

Standard Operating Procedure

Title: Preparation of Disinfectant Solutions for use in Sterile and Production

- 4.2.1. Bottles with the **RED** nozzle that are used in the Sterile Airlocks are **NOT TO BE TAKEN INTO THE STERILE AREA** and be re-filled. When empty, the Sterile Operator should contact a Production Operator to re-fill the bottles using the IPA vessel.
- 4.3. **WHITE** spray nozzles are to be used **INSIDE STERILE ONLY**, Environmental Grade B.
- 4.4. If a **White** spray nozzle, with bottle is found outside environmental grade B, the Production Operator should be notified and the bottle discarded. **Under NO circumstances can the bottle be reused.**
- 4.5. Clean Room Garments are to send the White nozzle spray bottles to the site Warehouse already rinsed with Distilled Water, dried and sterilised via Ethylene oxide.
- 4.6. Production personnel will then issue the White nozzle spray bottles from the site Warehouse to Production for use in Sterile.
- 4.7. If dirt or foreign matter is found inside the Alcohol spray bottle, or the outside is badly soiled by paint or ink - discard the spray bottle.

5. Disinfectants

Disinfectants used on critical surfaces or gloves in Sterile areas are to be supplied Sterile filtered. Therefore **ALL 70% IPA SOLUTIONS USED IN THE STERILE FILLING AREAS MUST BE FILTERED THROUGH A STERILE, STERILISING FILTER.**

6. Containers for Disinfectants

Containers for Disinfectants **should not be topped up**. Before filling Bioprep containers, they must be rinsed with Distilled Water until there are no traces of soap and Distilled Water must be pumped through the pump until it runs clear.

Microshield uses a new bottle but the pump must be cleaned the same way as the Bioprep pump. Before filling 70% IPA spray bottles, they should be emptied of all remaining alcohol and any alcohol in the nozzle must be pumped out.

7. Preparation of Sterile Filtered 70% IPA (% volume/volume)

- 7.1. Weigh one new 20L drum of IPA on the moveable Floor Scale.
Note the following in the 70% IPA Preparation Logbook:
 - The area where the IPA is issued
 - The full drum weight
 - The Product Code of the IPA
 - The date of preparation and the Manufacturer's batch number from the drum.
 - The logbook covers the IPA preparation areas:
- 7.2. Close the valves, release pressure from the vessel using the spring loaded release valve. Remove the pressure gauge and empty the contents of the IPA drum into the 40L Pressure vessel.
- 7.3. Weigh the empty new drum of IPA and calculate the amount of IPA filled into the Pressure vessel. The drum normally contains 20L of IPA = 15.6Kg of IPA,
e.g. Full drum weight 17.55Kg (gross)
 Empty drum weight - 1.83Kg (tare)
 IPA weight 15.72Kg (net)
Note in the logbook: (1) The weight of the empty drum and (2) the calculated net weight.

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Micro-Lab send to the Washroom 2L autoclaved bottles, which are filled to 1800ml. Production Services fill the empty bottles with 70% IPA and leave the bottles in the Washroom on the back bench for pick up by the Micro-Lab personnel.

11. Labelling and Expiry Dating

- 11.1. **All bottles containing 70% IPA, Microshield (brand) or Bioprep (brand) are to be clearly and adequately labelled** with the disinfectant solution and the Expiry Date.

The expiry date for all solutions is one (1) month from the date of preparation/date of opening the bottle,

e.g: Date of Preparation/Opening: dd/mm/yy Expiry Date: dd/mm/yy

- 11.2. The Sterile Area vessels 70% IPA MUST also be clearly labelled with the expiry date by the Production Operator.
- 11.3. Each bottle of Microshield and each box of Bioprep have a manufacturer's stamped Expiry Date. Check this date on each bottle/box before distribution to ensure that the one (1) month Expiry is within this date.

To label the Microshield bottles, write directly on the bottle with a permanent marker.

To label the Expiry Date on Bioprep containers, place an Expiry Date sticker on the container and write the Expiry Date on the sticker. Each time a new pouch of Bioprep is put into the container, remove the sticker and replace with a new sticker.

- 11.4. **Red** nozzle bottles for 70% IPA have an expiry date sticker.

12. Sterile Filter

- 12.1. Millipore filter type OPTISEAL DURAPORE.
- 12.2. The function of this filter is to remove impurities from the 70% IPA solution, including bacteria.
- 12.3. Testing of the filter is carried out to prove the integrity of the filter.
- 12.4. The **filter assembly must be tested once every fortnight using the ITX Integrity Testers.**
- 12.5. The IPA filters are tested/autoclaved approximately 6 times (i.e. every fortnight for 3 months) then discarded at the end of the three months usage after it has been tested then a new filter is installed.
- 12.6. When a new filter is installed, the Operator must place two pieces of autoclave tape on the filter housing. On the first piece, it needs to have written on it "Installed:" and the date of installation. The second piece needs to have written on it "S/N:" and the serial number of the filter. The serial number is found on the filter. Use a Black permanent marker to write on the autoclave tape.
- NOTE:** When the new filter is installed, it must be autoclaved, but **not** tested, before its first use.
- 12.7. Following the Integrity test, the filter assembly and the dispensing pipe must be re-autoclaved before use.