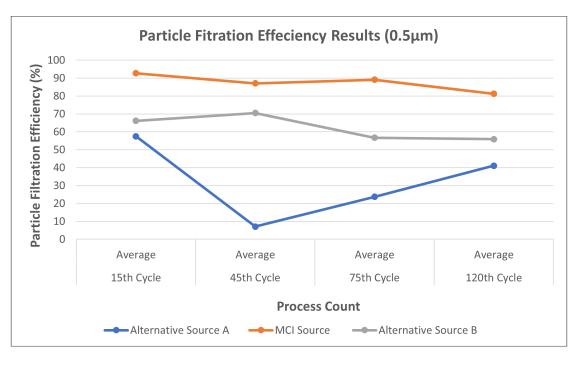


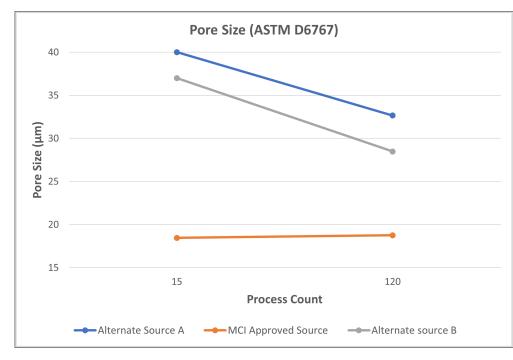
Figure 20 – Graph to show fabric particle filtration efficiency through life

In this test the particle filtration efficiency of the fabrics was measured. Test conditions were a particle size of 0.5µm, and a test time of 15 minutes. Results are expressed in percentage particle filtration efficiency. The x axis shows the number of process cycles (wash, dry, steam sterilisation) the fabric was exposed to.

As can be seen in **Figure 20**, as the number of process cycles increases, the particle filtration efficiency all the fabrics decreases. Micronclean Fabric shows a decrease from >90% at the starting point to >80% by 120 process cycles.

Alternative A and Alternative B fabrics show significantly lower starting particle filtration efficiencies of >75% and >65% respectively. Alternative A shows a reduction in performance to >55% by 120 process cycles, and Alternative B shows a reduction in performance to >40%.

The Micronclean fabric outperforms the other fabrics by a significant margin and performs consistently throughout the garment life cycle.



PORE SIZE

Figure 21 – Graph to show fabric pore size throughout garment life cycle

In this test the pore size of the fabrics was measured. Results are expressed in micrometres.

As can be seen in **Figure 21**, the three fabrics have significantly different pore sizes. Micronclean Fabric shows a pore size of 18µm remaining consistent up to 120 process cycles. Alternative A and Alternative B fabrics show much higher starting pore sizes at 40µm and 37µm respectively. Although both fabrics demonstrate a reduction in pore size with repeat processing, their pore size at 120 process cycles remains significantly higher than Micronclean Fabric; Alternative A at 33µm and Alternative B at 28µm.

The Micronclean Fabric outperforms the other fabrics by a significant margin and performs consistently throughout the garment life cycle.

TENSILE STRENGTH

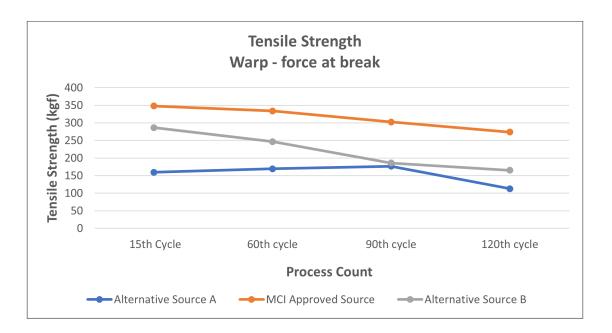


Figure 22 – Graph to show fabric tensile strength throughout garment life cycle

In this test the tensile strength (force required to break the fabric) of the fabrics was measured. Results are expressed in Kgf at the point of break.

As can be seen in **Figure 22**, the three fabrics have significantly different tensile strength. Micronclean Fabric begins with a strength of 350Kgf and, through repeat processing, this reduces to 270kgf by the end of the study. Alternative A and Alternative B show starting strength significantly lower than that of Micronclean Fabric at 160kgf and 290kgf respectively. Both Alternative A and Alternative B show reductions in strength when exposed to processing, with strengths after 120 process cycles of 110kgf and 160kgf respectively.

The Micronclean Fabric outperforms the other fabrics by a significant margin and performs consistently throughout the garment life cycle.

DISCUSSION

This extensive study demonstrated the effect of repeat laundering and sterilisation cycles in the Micronclean India laundry on leading cleanroom fabrics. The effect of these processes on the performance of Micronclean Fabric was compared fabrics from two leading competitors in India.

Investigation of particle filtration efficiency demonstrated that Micronclean Fabric achieved excellent barrier performance through to 120 process cycles. This excellent level of performance is explained by Micronclean Fabric showing a low and consistent pore size throughout 120 process cycles. Investigation of tensile strength demonstrated that Micronclean Fabric has excellent starting strength, and this strength is maintained throughout 120 process cycles.

These results suggest Micronclean Fabric will achieve excellent barrier performance throughout a cleanroom garment life cycle, contributing to maintaining low cleanroom contamination levels and a wider Contamination Control Strategy. Further, Micronclean Fabric will remain durable throughout a cleanroom garment life cycle, remaining able to withstand the stresses of use, providing performance assurance and value for money for the customer from first use to last use.

Comparatively, other leading cleanroom fabrics in India demonstrate lower levels of barrier performance and tensile strength that degrade significantly with repeat processing. Both leading alternative fabrics studied would offer customers poorer performance potentially leading to increased cleanroom contamination risk and poor value for money.

The potential impacts of cleanroom garment performance on a Contamination Control Strategy and cleanroom operational budget are significant; they must be understood with supporting analytical data. To make good decisions, customers should demand thorough data from their suppliers. It is not sensible to rely on 'as new' garment performance data to make decisions as performance changes through life. Micronclean supports its customers by investing in analysis and providing data to allow customers to make informed decisions on their Contamination Control Strategy.

NOTES



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Micronclean India Pvt Ltd Plot No. 24 & 25 | Vemagal Industrial Area | Vemagal | Kolar | 563102 | Karnataka | India T. +91 7829111150 | E. enquiries@micronclean.in W. www.micronclean.in



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