Technical Data

Sterile Beta Lactamase I Supplement (Ready to use) FD314

Sterile Beta Lactamase I Supplement is a highly purified enzyme based product specifically designed for the inactivation of Penicillins, thus finds its application in beta-lactams (Penicillins) sterility testing (either environmental or antibiotics sterility testing). It can be used for the inactivation of beta-lactams from blood or tissue sample prior to routine microbiological examination.

Composition

Each vial contains 20ml of

***Ingredients**

Penicillinase	Potency[1]: 2000 Levy Units/ml/min Inactivation of Pen G[2] :1,000,000 IU/ml/min

Directions:

Sterile Beta lactamase I Supplement is an optimized ready to use solution that can be directly added to the test sample. The amount of product to be added to the test sample should be determined and set-up depending on the application, concentration of antibiotic to be inactivated and depending on the specific beta-lactam that has to be inactivated. Add appropriate amount of solution depending on the application. Remaining solution can be stored at 2-8ºC. Aseptic techniques are to be followed throughout the procedure.

Note: 1: Levy Unit (LU): amount of Penicillinase that inactivates 593 IU of Sodium Penicillin G per minute at 25ºC and pH 7.0

2: Not all penicillins are comparable to Penicillin G in regards to their inactivation by Penicillinase. Some may require as much as 20 times more Penicillinase than does Penicillin G.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

*** Not For Medicinal Use**

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Date: 2021.03.10 11:57:41 EET
Reason: MoldSign Signature
Location: Moldova

Product Information

GRM159 Tween® 80

Product Number		Packing
GRM159	:	100G
GRM159	:	500G

Product Information

Product Code	:	GRM159
Product Name	:	Tween® 80
Synonym	:	Polyoxyethylenesorbitan monooleate; Polysorbate 80
CAS No.	:	9005-65-6
HS Code	:	3402 13 00
Other Information	:	Key : ® = Tween is a registered trademark of Croda International PLC
Shelf Life	:	4 years

Technical Specification

Appearance	:	Yellow to amber coloured viscous, oily liquid
Solubility	:	1 mL miscible in 1 mL of water
pH (5% in water at 25°C)	:	6.00 - 8.00
FTIR (Liqiud film)	:	Matches with the standard pattern
Hydroxyl value	:	65 - 80
Saponification value	:	45 - 55
Acid value	:	<= 2.0
Iodine value	:	18 - 24
Sulphated ash	:	<= 0.2%
Water (K.F.)	:	<= 3.0%

Risk and Safety Information

WGK	:	1
RTECS	:	WG2932500
Flash Point(°F)	:	>235.4 °F
Flash Point(°C)	:	>113 °C
Storage Temperature(°C)	:	Store below 30°C

Transport Information

Marine Pollutant	:	No
ADR/RID	:	Not Dangerous Goods
IMDG	:	Not Dangerous Goods
IATA	:	Not Dangerous Goods

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Fax:+91-022-6147 1920 Gram : STERILITY . email : info@himedialabs.com. Visit us at our website: www.himedialabs.com

Technical Data

LQ026

Fluid Thioglycollate Medium

Intended use

Recommended as sterility test medium prepared in accordance with USP, EP, BP & JP.

Composition**

Ingredients	Gms / Litre
Tryptone #	15.000
Yeast extract	5.000
Glucose monohydrate	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
Agar	0.750
pH after sterilization (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

- Equivalent to Pancreatic digest of casein

Directions

Label the ready to use LQ026 bottle. Inoculate 50-100 cfu sample and incubate at specified temperature and time.

Principle And Interpretation

Brewer (1) formulated Fluid Thioglycollate Medium for rapid cultivation of aerobes as well as anaerobes including microaerophiles by adding a reducing agent and small amount of agar. The USP (10), BP (2), EP (3) and AOAC (11) have recommended the media for sterility testing of antibiotics, biologicals and foods and for determining the phenol coefficient and sporicidal effect of disinfectants. However, it is intended for the examination of clear liquid or water-soluble materials. Fluid Thioglycollate Medium is also routinely used to check the sterility of stored blood in blood banks (9).

Tryptone, yeast extract, glucose provide carbon, nitrogen compounds, long chain amino acids, vitamin B complex growth factors necessary for bacterial multiplication. L-cystine and sodium thioglycollate allows *Clostridium* to grow in this medium even under aerobic conditions. Also the small amount of agar used in the medium favors the growth of aerobes as well as anaerobes in the medium by maintaining low redox potential for stabilizing the medium (1). Sodium thioglycollate act as a reducing agent and neutralizes the toxic effects of mercurial preservatives and peroxides formed in the medium, thereby promoting anaerobiosis, and making the medium suitable to test materials containing heavy metals (6). Any increase in the oxygen content is indicated by a colour change of redox indicator, resazurin to red (7,8,9).

Type of specimen

Pharmaceutical samples for sterility testing

Specimen Collection and Handling:

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (2,3,10)
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. It is intended for the examination of clear liquid or water-soluble materials.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Sterile clear Fluid Thioglycollate Medium in glass bottle .

Colour
Light straw coloured solution with upper 10% or less medium pink on standing.

Quantity of Medium
100 ml of medium in glass bottle.

pH
6.90- 7.30

Sterility test
Passes release criteria

Stability test
Light yellow coloured clear solution without any precipitation sedimentation at room temperature for 7 days

Growth Promotion Test

In accordance with the harmonized method of USP/EP/BP.

Cultural Response

Cultural characteristics observed after an incubation at 30-35°C for not more than 3 days.

Growth promoting properties
Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <=100 cfu(at 30-35°C for <=3 days.

Organism	Inoculum (CFU)	Growth
Clostridium sporogenes ATCC 19404 (00008*)	50 -100	luxuriant, incubated anaerobically
Clostridium sporogenes ATCC 11437	50 -100	luxuriant, incubated anaerobically
Clostridium sporogenes NBRC 14293	50 -100	luxuriant, incubated anaerobically
Clostridium perfringens ATCC 13124 (00007*)	50 -100	luxuriant, incubated anaerobically
Bacteroides fragilis ATCC 23745	50 -100	luxuriant, incubated anaerobically
Bacteroides vulgatus ATCC 8482	50 -100	luxuriant, incubated anaerobically
Staphylococcus aureus subsp. *aureus ATCC 25923 (00034*)*	50 -100	luxuriant
Staphylococcus aureus subsp. *aureus ATCC 6538 (00032*)*	50 -100	luxuriant

Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 9027 (00026*)	50 -100	luxuriant
Micrococcus luteus ATCC 9341	50 -100	luxuriant
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant
Escherichia coli NCTC 9002	50 -100	luxuriant
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant
Bacillus subtilis subsp. spizizenii ATCC 6633 (00003*)	50 -100	luxuriant

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 15-25°C. Use before expiry date on the label.
Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

1. Brewer, 1940, J. Am. Med. Assoc., 115:598.
2. British Pharmacopoeia, 2016, The Stationery office British Pharmacopoeia
3. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
6. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore.
7. Marshall, Gunnison and Luxen, 1940, Proc. Soc. Exp. Biol. Med., 43:672.
8. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med., 52:287.
9. Portwood, 1944, J. Bact., 48:255.
10. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention, Rockville, MD.
11. Williams H., (Ed.), 2005, Official Methods of Analysis of the Association of Official Analytical Chemists, 19th Ed., AOAC, Washington, D.C

Revision : 00 / 2019

Soyabean Casein Digest Medium

LQ027

Intended use

Recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (Medium 1).

Composition**

Ingredients	Gms / Litre
Tryptone	17.000
Soya peptone	3.000
Sodium chloride	5.000
Glucose monohydrate	2.500
Dipotassium hydrogen phosphate	2.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Equivalent to Pancreatic digest of casein

Equivalent Papaic digest of soyabean meal

Directions

Label the ready to use LQ027 bottle. Inoculate 50-100 cfu sample and Incubate at specified temperature and time.

Principle And Interpretation

Soybean Casein Digest Medium is recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (7,2,1,5,3). It is used for the sensitivity testing of antimicrobial agents by the tube dilution method (8). It is also employed in diagnostic research in microbiology. This medium is used as a diluent and suspending medium for preparation of samples or test strains. It is also employed in sample preparation for testing of products, wherein incubation is carried out, only to serve sufficient resuscitation of the cell, while avoiding multiplication of the organism. The combination of tryptone and soya peptone makes this medium nutritious by providing nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other minerals for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable source of carbon and dipotassium hydrogen phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

This medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (7,2,1,5,3). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protectivegloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.
2. This medium is general purpose medium and may not support the growth of fastidious organisms.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Sterile Soyabean Casein Digest Medium in glass bottle.

Colour
Light yellow coloured clear solution

Quantity of Medium
100 ml of medium in glass bottle.

pH
7.10- 7.50

Sterility Test
Passes release criteria.

Growth Promotion Test
In accordance with the harmonized method of USP/EP/BP/JP/IP.

Growth promoting properties
Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <=100 cfu(at 30-35°C for 18-24 hours for bacteria and 5 days for fungal). Growth promotion is carried out as per USP/EP/BP/JP.

Organism	Inoculum (CFU)	Growth	Incubation period	Incubation temperature
Growth promoting				
Salmonella Abony NCTC 6017 (00029)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli NCTC 9002	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 27853 (00025)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Bacillus subtilis subsp. spizizenii ATCC 6633 (00003)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Micrococcus luteus ATCC 9341	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Salmonella Typhimurium ATCC 14028 (00031)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 8739 (00012)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 25922 (00013)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 9027 (00026)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. aureus ATCC 6538 (00032)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. aureus ATCC 25923 (00034)*	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Candida albicans ATCC 10231 (00054)*	50 -100	luxuriant	<=3 d	30 -35 °C

Sterility Testing- Growth promotion+Validation

Candida albicans ATCC 2091 (00055)*	50 -100	luxuriant	<=5 d	20 -25 °C
Salmonella Abony NCTC 6017 (00029)*	50 -100	luxuriant	<=3 d	20 -25 °C
Candida albicans ATCC 10231 (00054)*	50 -100	luxuriant	<=5 d	20 -25 °C
#Aspergillus brasiliensis ATCC 16404 (00053)*	50 -100	luxuriant	<=5 d	20 -25 °C
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli NCTC 9002	50 -100	luxuriant	<=3 d	20 -25 °C
Pseudomonas aeruginosa ATCC 27853 (00025)*	50 -100	luxuriant	<=3 d	20 -25 °C
Micrococcus luteus ATCC 9341	50 -100	luxuriant	<=3 d	20 -25 °C
Salmonella Typhimurium ATCC 14028 (00031)*	50 -100	luxuriant	<=3 d	20 -25 °C
Staphylococcus aureus subsp. aureus ATCC 6538 (00032)*	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli ATCC 8739 (00012)*	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli ATCC 25922 (00013)*	50 -100	luxuriant	<=3 d	20 -25 °C
Pseudomonas aeruginosa ATCC 9027 (00026)*	50 -100	luxuriant	<=3 d	20 -25 °C
Bacillus subtilis subsp. spizizenii ATCC 6633 (00003)*	50 -100	luxuriant	<=3 d	20 -25 °C
Staphylococcus aureus subsp. aureus ATCC 25923 (00034)*	50 -100	luxuriant	<=3 d	20 -25 °C

Key : (#) Formerly known as *Aspergillus niger*, (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 15-25°C. Use before expiry date on the label.
Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,6).

Reference

1. British Pharmacopoeia, 2016, The Stationery office British Pharmacopoeia
2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
5. Japanese Pharmacopoeia, 2016.
6. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
7. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD.
8. Wright and Welch, 1959-60, Antibiotics Ann., 61.

Revision : 02 / 2019

Technical Data

Diluting Fluid K

LQ122L

Diluent in testing of pharmaceuticals in accordance with USP.

Composition**

Ingredients	Gms / Litre
Peptic digest of animal tissue	5.000
Beef extract	3.000
Polysorbate 80	10.000

**Formula adjusted, standardized to suit performance parameters

Principle And Interpretation

Diluting Fluid K is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP (1). After filtering the specified quantity of the test specimen the membrane is rinsed with measured portions of rinsing or diluting fluid.
This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen.

Quality Control

Appearance
Sterile clear Diluting Fluid K in bottle.

Colour
Light yellow coloured medium

Quantity of medium

300 ml of medium in bottle

pH
6.70- 7.10

Sterility test
Passes release criteria.

Growth Promotion Test
In accordance with the harmonized method of USP.

Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours

Organism	Inoculum (CFU)	Growth
Escherichia coli ATCC 25922	50-100	good
Staphylococcus aureus ATCC 25923	50-100	good
Staphylococcus aureus ATCC 6538	50-100	good
Candida albicans ATCC 10231	50-100	good

Storage and Shelf Life

Store between 2-8°C. Use before expiry date on the label.

Reference

1. The United States Pharmacopoeia / National Formulary, USP31 / NF26, 2008, Asian Edition, US Pharmacopeial convention Inc., Rockville, MD.

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Technical Data

Diluting Fluid D

LQ510L

Diluent in testing of pharmaceuticals in accordance with USP.

Composition**

Ingredients	Gms / Litre
Peptic digest of animal tissue	1.000
Polysorbate 80	1.000
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Diluting fluid is used as the diluting or rinsing solution for membrane filter techniques in pharmaceutical products. Measured portions of Diluting fluid D should be used to rinse the membrane after filtration. Inoculate this rinse with 50-100 cfu of test organisms. Simultaneously run a positive control of the same medium. Incubate both the set of medium at the specified time and temperature. Compare the growth obtained for the rinse with that obtained in the positive control after incubation.

Principle And Interpretation

Diluting Fluid D is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP (1). After filtering the specified quantity of the test specimen, the membrane is rinsed with measured portions of rinsing or diluting fluid.
This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen. This medium is recommended for articles containing lecithin or oil or for devices labeled as ‘sterile pathway”(1)

Quality Control

Appearance
Sterile clear Diluting Fluid D in bottle.

Colour
Light amber coloured medium

Quantity of medium
300ml of medium in bottle

pH
6.90- 7.30

Growth Promotion Test
In accordance with the harmonized method of USP.

Sterility test
Passes release criteria.

Cultural Response
LQ510L: Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth
Cultural response		
Candida albicans ATCC 10231	50-100	good
Escherichia coli ATCC 25922	50-100	good
Escherichia coli ATCC 8739	50-100	good
Staphylococcus aureus ATCC 25923	50-100	good
Staphylococcus aureus ATCC 6538	50-100	good

Storage and Shelf Life

Store between 2-8°C. Use before expiry date on the label.

Reference

1. The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, The US Pharmacopeial convention Inc., Rockville, MD.

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