TMH 103-SOYA CASEIN DIGEST AGAR (TRYPTONE SOYA AGAR) (CASO AGAR) (as per USP/EP/BP/JP/IP)

INTENDED USE

For the cultivation of various microorganisms from pharmaceuticals products in accordance with harmonized method.

PRODUCT SUMMARY AND EXPLANATION

Soybean Casein Digest Agar is recommended by various pharmacopoeia as sterility testing medium. It is also used in validation of sterility checking procedure in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/IP. This medium is used in microbial limit test and antimicrobial preservative- effective test. Gunn et al used this medium for the growth of fastidious organisms and study of hemolytic reaction after addition of 5% v/v blood.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Pancreatic digest of Casein	15.000
Papaic digest of Soybean	5.000
Sodium chloride	5.000

PRINCIPLE

Combination of Pancreatic digest of Casein and Papaic digest of Soybean makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance. Agar is the solidifying agent.

INSTRUCTION FOR USE

- Dissolve 40.00 grams in 1000 ml distilled water.
- Gently heat to boiling with gentle swirling to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi (121°C) for 15 minutes.
- Cool to 45-50°C.
- Mix well and pour into sterile Petri plates.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	:	Cream to yellow colour, homogeneous free flowing powder
Appearance of prepared medium	:	Light yellow colour, clear to slightly opalescent gel
pH (at 25°C)	:	7.3±0.2

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
Staphylococcus aureus	6538	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Staphylococcus aureus	25923	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Escherichia coli	8739	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Escherichia coli	25923	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours

Pseudomonas aeruginosa	9027	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Pseudomonas aeruginosa	27853	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Bacillus subtilis	6633	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Salmonella typhimurium	14028	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Klebsiella pneumoniae	13883	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Enterococcus faecalis	29212	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
Streptococcus pneumoniae	6305	50-100	Luxuriant	≥ 70%	30-35°C	18-48 hours
Micrococcus luteus	9341	50-100	Luxuriant	≥ 70%	30-35°C	18-48 hours
**Clostridium sporogenes*	19404	50-100	Luxuriant	≥ 70%	30-35°C	18-48 hours
Candida albicans	10231	50-100	Luxuriant	≥ 70%	30-35°C	<=5 days
#Aspergillus brasiliensis	16404	10-100	Good-Luxuriant	50-70%	30-35°C	<=5 days

**Anaerobic incubation*
#Formerly known as Aspergillus niger

PACKAGING:

In 100 & 500 gm packaging size.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers below 25°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

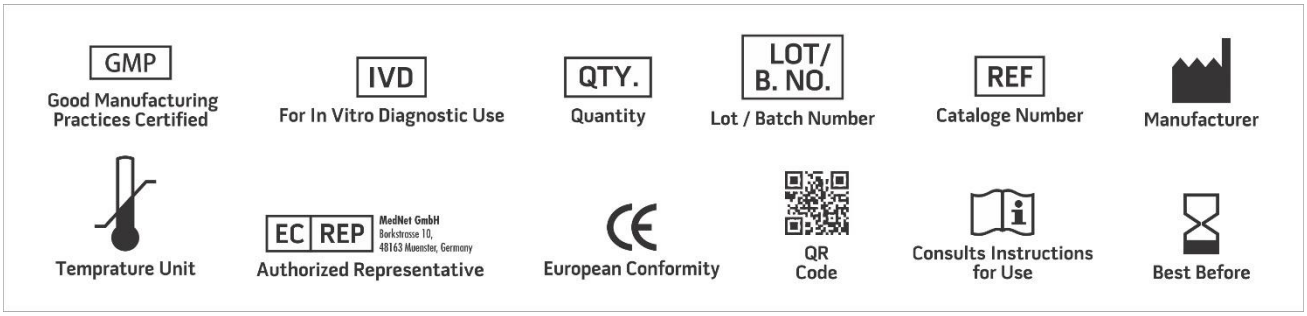
Product Deterioration: Do not use, if powder show evidence of microbial contamination, discoloration, drying, or other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1. British Pharmacopoeia, 2016, The Stationery Office British Pharmacopoeia
2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Japanese Pharmacopoeia, 2016.
4. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.
5. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD



NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For professional use only.**
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