CM 22253 – COMBO STERILITY KIT (USP/EP/JP/IP)

INTENDED USE

Sterilitytest media prepared in accordancewith USP/EP/JP/IP. Each kit consists of 2 glass bottles (100ml) of Fluid Thioglycollate Medium and SoyaCasein Digest Medium. Recommended for all purpose.

PRODUCT SUMMARY ANDEXPLANATION

Combosterilitykit isready to use sterilemediakit containing for sterility Tests in accordance with USP/EP/JP/IP. These are used for validation of the compliance of pharmacopoeial raw materials, finished products and other articles. The Ready Prepared Mediameet the requirements of Growth Promotion Test.

COMPOSITION

Ingredients	Gms / Ltr
FLUID THIOGLYCOLLATE MEDIUM	
Pancreatic digest of casein	15.000
Dextrose	5.500
Yeast extract	5.000
Sodium chloride	2.500
Agar	0.750
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
SOYA CASEIN DIGEST MEDIUM	
Pancreatic digest of casein	17.000
Sodium chloride	5.000
Papaic digest of soybean (soyabean)	3.000
Dipotassium hydrogen phosphate	2.500
Glucose	2.500

PRINCIPLE

Fluid ThioglycollateMedium is used for sterility testing of biological and for cultivation of aerobes, anaerobes and microaerophilic organisms.Soybean Casein Digest Medium is recommended for sterility checking and for studying total aerobic microbialcount in verification of microbiological testing procedures employed for sterility checking. This medium is a highly nutritious medium used for cultivation of a wide variety of organisms.

INSTRUCTION FOR USE

1. Remove the plastic cap.
2. Disinfect the part of the rubber stopper which is now exposed.
3. With the sterile or disposable needle and syringe.
4. Transfer the sample immediately into the culture bottle by puncturing the rubber stopper with the needle and injecting the sample.

5. Venting may be required for aerobic culture and not in case of anaerobic cultures.
6. Incubate at 30-35°C for not more than 3days and at 30-35°C for 18-24 hours for bacteria and 5 days for fungus.

QUALITY CONTROL SPECIFICATIONS

Appearance		
001	:	Light straw coloured solution with upper 10% or less medium pink on standing.
003	:	Light yellow coloured clear solution.
Quantity of Medium	:	100/200/500 ml of the medium in glass bottle
pH (at 25°C)		
	:	7.1± 0.2
Sterility Check	:	7.3± 0.2
	:	Passes release criteria

INTERPRETATION

Culturalcharacteristics observed after Incubation for aerobic and anaerobic bacteria. (*Incubate anaerobically).

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
Fluid Thioglycollate Medium					
Staphylococcus	6538	50-100	Luxuriant	30-35°C	= <3 days
aureus Escherichia	8739	50-100	Luxuriant	30-35°C	= <3 days
coli Bacillus subtilis	6633	50-100	Luxuriant	30-35°C	= <3 days
Pseudomonas aeruginosa	27853	50-100	Luxuriant	30-35°C	= <3 days
**Clostridium sporogenes*	19404	50-100	Luxuriant incubated anaerobically	30-35°C	= <3 days
**Clostridium perfringens*	13124	50-100	Luxuriant incubated anaerobically	30-35°C	= <3 days
Soybean Casein Digest Medium					
Streptococcus pneumoniae	6305	50 -100	Luxuriant	30-35°C	18-24 hours
Pseudomonas aeruginosa	27853	50 -100	Luxuriant	30-35°C	18-24 hours
Bacillus subtilis	6633	50 -100	Luxuriant	30-35°C	18-24 hours
Salmonella Typhimurium	14028	50 -100	Luxuriant	30-35°C	18-24 hours
Escherichia coli	8739	50 -100	Luxuriant	30-35°C	18-24 hours
Escherichia coli	25922	50 -100	Luxuriant	30-35°C	18-24 hours
Staphylococcus aureus	25923	50 -100	Luxuriant	30-35°C	18-24 hours
Candida albicans	10231	50 -100	Luxuriant	30-35°C	5 Days

PACKAGING:

Inpacksizeof100 ml, 200ml and 500 ml glass bottles

STORAGE

On receipt, store bottles in the dark at 10 to 25° C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Bottles from unopened packages can be used up to the expiration date. Opened bottles must be used immediately.
Product Deterioration: Do not use bottles if they show evidence of microbial contamination, discoloration, or any other signs of deterioration.

DISPOSAL

Afteruse,prepared media, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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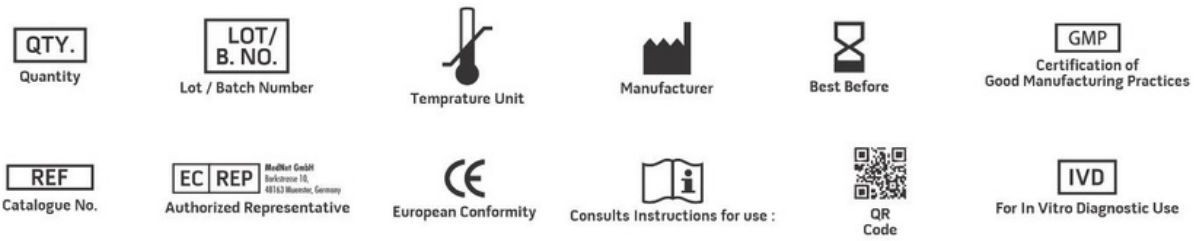

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For LabUse Only**