Reference: 141114RY **Technical Data Sheet**

Product: **TSA TLHTh Penase**

Specification

General purpose medium for isolation and culture of microorganisms with neutralisers and penase

Presentation

	Packaging Details	Shelf Life	Storage
80 Prepared Plates - Irradiated Contact Plates - Triple Wrapping with: 15 ± 2 ml	1 box with 8 RD-PACK with 10 contact plates/pack; and double wrapping cellophane. Every pack exhibitis an irradiation indicator (8-14 kGy).	4 months	2-14 ºC

Composition

Compostion (g/l):

Peptone from casein	15.00
Soya peptone	5.00
Sodium chloride	5.00
Histidin	1.00
Lecithin	0.70
Polysorbate 80	5.00
Sodium thiosulphate	0.50
Agar	15.00

Penicillinase to inactivate
10.000.000 UI PenG/L/min

Description /Technique

Description:
Soy Tripticase Agar with Penicillinase and Neutralizers (TSA TLHTh Penase) is used in the environmental monitoring of air and surfaces in areas where residues of disinfectants and penicillins or cephalosporins may remain.
This widely used culture medium contains soya and casein peptones in proven proportions to support the growth of most microorganisms, including some very fastidious ones. It has been formulated according to the harmonized method of pharmacopoeias and ISO standards and is regularly used in routine diagnostic work for its reliability in the morphological aspects and reproducibility of the results.
Penicillinase ensures the inactivation of penicillins or cephalosporins that may be present in the air or surfaces to be sampled, while the other neutralizers (TLHTh = Tween® 80 - Lecithin - Histidine - sodium thiosulfate) do so with a variety of disinfectants and conservatives:
• Histidine neutralizes formaldehyde
• Lecithin inactivates chlorhexidine
• Sodium Thiosulphate neutralizes halogenated compounds
• Polysorbate (Tween®) 80 inactivates hexachlorophene and mercury derivatives
• The combination Lecithin + Polysorbate 80 neutralizes quaternary ammonium
• Lecithin-Polysorbate 80-Histidine combination inactivates aldehydes and phenolic compounds.
Note: Contact plates are used for monitoring the microbiological contamination of surface and air inside cleanrooms, isolators, RABS, food industries and hospitals. The double/triple irradiated wrapping ensures that the package itself doesn't contaminate the environment as the first wrapper is removed just before entering the clean area.

Technique:
In the microbiological control of cleaning and disinfection of surfaces in the "clean zones" the contact plates are used as a plug or copy-pad that acts simultaneously as a sampler and culture medium to be incubated, without other intermediate operations. For this, the 65 mm diameter plates are filled so that the medium forms a suitable meniscus to produce a contact surface of approximately 25 cm2.
At the time of use the plates remove the outer shell, remove the cover of the plate and support the culture medium on the surface to be controlled, exerting a gentle pressure for about 10-15 seconds, to ensure good contact between the two surfaces. The plate is removed without rubbing and covered with its cover to avoid contamination. They are labeled appropriately with the sampling data (place, date and time) and are incubated. The inoculated plates are incubated at 30-35 º C for 24-72 h (bacteria) and 3-5 days for fungi (yeast & molds). Examined daily.
When the effectiveness of a cleaning and / or disinfection process is verified, sampling with the contact plates should be done within two hours of the completion of the process, ensuring that the surfaces to be sampled are dry. Positive controls should always be included, sampling the area prior to disinfection or simultaneously monitoring unclean areas adjacent to the disinfected.
The frequency of cleaning / disinfection and subsequent sampling will be established by the responsible technician, depending on the results obtained and the proposed objectives.

Quality control

Physical/Chemical control

Color : Straw-coloured yellow pH: 7.3 ± 0.2 at 25ºC

Microbiological control

Control post addition of Penicillin - According to harmonized pharmacopoeial monographs and test methods

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020.

Aerobiosis. Incubation at 30-35-37 ºC. Read after 18-24 h to 72 h for bacteria and 3-5 days for fungi.

Microorganism	Growth
Escherichia coli ATCC® 8739, WDCM 00012	Good (≥70%)
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good (≥70%)
Bacillus subtilis ATCC® 6633, WDCM 00003	Good (≥70%)
Candida albicans ATCC® 10231, WDCM 00054	Good (≥70%)
Ps. aeruginosa ATCC® 9027, WDCM 00026	Good (≥70%)
Salmonella typhimurium ATCC® 14028, WDCM 00031	Good (≥70%)
Aspergillus brasiliensis ATCC® 16404, WDCM 00053	Good (≥70%)
L. monocytogenes ATCC® 13932, WDCM 00021	Good (≥70%)
Bacillus cereus ATCC® 11778, WDCM 00001	Good (≥70%)
Enterococcus faecalis ATCC® 29212, WDCM 00087	Good (≥70%)
Clostridium perfringens ATCC® 13124, WDCM 00007, NCTC® 8237	Good (≥70%)
Clostridium sporogenes ATCC® 19404, WDCM 00008	Good (≥70%)
Stph. aureus ATCC® 25923, WDCM 00034	Good (≥70%)
Escherichia coli ATCC® 11775, WDCM 00090	Good (≥70%)

Sterility Control

Incubation 48 h at 30-35 ºC and 48 h at 20-25 ºC: NO GROWTH.
Check at 7 days after incubation in same conditions.

Bibliography

· ATLAS, R.M. & L.C. PARKS (1993) Handbook of Microbiological Media. CRC Press, Inc. London.
· COLIPA (1997) Guidelines on Microbial Quality Management (MQM). Brussels.
· DOWNES, F.P. & K. ITO (2001) Compendium of Methods for the Microbiological Examination of Food, 4th ed, ASM, Washington D.C.
· EUROPEAN PHARMACOPOEIA 11.0 (2023) 11th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
· FDA (Food and Drug Adminstrations) (1998) Bacteriological Analytical Manual. 8th ed. Revision A. AOAC International. Gaithersburg. MD.
· HORWITZ, W. (2000) Official Methods of Analysis of AOAC INTERNATIONAL, 17th ed. Gaithersburg, MD. USA.
. ISO 11133:2014/ Adm 1:2018. Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media.
. ISO 4973:2023. Quality control of culture media and diluents used in cosmetics standards.
· ISO 18415 Standard (2017) Cosmetics - Microbiology - Detection of specified and non-specified microorganisms.
· ISO 21149 Standard (2017) Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria.
· ISO 21150 Standard (2015) Cosmetics - Microbiology - Detection of Escherichia coli.
· ISO 22717 Standard (2015) Cosmetics - Microbiology - Detection of Pseudomonas aeuruginosa.
· ISO 22718 Standard (2015) . Cosmetics - Microbiology - Detection of Staphylococcus aureus.
· ISO 22964 (2017) Microbiology of the food chain.- Horizontal method for the detection of *Cronobacter spp*
· PASCUAL ANDERSON, MªRª (1992) Microbiología Alimentaria. Díaz de Santos S.A., Madrid.
· USP 31 - NF 26 (2008) <61> Microbial Limit Tests. US Phamacopoeial Conv. Inc. Rockville. MD. USA
· USP 33 - NF 28 (2011)<62>Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.
· USP 33 - NF 28 (2011) <71> Sterility Tests. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.