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Microbial control of isolators and cleanrooms: post-webinar Q and A session

11-Jun-2014 Share

Cleanroom Technology and Thermo Fisher Scientific recently presented a webinar entitled Microbial Control of Isolators and Cleanrooms: How to Validate the Use of a New Plate. The subsequent Q&A session is transcribed here

Boaz Granot, TSI Inc.

Is water activity on the culture media tested?

Aw (water activity) is not a routine QC test performed on culture media, either dehydrated or ready prepared. However, with the new TWI product by Thermo Scientific, the packs are sealed and at an equilibrium 'state', so perhaps Aw could be incorporated as a QC test for shelf-life studies.

Yvonne Appel, Cook Medical Europe

GMP has a recommendation of an exposure time of four hours. Would we be okay to have an exposure time of three hours in a Grade B?

Settle plates are 'passive' air sampling plates and measure the deposition of CFUs that might fall onto the product being manufactured, over a 4-hour period. My understanding is that regulators are not happy to accept counts from a shorter sampling period that are then multiplied up to the expected time period (4 hours). The whole idea of a settle plate is to 'monitor' over a 4-hour period.

Abdul Raji, Cherwell Laboratories Ltd

What is the benefit of using your local isolate in growth promotion tests, since this isolate might be different from the ones isolated by the customer?

The normal range of pharmacopoeial/lab strain control organisms allows us to compare different batches with control plates, to check performance is within specification. If wild type isolates from your own EM studies are included in your test panel, I think it gives more credibility to your performance testing. The inclusion of wild type organisms by pharma companies is pretty much a requirement sought after by inspectors these days.

Boaz Granot, TSI Inc.

Do we have the right neutralisers? Is this need to be evaluated by the end user of the media?

TWI Culture Media manufacturers include a range of neutralisers in their TSA media used as finger dab plates and contact plates. They should have their media tested against a broad range of disinfectants and a level of neutralising efficacy should be established and validated. This information should be available to the client on request. In house, the end user should also perform some tests with their own chosen disinfectants and the neutralising media of choice.

I always recommend a 1:10 and 1:100 dilution of the working strength of a disinfectant be tested, by dipping a swab into the solution and inoculating the surface of the neutralising media, allow to dry, then perform a sub-100 Challenge Test on the plate. You are not looking for log reductions, just testing there is some neutralising tendency.

Dan Mazur, GE Healthcare

Where do we find the documented requirements (i.e. Regulations or standards) for supplier approval/qualifications?

Section 5 of the WHO Technical Report Series, No 961 (2011) Annex 2 explains that you need to test to pharmacopoeial levels and audit your chosen manufacturing partner. I'm sure the need to audit and approve your supplier is also documented elsewhere, but this WHO document is very clear and helpful.

Boaz Granot, TSI Inc.

Resuscitation of VBNCs?

A viable but non culturable (VBNC) organism, by definition, is 'non culturable'! VBNCs typically include not only organisms damaged by disinfectants or the harshness of the environment they are in, but also include organisms that won't grow on the culture media being employed. Longer incubation may allow some damaged organisms to repair and grow, but I would not class them as VBNCs, just damaged organisms.

Other non-culture based methods used in Real Time Microbiology, based on laser-induced fluorescence, may well count VBNCs and allow us to 'see' more accurately what is in proximity to critical areas more effectively.

Abdul Raji, Cherwell Laboratories Ltd

Is the sterility testing method of media covered by any regulation? How many plates or percentage of batch should be used for sterility test?

We manufactured TWI plates to GMP standards (meeting the Pharmaceutical Suppliers Code of Practice), which stated sterility testing should be performed by the manufacturer by taking samples at the start, middle and end of each batch, immediately post manufacture but prior to irradiation (to test that the batch was made aseptically). Incubation should be for a minimum of two days at 30–35°C and three days at 20–25°C.

Post irradiation dosimetry tests should show the entire batch has received the minimum targeted level of gamma irradiation. Again, more packs of plates were then incubated at the two temperatures to check sterility (even though the plates had been irradiated!). This was a random test in which bags seals were tested to see if they were intact after the manufacturing process. The sampling regime for sterility testing of the batch, pre and post irradiation, was not done on a % basis, but as a random test across the batch.

Boaz Granot, TSI Inc.

What is the silica gel water activity? What is the water activity of the agar media?

Silica gel activity and water activity of the TWI plates are not quoted.

The moisture retained in the TWI plates, post irradiation and QC release of the product, has been calculated and validated to be sufficient to support the stipulated shelf-life of the product. The volume of silica gel used is calculated to be sufficient to mop up excess moisture released during irradiation and/or condensation from temperature fluctuation. A 10% reduction in weight of the plates by loss of moisture during the product's shelf-life, is sufficient to fail a batch.

Boaz Granot, TSI Inc.

What is the concentration of the sodium thiosulfate? What is the limit amount of H_2O_2 from VHP on the plate concentration it can neutralise?

Sodium thiosulphate is included at a concentration of 0.5g/L. Full product specification may be downloaded at www.thermoscientific.com/triplewrap (http://www.thermoscientific.com/triplewrap).

Stephen Adams, Pall Ilfracombe

As plates are validated with known organisms is there need to validate again on site?

For pharma industry users of TWI PPM from an 'Approved' (by audit) manufacturer, physical (pH, gel strength, etc.) and biological performance testing and sterility testing of each batch and/or delivery of media, needs to be performed in-house by the end user for at least the first two years. If after this period of time dealings with the manufacturer have proved to be satisfactory, then a second audit could 'Certify' the manufacturer. At this point, the level of QC testing can be reduced to periodic only. The reduced sampling regime needs to be documented.

Pharmacy practice units, working to ISO 17025, need to sample all incoming batches for sterility and fertility, with no exceptions.

Kate Jones, Berkshire

Can the outer wrap be wiped down prior to being brought into an isolator?

Absolutely. The outer bag is impermeable to all normal disinfectants and had been validated for wiping down

Dorte Kepp Hvid, Region Hovedstadens Sygehusapotek

Did you say that you should incubate plates at high (32.5°C) temperature first? And why?

It is recommended to incubate plates used during EM initially for two days at 30–35°C, followed by three days at 20–25°C. The two days at 30–35°C is the target temperature for organisms from the human host, which are thought to be the most significant source of contamination in cleanrooms.

Environmental isolates survive longer at lower temperatures and should be incubated at 20 to 25°C after the higher temperature.

If you missed the opportunity to participate in this informative and interactive webinar, you now have the chance to watch it online here (http://www.hpcimedia.com/Documents/webinars/ThermoFisher3).

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