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EVALUATION OF CRITICAL CONSUMABLES IN CLEANROOM OF ASEPTIC AREA

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ABSTRACT: Sterility is the complete absence of any viable microorganism in a drug product. The Specification of sterility is unchanging and is independent of the kind of manufacturing Process. Sterilisation of the final product in its container closure system or aseptic manufacturing is followed. Under Terminal sterilisation usually it involves filling and sealing product containers under high quality Environmental conditions. Products are filled and sealed in this type of environment, so as to minimise the microbiological content of the in-process product and also to help ensure that the Subsequent sterilisation process is successful. The main complicating factors are the temperature and humidity of the cleanroom and the variations between people. The length of time will also depend upon the grade of the cleanroom. Critical Consumables are designed to provide protection for the head, body, hands and feet. In the process of establishing a system for garment selection, it is important to consider the broader aspects of cleanroom use. The main purpose of this study is to check the level of contamination in aseptic manufacturing and to minimize it by the use of specific type of garments and Gloves in specified areas in accordance with Institute of environmental science and technology. This Article provides detailed information on how to properly gown and de-gown the Consumables in cleanroom.

INTRODUCTION: The main task of Cleanroom Consumables is to protect the product and process from contamination that take place by human beings and their personal garments. The requirements for cleanroom Garments and Gloves and other consumables will vary from location to location. It is important to know that the Consumables requirements for the cleanroom management. Particles that are external to clean room facilities have a variety of origins in nature, which also including volcanic releases and windblown dust.

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Most particles that originate from such sources and can be efficiently controlled or reduced by filtration systems. In the procedure of establishing a system for consumables selection, it is important to consider in a broader aspects of cleanroom use. The suitability of fabric, garment style, layers, and the nature of the tasks involved, costs, regulatory requirements, and any specific customer requirements are considered. [1, 2]

For this purpose it requires the fabric or material to be stable, processing a high ability to resist breakdown. Other than the costs associated with high batch failure rates, contamination by biological agents of parenteral drugs can have serious consequences for patients and other users. Being a health care professional, it is an important to protect yourself first from daily exposure to bacteria, viruses and infectious fluids.

The examination consumables you wear provide a barrier between you and infectious organisms and other hazardous substances. So it is necessary to wear consumables to protect person and product. [3]

MATERIALS AND METHODS:

Materials Required in Clean Room: [4, 5]

A) Coverall: It is used to cover body from ankles to neck.

FIG. 1: COVERALL

B) Shoe covers: It prevent excessive dirt and sand contamination coming off from street shoes.

FIG. 2: SHOE COVER

C) Bouffant: It contains hair and holds hair in it and minimizes shedding of particles.

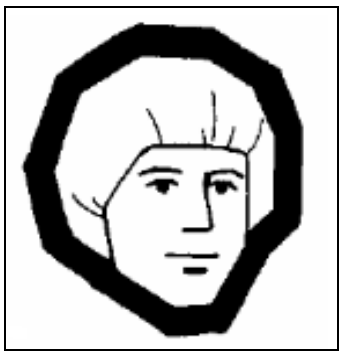


FIG. 3: BOUFFANT

D) Hood: Used to cover body from head to neck. [6]

E) Face-mask: It involves in minimizing particle contamination from Beard and breathing.

FIG. 4: FACE-MASK

F) Booties: Used to contain particles from shoes within the booties and serves as "clean shoes".

G) Cleanroom gloves: It is used to prevent oils, skin particles and microbes from contaminating the surface of the work benches and equipment and finally Product.

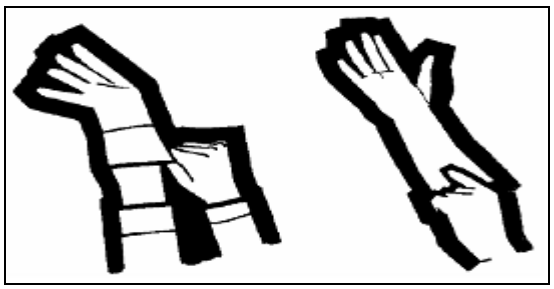
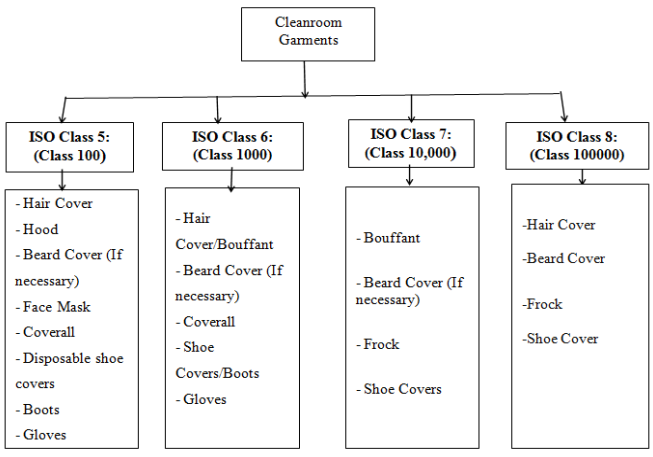


FIG. 5: GLOVES

H) Safety eyewear: It protects against particles from entering inside the eyes.

Classification of Garments:

TABLE 1: ACCORDING TO INTERNATIONAL ORGANISATION FOR STANDARDISATION (ISO) THE CLEANROOM GARMENTS ARE CLASSIFIED INTO [7]



Quality of material in garment:

Fabric: In the manufacturing of cleanroom garments the suitability of fabric is important. Fabric is one kind of yarn sheet that have a bound which is made by chemical or mechanical bond and for that which has strength and show many properties. [8]

Types of fabric:

A. Woven fabric
B. Non-woven fabric
C. Knitted fabric

A. Woven fabric: Woven fabric is a fabric, which is prepared by the interlacement of two sets of warp and weft yarn. Minimum of two set of yarn needed to make a woven fabric.

B. Non-woven fabric: Non-woven fabric is a fabric, which is made by the creation of fibre weft and also the fabric having mechanical and chemical bonding.

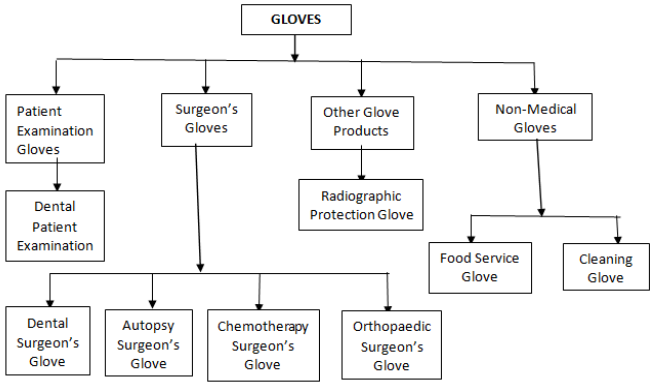
C. Knitted fabric: When a fabric is manufactured by interloping of one set of yarns is called knitted fabric. At least one or one set of yarns is needed to make a knit fabric.

Properties of fabric: Fabrics used in the manufacture of cleanroom garments must have the following features:

- It should be low in particulate shedding
- It should permit the body to breathe while trapping particles within the garment. The contaminant should be retained within the garment and not released into the surrounding atmosphere
- It should be flexible enough for comfortable wearing
- It should withstand repeated cleaning and sterilization cycles
- It should meet any specific requirements such as control of static charges
- It should meet opacity requirements
- It should look and feel as good as possible
- It should be cost-effective
- It should be lint free fabric

Cleanroom lint free fabric: Lint free fabric is manufactured from long chain synthetic polyester continuous filament yarn which gives it a non-linting property. The fabric exhibits good resistance activity to most of the mineral and organic acids and alkalis at room temperature. Lint free fabric is not affected by alcohol, bleaching agents, soaps, synthetic detergents and perspiration. It shows excellent resistance to deterioration by mildew, aging and sunlight and very good resistance to abrasion (greater than 25000 abrasions). And it can with stands above 80-90 sterilizing cycles in the pharmaceutical industries when washing is done in house. [9]

TABLE 2: CLASSIFICATION OF GLOVES [10, 11]



Glove Materials: Cleanroom gloves are typically made from vinyl, natural rubber latex, nitrile or chloroprene. The Global Society for Contamination Control describes advantages and disadvantages of each: [12, 13]

- Vinyl – this is known for being very clean, inexpensive and static dissipative. However, vinyl gloves retain heat and have poor moisture vapour transmission.
- Natural Rubber Latex – it has the best cost/performance ratio of any material available.
- It is durable and very easy to manufacture. However, it does not have inherent static dissipative features. Some of the people have allergies to the proteins found in natural latex, which can cause painful rashes.
- Nitrile – this offers very good puncture resistance and exhibits broader chemical resistance than that of natural latex, especially with solvents. Nitrile also has very good static dissipative features not found in natural rubber latex.
- Chloroprene – it is not widely used in the cleanroom industry, but has the characteristics similar to those of nitrile.

TABLE 3: SUITABILITY OF GLOVES [14-17]

	Comfort	Elasticity	Strength	Durability	Electrostatic Discharge Performance
Latex	Excellent	Excellent	Excellent	Good, but punctures can be hard to spot	Very poor Latex is an excellent insulator
Poly chloroprene	Good, very close to latex	Good	Good	Good	Poor-good insulator
Nitrile	Good, comfort improve with wearing	Medium	Medium	Good	Good, static dissipative and improve with wearing
Vinyl	Fair, relatively stiff	Low	Low	Medium	Good, static dissipative and improve with wearing

Cleanroom Gowning Procedure: By far the dirtiest thing in the cleanroom will be the people who use garments. Even the most carefully manicured person generates a shroud of particles from their skin, hair, clothing, and breath. [18]

Consequently, all cleanroom users must wear cleanroom garments which trap and stop the particles emitted by their bodies and clothing.

The support equipment building (SEB) Cleanroom has adopted the following gowning procedure for use in the Cleanroom.

It is important that each person who enters the cleanroom must carefully follow this procedure. Frequent cleanroom users should tag a garment hanger with their name using cleanroom tape.

Their gown, hood and booties must be disposed of approximately after two weeks of use.

A. Remove unnecessary items and place hat, coat, and any other street garments in their particular locker: Enter into service corridor. Remove street garments not needed for modesty and warmth along with valuables; secure in designated locker. The individual will be provided with his/her own lock.

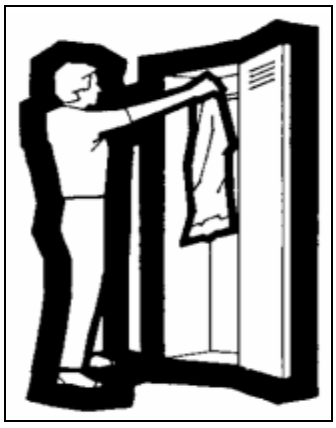


FIG. 6: REMOVAL OF UNNECESSARY ITEMS

B. Swipe into the gown room using your Marlok card: All users are required to use their own Marlok card even if they are entering behind someone else. Before entering the door, be sure to do this, which is that step THREE times on the sticky mat. [19]

C. Put on the shoe covers which is located just inside the entrance of the gowning room. Only flat or very low-heeled shoes may be permitted to worn. Sandals or open-toed shoes are not allowed inside. Upon entering the gown room, immediately step to the bench on the left and have a seat. Grab a set of shoe covers from the bin next to the bench and place over shoes to minimize contamination from shoe. Shoe covers must be worn at all times while in the gown room.

D. Put on face mask and bouffant: Bouffant which are required to extend the life of the hood, help to contain the hair within, and reduce contaminants while gowning.

E. If you are a new user, you will need to assemble your gown then label the coverall, hood, and shoe covers with the date it was assembled and last name. The labelling of these items should only be with a cleanroom pen. The gown should be labelled inside on the back, at the collar. The hood should also be labelled inside on the back side. The shoe covers should be labelled on the side inside both the left and right portions. [20]

F. Carefully put on a hood: The hood must completely cover your hair and ears.

G. Inspect the cover all of your gown. Take care to keep the garment completely off of the floor at full times. Inspect your garment every time before donning, look for tears or soiling. If damaged, do not wear and dispose.

FIG. 7: INSPECT THE COVERALL OF YOUR GOWN

H. Put on your cleanroom gown. First, step into the gown legs, taking care should be taken not to let the garment touch the ground at any time. Then pull on the upper half of the gown and zip it all of the way up. While wearing a hood, be sure the "skirt" of the hood is completely inside the collar of the jumpsuit.

FIG. 8 AND 9: PUT ON OF GOWN

I. Put on Shoe Covers: To put on cleanroom shoe covers, sit on the gowning bench with your feet on the dirty side of the bench. Put on one bootie and swing the "clean" foot to the clean side of the gown room. After first put on second cleanroom shoe cover and swing fully to the clean side and stand up. Be careful that the top of the boot is over the bottom of the jumpsuit leg so that any particles falling down the gown leg will be trapped in the shoe cover.

Note: Shoe covers should never be worn on the dirty side of the gowning room. Only booties are allowed on the dirty side. Shoe covers should only be worn on clean side of the gowning room or in the cleanroom. [21]

FIG. 10: PUT ON SHOE COVERS

J. Put on Cleanroom Gloves: Carefully put on the first glove, touching the outside of this glove as little as possible. Then put on the second glove using the previously gloved hand, taking care not to touch your skin with the gloved hand. Pull the cuff of the gloves over the sleeve of the jumpsuit because any particles falling from your sleeves are trapped in the glove. Gloves should be worn at all times, no bare hands or fingers.

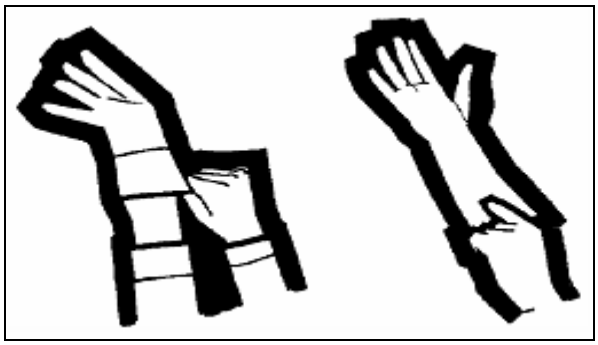


FIG. 11: PUT ON CLEANROOM GLOVES

K. Put on Goggles/Safety Eyewear: Before the goggles are put on, make sure to wipe them down with an Isopropyl alcohol (IPA) wipe provided in gown room. This will ensure that the glasses are free of any particles and clear in vision. [22]

L. Step on sticky mat THREE times upon entrance into the cleanroom: Stepping on the sticky mat THREE times just within the cleanroom area is required in order to reduce particles and to begin work.

M. Notes [23]

1. Use mirror to verify proper closure of garments: ensure all hair and clothing is covered inside the garments worn.
2. Cleanroom garments shall be worn only within the cleanroom complex, except under emergency conditions.
3. Do not wear soiled, dirty or lint-producing street clothes under cleanroom garments.
4. Do not hang street clothes or lab coats in the gown room. Use lockers located outside the gowning room in the service corridor.
5. Facemasks are to be worn over the top of the nose.
6. Never open your gown in the cleanroom.
7. Change cleanroom garments completely, once after two weeks of use (14 working days)
8. If garment is ripped during use, replace immediately
9. Gloves are to be disposed of upon leaving the cleanroom. Booties and bouffant are to be disposed upon leaving the work area.

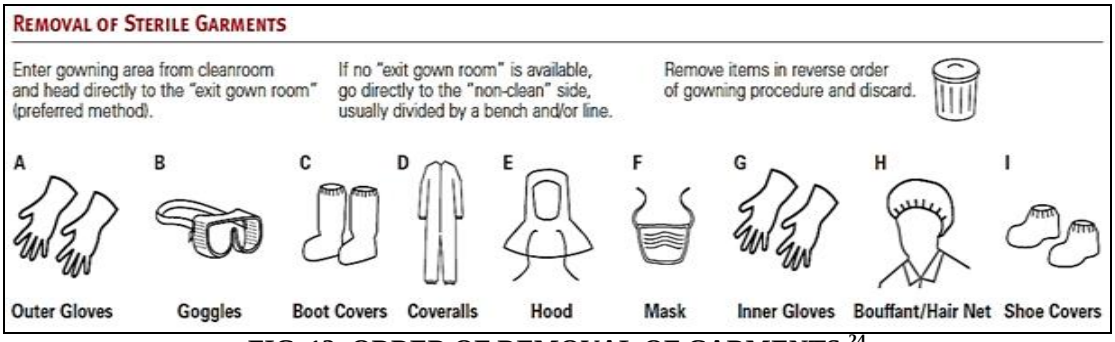


FIG. 12: ORDER OF REMOVAL OF GARMENTS [24]

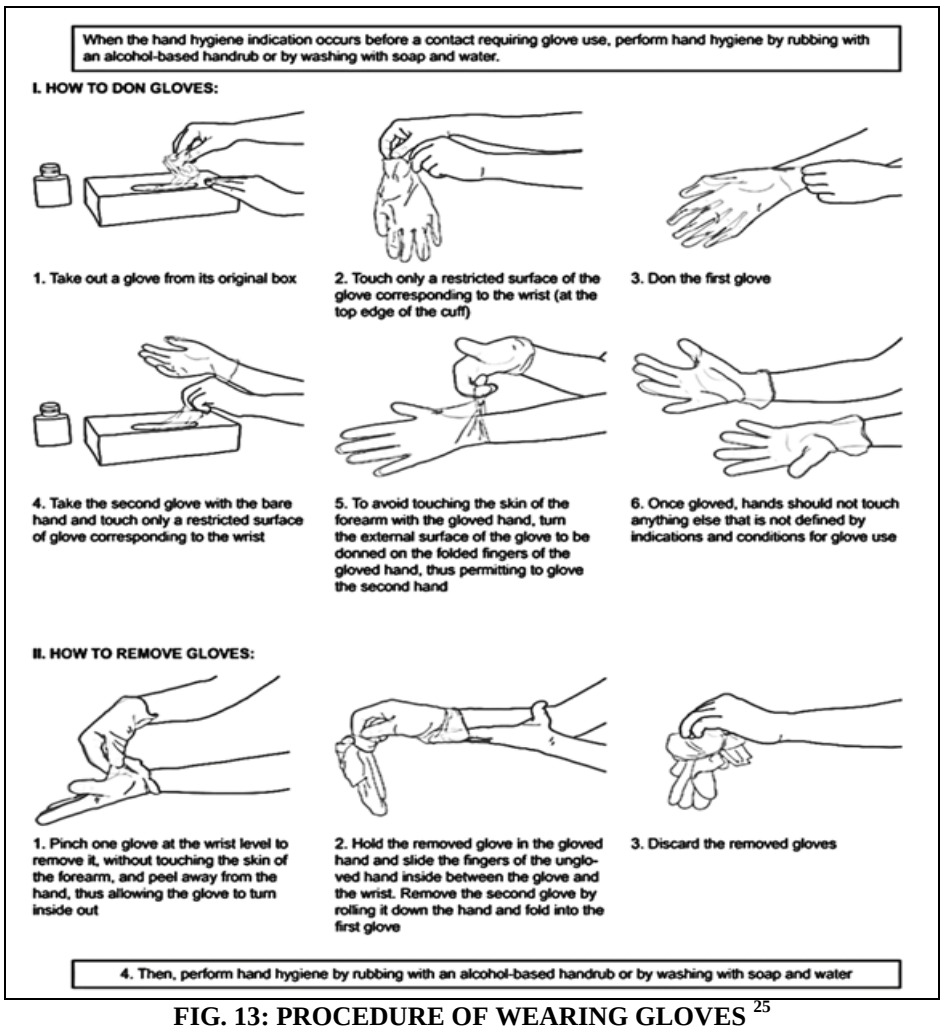


FIG. 13: PROCEDURE OF WEARING GLOVES [25]

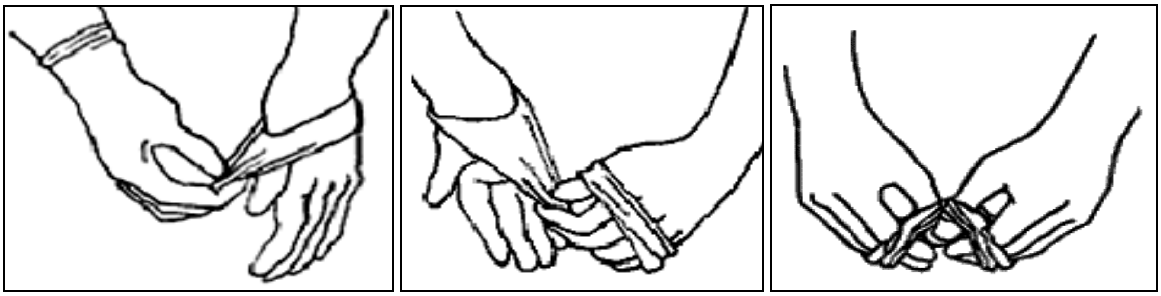


FIG. 14: REMOVAL OF GLOVES

Grasp one of the gloves and cuff and pull it partway off. The glove will turn inside out. It is most important to keep the first glove partially on your hand before removing the second glove. [26]

This is made to protect you from touching the outside of either glove with your bare hands.

Leaving the first glove over your fingers, grasp the second glove near the cuff and pull it part of the way off. The glove will turn inside out.

It is important to keep the second glove partially on your hand to protect you from touching the outside surface of the first glove with your bare hand.

- Pull off the two gloves at the same time, care must be taken to touch only the inside surfaces of the gloves with your bare hands.
- Dispose of the gloves by placing inside out in the trash.
- Wash hands thoroughly after removal of gloves.
- Work from clean to dirty — because this will help to prevent contamination.
- Don't touch your face or adjust personal protective equipment (PPE) with contaminated gloves.
- Change gloves when heavily soiled or if they are torn.
- Discard gloves after use, never wash or reuse disposable gloves.

Dispose of gloves: [27, 28] When the glove is contaminated with a toxic compound or biological material which is covered by any disposal regulations, the gloves must be handled in the same way as the toxic material itself. If gloves are not contaminated or have been properly decontaminated, either of the method landfill or incineration is a satisfactory means of disposal. [29]

Since ordinary aerobic or anaerobic decomposition processes in gloves will not form any toxic products, they may be disposed of in any landfill. Breakdown in landfill will be very much slow except for products made of natural rubber. Incineration is a good choice, but glove disposal by incineration can lead to pollution by the release of toxins. However, a good incinerator unit will completely burn all types of gloves as well as any intermediate decomposition products formed during the process.

Layouts of Rooms: In the **Fig. 15** we can see a typical suite of cleanrooms designed to meet the requirements to produce an injectable product that can be terminally sterilized. The staff who works in this manufacture would enter the suite of cleanrooms through the 'clean changing area'. In this room factory clothes are removed, hands washed, and appropriate cleanroom clothes must be put on. Raw materials and components, such as containers, would enter through their corresponding entry airlocks. In these airlocks procedures are used to decrease the contamination which may come from outside to the cleanrooms. [30, 31]

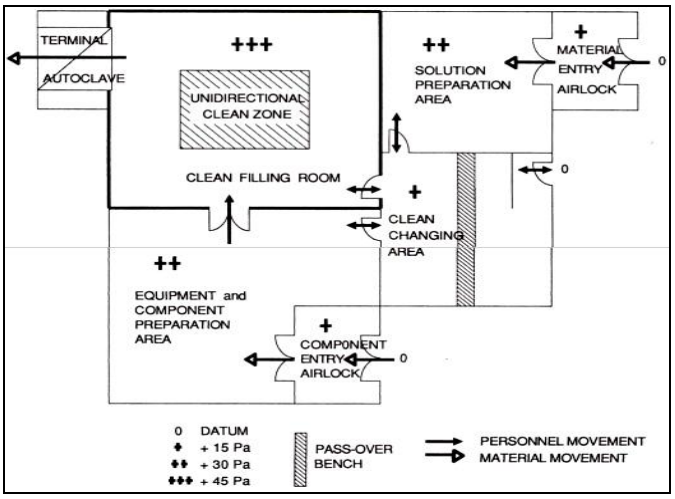


FIG. 15: TYPICAL SUITE OF ROOMS FOR TERMINALLY STERILIZED INJECTABLE [32]

Fig. 16 shows a typical suite of cleanrooms designed for the production of a product employing an aseptic filling technique. The differences in the process requirements refer to the following key variations: the rooms are differentiated into clean and aseptic rooms. [33] The barriers between them are created by the oven, autoclave and transfer hatch for items entering the aseptic suite, and through the separation of the "solution preparation" and "aseptic filling" rooms.

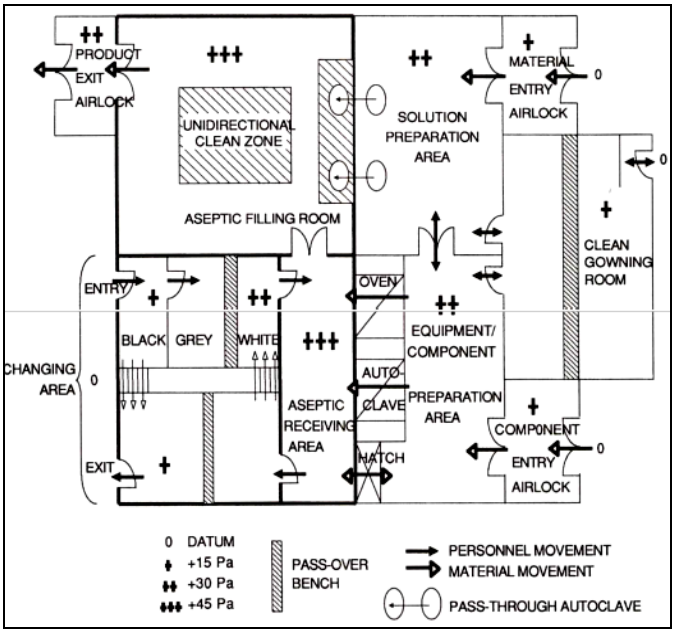


FIG. 16: TYPICAL SUITE OF ROOMS FOR ASEPTIC FILLING [34]

Evaluation of Garments:

A. Description: [35] Garment samples were taken for visual inspection table to check whether each garment for appearance as described in specification and observation were to be recorded.

B. Visual examination: Garment sample was collected and it was inspected for visual examination of physical defects as per inspection Acceptance Quality Limit (AQL) G1 6.5 and observation was recorded.

C. Weight: Garment sample were taken and measurement were made in gram per square meter to check the heaviness of the garment and observation was recorded. [36]

D. Thickness: Thickness was measured using an instrument called dial micrometre in different locations and is expressed in millimetre.

E. Grab tensile: [37] Garment sample was collected from different places and measured the breaking strength of the yarns and durability of the fabric.

F. Moisture vapour transmission rate (MVTR): One square meter garment sample was taken to measure the moisture vapour transmission rate, water passed through measured one square meter surface area for 24 hours and the amount of water is present in grams has to be observed.

G. Air permeability: Garment sample were collected and 5 measurements were made in different areas without cutting specimen and allow air to pass through it, which is quantified by a volume: time ratio per area. [38]

H. Abrasion: Garment sample were taken and measured the abrasion resistance of a garment sample by rubbing the fabric against a wire screen.

I. Surface resistivity: The 2 point electrodes connected to an ohmmeter and it is positioned on the coverall in distance of 30 cm at a different positions in length and cross directions and a voltage of 100 ± 5 V is applied.[39] the resistance is measured after 15 ± 1 second.

J. Helmke drum test: The garment is folded randomly and it is placed in a stainless steel rotating drum which is opened at one end and rotated at 10 rpm ± 1 rpm. An optical or laser automatic particle counter is utilized to sample the air within the drum to determine the average particle (≥0.3 μm and ≥0.5μm) and also release rate of particles per minute. [40]

The particle counts and size spectra are determined at every ten-minute intervals. Alternatively, the air from the drum may be drawn through a filter cassette placed in line between the drum and vacuum pump, and analysed microscopically.

K. Sterility test: [41]

Sample preparation:

- One set of garment sample was collected (collar hood, headgear, boot and mask)
- Collected garments are transferred to Laminar air flow (LAF) of sterility testing area
- Aseptically cut each of collar hood, headgear, boot and mask by using sterile scissors into one

portion, one after the other (approximately cut 25-30 Sq.cm of each component in to two portions)

- Aseptically transferred all the portions of each component by using sterile forceps into a flask or suitable container containing 300 ml of Soyabean casein digest media (SCDM), which is sufficient to suspend the sample completely. Swirl slowly to ensure the complete contact of the media with sample.

Incubation and result recording:

- Incubate the inoculated sample containers of Soyabean casein digest (SCD) at 3 .5 .5 for days
- The observation was recorded in respect to sterility raw data sheet

Observation:

- If there is no evidence of microbial growth is found, the product examined complies with the test for sterility.
- If evidence of microbial growth is found, the product examined does not complies with the test for sterility.

Physical Glove integrity Test methods:

1. Flow Test: An air pressure of about 600 to 1800Pa is used to blow up the glove and is then held to a constant value. Leakage is detected by flow through the glove which is measured by means of a sensitive flow meter (per glove) for a period of 5 to 60 min. If the flow values are obtained above a set limit value are considered to indicate a pinhole. Higher test pressures enhance detection of pinholes. [42]

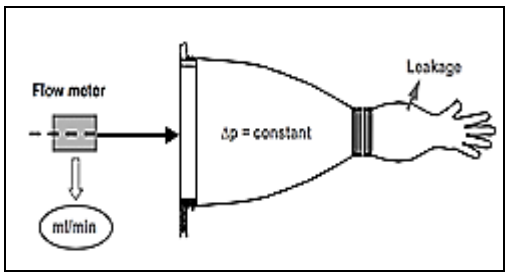


FIG. 17: FLOW TEST

2. Pressure Drop Test: The pressure drop test consists of virtually the same principle as the of flow test, which involves difference to monitor the pressure decay (instead of the flow) as an indicator of a leaky glove. Advantages and disadvantages are therefore the same as for the flow test.

Leak test: It is a physical test to identify a quantifiable leakage rate under specified test conditions by using pressure change (Pressure decay) method.

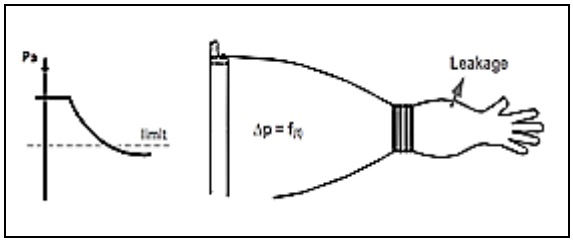


FIG. 18: PRESSURE DROP TEST

3. Water Breakthrough Test or Leak Test: [43] The water breakthrough test is similar to the principle of flow test, but utilizes water pressure to inflate the glove. Visual inspection of the glove to recognize penetrated water droplets allows the localization of a leak. The advantages are reproducibility, detection capability, and sensitivity are good and localization of a hole is well possible, the test can be done by performed with hanging gloves, water volumes exceed easily 1L for the glove (and several litres including the arm sleeves).

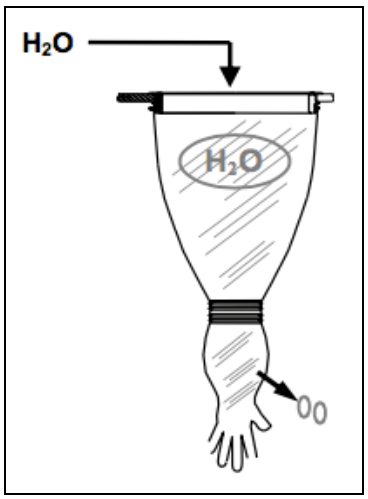


FIG. 19: LEAK TEST

4. Particle Penetrating Test: In the particle penetrating test, a high-particle or aerosol (*e.g.*, diethyl hexyl-sebacate) concentration is applied to challenge one side of the glove. Where by the scanning the other surface side with a particle counter probe, leaks can be detected by raised particle counts around these areas.

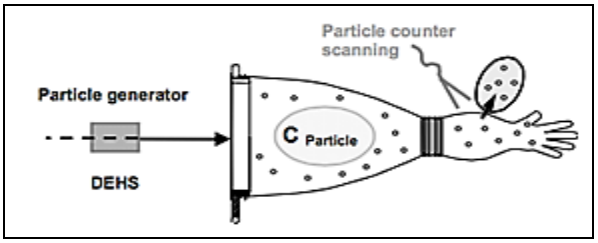


FIG. 20: PARTICLE PENETRATING TEST

5. Diffusional Test (with Different Types of Chemicals Including Helium, Ammonia, and Peracetic acid): Diffusional tests using chemicals have been widely applied for leak/tightness testing (*e.g.* flexible film isolators). The principle is the same as that of flow test with the difference in leaks are detected by specific chemical indicator probes instead of flow or pressure monitoring. Whereas helium is "clean" and non-contaminating and scanning can be done with an electronic probe. The disadvantages are sensitivity and practicability are fairly poor and spurious noise signal may interfere. But both peracetic acid and ammonia give better results in these respects and they contaminate the gloves (and more), have very strong odour, and need special pH indicator towels for wiping the gloves to detect leaks. [44]

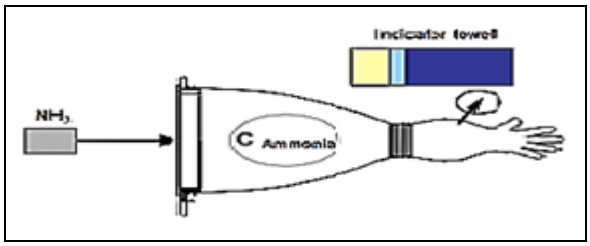


FIG. 21: DIFFUSIONAL TEST

6. Visual Inspection: In visual inspection there is no need of specific equipment. Evaluation of the method led to the clear result that untrained personnel will detect only about one third of leaks. However, a trained operators will be able to identify 99 of 100 leaks. This is as good as with the water breakthrough test but without the drawbacks.

Cleanroom Qualification: Qualification of an aseptic processing facility is a tedious project including qualification of the cleanrooms in the facility, IQ/OQ of the equipment and utilities in the facility, airflow visualization studies, personnel training and qualification, aseptic process simulations, process validation, conformance runs, and other validation activities. This article focuses on the activities involved in certification and qualification of the cleanroom itself. [45]

Installation Qualification:
Installation qualification activities is carried out in a new cleanroom which typically include the following items:

- Verification that the materials of construction are as specified in Guidelines (e.g., Epoxy Terrazzo flooring, smooth hard walls compatible with cleaning chemicals such as phenolic compounds or sodium hypochlorite, etc.)
- Verification of adequate and proper lighting (typically defined in user requirements) at work height
- Verification of appropriate installation of air handling units (AHU) and ductwork or laminar flow units
- Verification that air handling ductwork has been adequately and sufficiently cleaned. This is very important, as improperly cleaned ductwork can cause High-Efficiency particulate air filter (HEPA) leaks in some cases.
- Verification that the specified HEPA or ultra-low particulate air (ULPA) filters have been installed and installed properly. [46, 47]

Operational Qualification:
Operational qualification for a clean room might include the following:

- Verification of proper operation of AHU, humidifiers and dehumidifiers, duct heaters, smoke alarms, dampers, and other controls in more important.
- Verification of proper working of the building management system (BMS) or other control system for the cleanroom
- Measurement of vibration and noise level in the cleanroom
- Cleanroom classification activities. [48-50]

Packaging & Sterility of Gloves: Cleanroom design, operator procedures, correct cleaning and sanitization are very critical when it comes to cleanrooms, whereas the incoming items are not controlled, cleaned and monitored, the contamination will walk right in. So pay special attention to how and where gloves are packaged. [51-53]

Are the gloves packaged in a cleanroom environment? Are they double-bagged with an additional case liner to ensure cleanliness? If you operate in an aseptic/sterile environment, we have to look for sterile gloves that are processed for cleanrooms (not surgical), are that is packaged in poly wallets and pouches and are also sterilized through gamma irradiation or other methods so as to reduce potential bio burden. Sterilization completely removes and/or destroys viable organisms, rendering them unable to reproduce.

The most important to be noted is that there is a huge difference between cleanroom sterile gloves and surgical sterile gloves. Cleanroom sterile gloves typically undergo additional processing to reduce particulates and extractables from the finished product. They are packaged within a cleanroom before being sent on for sterilization. Moreover, cleanroom sterile gloves are manufactured consistent with ASTM requirements, while surgical gloves are not. Instead of this, they are cleared by the Food and drug administration (FDA) as medical devices. [54, 55]

Critical assurance sterile apparel multi-level packaging of Garments: [56]

A. External outer shipping carton is securely sealed. And the carton displays product label, sterile dot indicator and fully traceable lot number.

B. There are multilevel interior packaging features one or two polyethylene carton liners secured with twist ties. The outer liner helps in providing protection from dust and contamination, particularly if outer carton is discarded, then a lot specific Certificate of Conformance is placed between the two liners. The inner liner allows transportation of product to a cleaner, more controlled environment.

C. It is completely heat sealed, airtight individual garment polybag is made from durable polyethylene film and features a varnish-coated ink, easy-to-open linear-tear and embossed lot number.

D. Usually sterile garment consistently folded and packaged to ease aseptic donning. Traceable lot numbers are stamped on each individual sterile garment.

CONCLUSION: A clean facility is essential to meet the analytical challenges of today and tomorrow. Steps must be taken to establish such facilities for trace element and radionuclide monitoring and research. As the attitude of man and awareness about latest developments are essential in maintaining and using a clean facility, continued education and training activities of laboratory staff to stimulate further advancement are very important. Validating a new sterile cleanroom consumables is not a task to be undertaken lightly. However, when a new approach to sterile gowning can help improve the gowning process, reduce opportunities for operator error, and minimize the risk of contamination, it provides a strong incentive for pharmaceutical companies to consider switching.

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