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Technical Data Sheet

HYCON® Contact Slides TC-Y

Ordering number: 1440220020, 1440220100

HYCON® Contact Slides TC-Y are designed for the determination of the total microbial count on dry, sanitized surfaces as well as personnel in controlled clean room environments of production lines, i.e. grade A and B cleanrooms, RABS or isolators.

Each contact slide is individually sealed in the transparent and flexible primary backing film made from PET and provides a rectangular surface of 25 cm^2. The individually sealed film is double bagged in PP/PA/PA bags and gamma-irradiated at a dose of 16-27 kGy within the polystyrene box. The formulation of the basic medium (Soybean-Casein Digest Agar) complies with the recommendations of the current European, Japanese and United States Pharmacopoeia and is supplemented with neutralizers.

Mode of Action

Tryptic Soy Agar (TSA, Soybean Casein Digest Agar) is a complex medium for cultivation and isolation of a wide range of bacteria, yeasts and molds. The medium is supplemented with the neutralizers lecithin, polysorbate 80 and histidine.

The neutralizing efficiency towards residues of disinfectants in use should be validated at the sampling site.

Typical Composition

Pancreatic digest of casein	15 g/L
Soy bean peptone	5 g/L
NaCl	5 g/L
Agar	15 g/L
Neutralizers: lecithin, polysorbate 80	–
Supplements such as buffer	–

The appearance of the medium is clear and yellowish. The pH value is in the range of 7.1 to 7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

The slides are introduced into cleanrooms grade A or B by removing one bag in each material lock.

Prior to use the contact slides should be equilibrated to room temperature. Please check each contact slide before use to verify sterility and take care on aseptic handling in order to avoid false positive results. Contaminated or dehydrated contact slides should not be used for sampling.

It is recommended to put the cover slide in place before opening the contact slide. For sampling, the sealing of the primary packaging is opened by approximately one third. The backing film filled with agar facing downwards is removed while taking care of aseptic handling and the agar surface is pressed on the dry surface to be tested for some seconds with a steady pressure (see also ISO 14698). Afterwards the backing film is returned into the primary packaging with the agar facing downwards and closed by moving the cover slide to the opening end of the contact slide. Please take care on cleaning the surface which came into contact with the agar medium. The closed contact slides are transferred to an incubator.

Several recommendations are given by different guidelines for incubation: according to USP <1116> the agar media used for environmental monitoring should be incubated between 20 and 35°C for not less than 72 hours. According to the FDA Aseptic Guide the slides for determination of the total aerobic bacterial count should be incubated at 30 to 35°C for 48 to 72 hours, while the slides for determination of the total yeast and mold count should be incubated at 20 to 25°C for 5 to 7 days. Individual incubation conditions can be chosen and should be validated at the application site.

Finally, the number of CFU per slide is examined.

Grown colonies may be identified using suitable methods related to root cause analysis programs or to support sanitizing management.

Important Notes

- Practice aseptic technique when handling contact slides
- The coated surface of the contact slides should face down during incubation in order to avoid the formation of satellites by condensing water

Storage

The product can be used until the expiry date if stored in the original box, protected from light and properly sealed at the temperature range indicated on the box label. The total shelf life from date of production is 6 months.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress. Upon storage contact slides should not be placed near heat sources such as refrigerators with heat-emitting condensers. Boxes should be stored with the coated side of the contact slide facing downwards.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121°C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum	Incubation	Recovery
Staphylococcus aureus	6538	10-100 CFU	24-48h at 30-35°C	50-200%
Escherichia coli	8739	10-100 CFU	24-48h at 30-35°C	50-200%
Pseudomonas aeruginosa	9027	10-100 CFU	24-48h at 30-35°C	50-200%
Bacillus subtilis	6633	10-100 CFU	24-48h at 30-35°C	50-200%
Candida albicans	10231	10-100 CFU	≤ 72h at 20-25°C	50-200%
Aspergillus brasiliensis	16404	10-100 CFU	≤ 72h at 20-25°C	50-200%

Please refer to the actual batch related Certificate of Analysis.

Quality

This product is manufactured in a Millipore SAS facility whose quality management system is approved by an accredited registration body to ISO 9001 quality standard.

This product is manufactured in a Millipore SAS facility whose environmental management is approved by an accredited registration body to the appropriate ISO 14001 systems standard.

Literature

EUROPEAN COMMISSION (2008) Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 1 Manufacture of Sterile Medicinal Products (corrected version).

European Pharmacopoeia 8th Edition (2016): 2.6.12. Microbiological examination of non-sterile products: Microbial Enumeration Tests.

FDA (2004) Guidance for industry: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice.

ISO 14698-1:2003: Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods.

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological Examination of Non-sterile Products: Total viable aerobic count. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

United States Pharmacopoeia 39 NF 34 (2016): <1116> Microbiological Control and Monitoring of Aseptic Processing Environments and <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.

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