Condalab

Inspired by knowledge

MICROBIOLOGICAL ANALYSIS IN THE PHARMACEUTICAL INDUSTRY

PROCEDURE ACCORDING TO THE EUROPEAN PHARMACOPOEIA

Edition No. 2

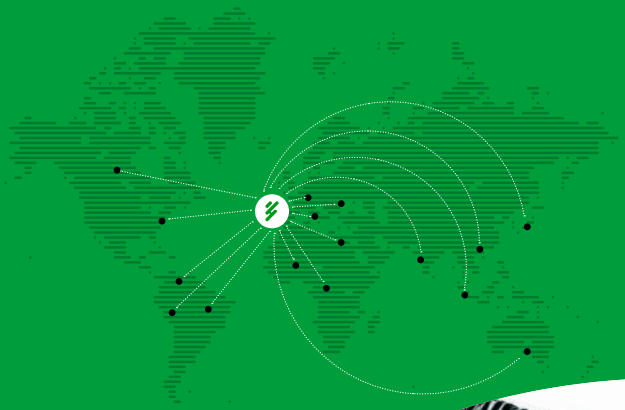
Index

Who are we?

European leaders in the manufacture of culture media.

Founded in 1960, we are one of the leading manufacturers of dehydrated culture media for microbiology and molecular biology in Europe and we have positioned ourselves as a leading private company in the international market.

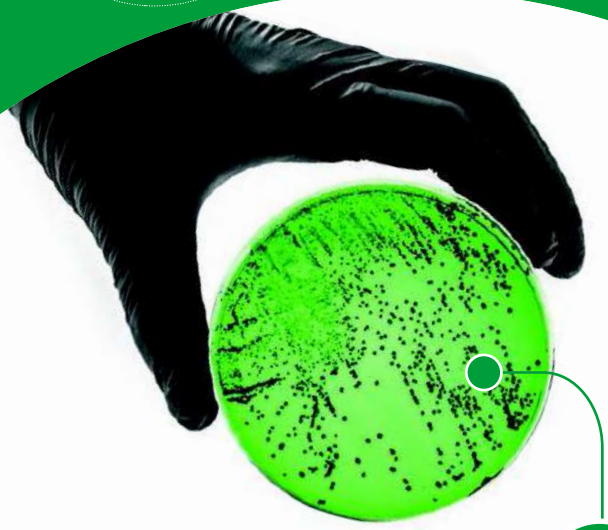
From our factory located in Madrid, Spain, we export to more than 130 countries worldwide directly or through an extensive network of authorised distributors.
The key to success is our distribution channel together with a professional team and the wide range of products we offer.



Experts.
Mastery of culture media.

Flexible and reliable.
Tailored to the needs of our customers.

Innovators.
Inspiring the future.



What do we do?

We develop, manufacture and distribute high-quality culture media for microbiology and molecular biology.

The experience gained in the design and manufacture of culture media has made us specialists. We develop, produce and distribute culture media of the highest quality for microbiology and molecular biology with the design of more than 700 dehydrated media. Condalab is also known for providing key ingredients such as agar, peptones and agarose among others. Our catalogue also includes media for molecular biology.

Microbiology.
Dehydrated culture media
Prepared culture media
Supplements
Microbial sensitivity tests
Condagene®
Dyes

Molecular biology.
Dehydrated culture media
Agaroses
Dyes for molecular biology

Bio-ingredients.
Agars
Peptones
Carbohydrates

Who do we do it for?

We have an extensive network of clients as a result of active listening and the search for optimal solutions for them.

Condalab products target the following market niches:

Quality control.

Food and beverage industry, breweries, pharmaceutical industry and cosmetic industry.

Clinical analysis.

Hospitals, veterinary clinics, clinical and food control laboratories.

Production processes.

Fermentation processes, vaccines, probiotics and manufacturers of culture media.

R+D.

Laboratories, research centres and universities.

How do we do it?

We bet on quality.

We continue to improve and increase our production to achieve the highest quality standards. We possess ISO 9001:2015, ISO 13485:2018 and the CE standard for Invitro medical devices.

Our formulations meet the international standards of European Pharmacopoeia, FDA, APHA, USP and AOAC. We follow strict controls throughout production before, during and after each manufacturing process to ensure quality and consistency from batch to batch.

THE IMPORTANCE OF REGULATION IN THE PHARMACEUTICAL INDUSTRY

Drugs must pass through a strict control and regulation process by different agencies

European Agency for Medicines

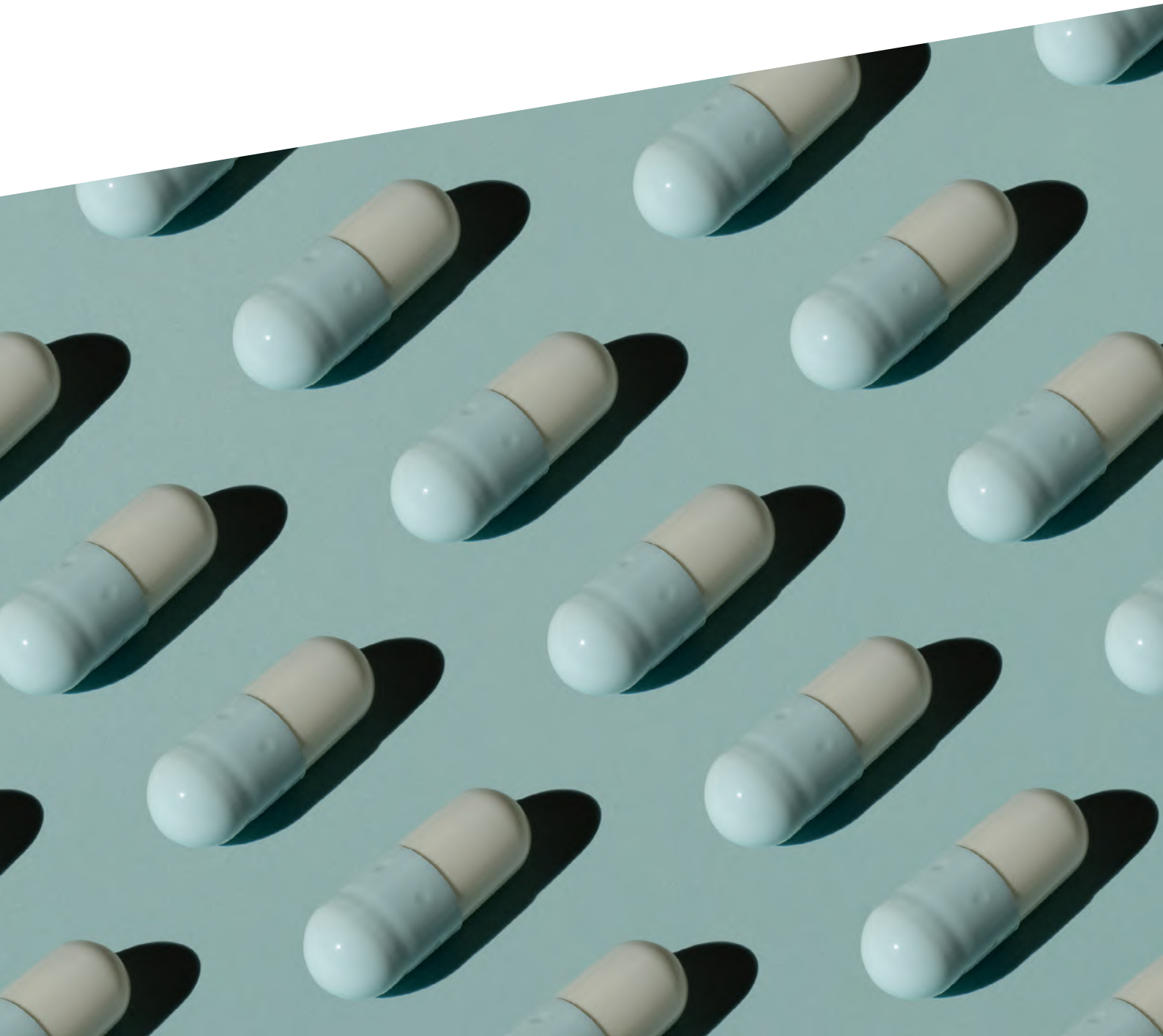
Pharmacopoeia

National regulatory bodies

WITHIN DRUGS, WE CAN DISTINGUISH TWO LARGE TYPES ACCORDING TO THEIR MICROBIAL QUALITY

Sterile

Non-sterile



The pharmaceutical industry is one of the most influential business sectors in the world, comprised of public and private organisations dedicated exclusively to the research, manufacture, marketing and distribution of pharmaceutical chemicals intended for human and animal health.

The regulation of the analysis and control of medicines in this sector is of vital importance both in the development of new drugs and in the control of existing ones, in order to guarantee the quality, efficacy and safety thereof.

The European Pharmacopoeia is the official legal instrument in the EU established to guarantee the quality of this type of product. It includes quality guides for active ingredients and general indications for formulating and manufacturing medicines.
It consists of Committees of Experts from the countries concerned, and other countries participate as observers alongside WHO.

This regulation includes, among others, **the microbial analysis of pharmaceuticals,** raw materials used, water for manufacture, air, equipment or packaging material, vital to minimise the type and number of micro-organisms present, and depending on their application and microbial quality requirement, products may be sterile or non-sterile.
A drug is considered contaminated when it exceeds a limit of micro-organisms

which are pathogenic, opportunistic or objectionable. The latter being understood as those that have the ability to limit the efficacy of the product when they present toxic metabolites or physical or chemical deterioration. The infective dose varies between species and even between individuals.

HOW TO READ A

WORKFLOW

Title

Test

DETECTION OF GRAM-NEGATIVE BILE TOLERANT BACTERIA

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Chapter and edition Ph. Eur.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, prepare a dilution 1:10 in TSB broth*.

More information in chapter 2.6.12. and 2.6.13. from the Ph. Eur.

20°C – 25°C | 2 h – 5 h

*This solution can be supplemented with neutralisers and surfactants.

Culture media and proportions

Enrichment.

A. ABSENCE TEST

Inoculate, unless otherwise indicated, the volume corresponding to 1 g of the product in EE Mossel broth.

B. QUANTITATIVE TESTING

Inoculate 0.1g/ml, 0.01g/ml and 0.001g/ml respectively of the product in EE Mossel broth

Different testing options

30°C – 35°C | 24 h – 48 h

Presumptive isolation.

Cultivate in Agar VRBG.

30°C – 35°C | 18 h – 24 h

Incubation conditions

Interpretation of results.

A. ABSENCE TEST

The product satisfies the test if no colony growth is observed.

B. QUANTITATIVE TESTING

The growth of colonies is a positive result.

Write down the smallest amount of the product that gives a positive result and the largest amount that gives a negative result.

Determine the NMP with Table 2.6.13.2 from the Ph Eur.

Results

Microbiological water control

Preparation of the sample.

Determination by filtration membrane with a pore size not exceeding 0.45 µm.

Presumptive isolation.

A. ABSENCE TEST	**B. QUANTITATIVE TEST**
10 CFU/100 ml	100 CFU/ml
PURIFIED WATER	**WATER FOR EXTRACTS**
10 CFU/100 ml	100 CFU/ml
R2A Agar	Agar TSA

30°C – 35°C | 5 days

Interpretation of results.

It complies, if the number of CFU/ml is less than the established microbiological limit.

Sterility analysis

Test to promote the growth of aerobes, anaerobes and fungi.

Preparation of the sample.

The appropriate strains of each micro-organism are indicated in Table 2.6.1.-1. from Ph. Eur.

Presumptive isolation.

AEROBIC BACTERIA

(Staphylococcus aureus, Pseudomonas aeruginosa)

ANAEROBIC BACTERIA

(Clostridium sporogenes)

Inoculate each of the micro-organisms separately with <100 CFU in Liquid Medium Thioglycholate.

30°C – 35°C | max. 3 days

AEROBIC BACTERIA

(Bacillus subtilis)

ANAEROBIC BACTERIA

(Candida albicans, Aspergillus brasiliensis)

Inoculate each of the micro-organisms separately with <100 CFU in TSB Broth.

20°C – 25°C | max. 5 days

Interpretation of results.

The culture medium is suitable if visible growth of micro-organisms is observed.

Aptitude test of the method.

It employs exactly the same procedure used in the sterility test of the product to be examined, except for the following modifications:

MEMBRANE FILTRATION METHOD

After filtering the product to be examined, inoculate the final amount of sterile diluent used to rinse the filter with <100 CFU viable micro-organisms.

DIRECT TRANSFER METHOD

After transferring the product to be examined to the culture medium, inoculate it with <100 CFU of viable micro-organisms.

20°C - 35°C* | max. 5 days

*Depending on the growing medium and product, in exceptional cases it can increase up to 44°C.

Use the same micro-organisms described in the growth promotion test of aerobic, anaerobic, fungi and yeasts.

Perform a growth promotion test as a positive control.

If clearly visible growth is not obtained, visually comparable to the control without the product, the product has antimicrobial activity; modify the conditions to eliminate antimicrobial activity and repeat the test.

Sterility test of the product to be examined.

Preparation of the sample.

Select the suitable method and sample quantity (Table 2.6.1.-2. Ph. Eur.) depending on the nature of the product.

MEMBRANE FILTRATION METHOD

- Aqueous solutions
- Soluble solids
- Oils and oily solutions
- Creams and ointments

DIRECT TRANSFER METHOD

- Oily liquids
- Creams and ointments
- Suture thread and other related products for veterinary use

Presumptive isolation.

Inoculate in Liquid Medium Thioglycholate or TSB Broth.

20°C – 35°C | 14 days *Depending on the growing medium and product, in exceptional cases it can increase up to 44°C.

Observe during the incubation time and once it has finished, if the medium becomes so cloudy that it does not allow the reading of the presence/absence of microbial growth, transfer at least 1 ml to a new medium and incubate for at least 4 days.

Interpretation of results.

If there is no evidence of microbial growth, the product complies with the sterility test.

Analysis of non-sterile products

Analysis of non-sterile products

MICROBIOLOGICAL (TAMC & TYMC) COUNT

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: MICROBIAL COUNT TESTS
EUR.PH. 11.5
2.6.12.
1. FILTRATION BY MEMBRANE

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. from Ph. Eur.

Transfer to the membrane an appropriate amount representing 1 g of the product or less if a high number of CFU is expected and wash with the appropriate diluent.

Presumptive isolation.

TOTAL AEROBIC MICRO-ORGANISMS

Transfer the membrane to TSA Agar.

30°C - 35°C | ≤ 3 ≤ 5 days*

TOTAL MOLDS AND YEASTS

Transfer the membrane to Sabouraud Dextrose Agar (SDA).

20°C - 25°C | ≤ 5 days

*The incubation time varies depending on the micro-organism

Interpretation of results.

Perform the colony count.

A) Method of discharging in plate.

Perform each method in duplicate.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

More information is available in chapter 2.6.12. from Ph. Eur.

Transfer 1 ml to 90 mm petri dishes or adjust the amount depending on the size of the dish.

*This solution can be supplemented with neutralisers and surfactants.

Presumptive isolation.

TOTAL AEROBIC MICRO-ORGANISMS

Incubate in TSA Agar,
at least 2 plates per micro-organism

30°C - 35°C | ≤ 3 ≤ 5 days*

TOTAL MOULDS AND YEASTS

Incubate in SDA Agar,
at least 2 plates per micro-organism

20°C - 25°C | ≤ 5 days

*The incubation time varies depending on the micro-organism

Interpretation of results.

Take the average of the counts by medium and calculate the number of CFU.

B) Surface method.

Perform each method in duplicate.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

More information in Chapter 2.6.12 from Ph. Eur.

Of each culture medium, transfer at least 0.1 ml to plates.

*This solution can be supplemented with neutralisers and surfactants.

Presumptive isolation.

TOTAL AEROBIC MICRO-ORGANISMS

Incubate in TSA Agar,
at least 2 plates per micro-organism.

30°C - 35°C | ≤ 3 ≤ 5 days*

TOTAL MOULDS AND YEASTS

Incubate in SDA Agar,
at least 2 plates per micro-organism.

20°C - 25°C | ≤ 5 days

*The incubation time varies depending on the micro-organism

Interpretation of results.

Take the average of the counts by medium and calculate the number of CFU.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. from Ph. Eur.

Prepare a series of at least 3 serial decimal dilutions of the product.

Presumptive isolation.

From dilutions, prepare three aliquots of 1 g/ml to inoculate 3 tubes with 9-10 ml of TSB broth*

30°C - 35°C | < 3 days

*This medium can be supplemented with neutralisers and surfactants.

If the reading of results is not possible or of doubtful reliability due to the nature of the product examined, prepare a co-culture in the same medium or in TSA Agar.

30°C - 35°C | 1 - 2 days

Interpretation of results.

Determine the MLN of micro-organisms per g/ml of product with Table 2.6.12.-3.

DETECTION OF GRAM-NEGATIVE BILE TOLERANT BACTERIA

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, prepare a dilution 1:10 in TSB broth*

*This solution can be supplemented with neutralisers and surfactants

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

20°C - 25°C | 2 h - 5 h

Enrichment.

A. ABSENCE TEST

Inoculate, unless otherwise indicated, the volume corresponding to 1g of the product in EE Mossel broth.

B. QUANTITATIVE TEST

Inoculate 0.1g/ml, 0.01g/ml and 0.001g/ml respectively of the product in EE Mossel broth

30°C - 35°C | 24 h - 48 h

Presumptive isolation.

Cultivate in VRBG Agar.

30°C - 35°C | 18 h - 24 h

Interpretation of results.

A. ABSENCE TEST

The product satisfies the test, if no colony growth is observed.

B. QUANTITATIVE TEST

The growth of colonies is a positive result.

Write down the smallest amount of the product that gives a positive result and the largest amount that gives a negative result.

Determine the NMP with Table 2.6.13.2 from Eur. el MLN.

DETECTION OF *ESCHERICHIA COLI*

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

Add 10 ml of the solution or the amount corresponding to 1 g/ml of the product into a suitable volume of TSB broth.

30°C - 35°C | 18 - 24 h

Enrichment.

Transfer 1 ml of TSB broth in 100 ml of MacConkey broth.

42°C - 44°C | 24 - 48 h

Presumptive isolation.

Cultivate in MacConkey Agar.

30°C - 35°C | 18 - 72 h

Interpretation of results.

The growth of colonies indicates the possible presence of E. coli, to make the confirmation by identification test. The product satisfies the test if no colonies are observed or if the identification tests are negative.

DETECTION OF *SALMONELLA*

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS EUR.PH. 11.5 2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

Inoculate the amount corresponding to 10 g/ml of the product in an appropriate volume of TSB broth.

30°C - 35°C | 18 h - 24 h

Enrichment.

Transfer 0.1 ml of TSB broth to 10 ml of Rappaport Vassiliadis broth.

30°C - 35°C | 18 h - 24 h

Presumptive isolation.

Cultivate in XLD Agar.

30°C - 35°C | 18 h - 48 h

Interpretation of results.

All red colonies with/without black core are susceptible to *Salmonella*.

Confirmation by identification tests.

The product satisfies the test if no colonies of the types described are observed or if the confirmation tests are negative.

DETECTION OF *PSEUDOMONAS AERUGINOSA*

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

Pre-enrichment.

Inoculate 10 ml or the amount corresponding to 1 g/ml of the product in an appropriate volume of TSB broth.

30°C - 35°C | 18 h - 24 h

Presumptive isolation.

Cultivate in Cetrimide Agar.

30°C - 35°C | 18 h - 72 h

Interpretation of results.

The growth of colonies (opaque white) in the medium indicates the possible presence of *Pseudomonas aeruginosa*.

Confirmation by identification tests.

The product satisfies the test if there are no colonies present in the medium or if the confirmation tests are negative.

DETECTION OF *STAPHYLOCOCCUS AUREUS*

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, prepare a dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

Enrichment.

Inoculate 10 ml or the amount corresponding to 1 g/ml of the product in an appropriate volume of TSB broth.

30°C - 35°C | 18 h - 24 h

Presumptive isolation.

Cultivate in MSA Agar (Chapman Medium).

30°C - 35°C | 18 h - 72 h

Interpretation of results.

The growth of yellow/white colonies surrounded by a yellow zone indicates the possible presence of *Staphyloccocus aureus*.

Confirmation by identification tests.

The product satisfies the test if no colonies of the types described are observed or if the confirmation tests are negative.

DETECTION OF *CLOSTRIDIA*

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, prepare a dilution 1:10 (minimum total volume of 20 ml) using at least 2 g/ml of the product in buffered PEPTONADA water, TSB broth or other thinners*

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

HEAT TREATMENT

Divide the sample into 2 portions with at least 10 ml each.

1ST PORTION

Heat for the indicated time and cool quickly.

80°C | 10 minutes

+

2ND PORTION

Do not heat.

Enrichment.

Transfer 10 ml or the amount corresponding to 1 g/ml of the product from each portion to Reinforced *Clostridial* Medium.

30°C - 35°C | 48 h*

*Anaerobic conditions

Presumptive isolation.

Grow in Columbia Agar under anaerobic conditions.

30°C - 35°C | 48 h - 72 h

Interpretation of results.

The growth of colonies (with/without spores) give a negative reaction to catalase indicating the presence of *Clostridia*.

Confirmation by identification tests.

The product satisfies the test if no colonies of the types described are observed or if the confirmation tests are negative.

DETECTION OF *CANDIDA ALBICANS*

MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: TESTS FOR SPECIFIED MICRO-ORGANISMS
EUR.PH. 11.5
2.6.13.

Preparation of the sample.

The method of sample preparation depends on the physical characteristics of the product, usually dilution 1:10 in buffered PEPTONADA water, TSB broth or other thinners*.

*This solution can be supplemented with neutralisers and surfactants.

More information is available in chapter 2.6.12. and 2.6.13. From Ph. Eur.

Enrichment.

Transfer 10 ml of the suspension or 1 g/ml of the product into 100 ml of Sabouraud dextrose broth.

30°C - 35°C | 3 - 5 days

Presumptive isolation.

Cultivate in Dextrose Sabouraud Agar.

30°C - 35°C | 24 h - 48 h

Interpretation of results.

The growth of white colonies indicates the possible presence of *Candida albicans*.

Confirmation by identification tests.

The product satisfies the test if no colonies of the types described are observed or if the confirmation tests are negative.

Product list

Microbiological water control

Water for Injectables & Purified Water

CAT	PRODUCT	FORMAT
1071	Agar R2A	500 g
993	Agar R2A	20 dishes
792	LC Agar R2A. Irradiado	20 dishes
4711	Agar R2A	30 dishes

Stored Purified Water & Water for Extracts

CAT	PRODUCT	FORMAT
1068	Agar Soja y Tripticaseína (TSA)	500 g
904	Agar Soja y Tripticaseína (TSA)	20 dishes
804	LC Agar Soja y Tripticaseína (TSA). Doble Bolsa. Irradiado	20 dishes
810	LC Agar Soja y Tripticaseína (TSA). Triple Bolsa. Irradiado	20 dishes
4003	Agar Soja y Tripticaseína (TSA)	20 tubes
5000	Agar Soja y Tripticaseína (TSA)	10 x 100 ml
5157	Agar Soja y Tripticaseína (TSA)	10 x 200 ml

Sterility analysis

Aerobic & anaerobic bacteria

CAT	PRODUCT	FORMAT
1508	Medio Líquido Tioglicolato	500 g
4004	Medio Líquido Tioglicolato	20 tubes
5128	Medio Líquido Tioglicolato	10 x 100 ml
5183	Medio Líquido Tioglicolato	10 x 200 ml
4662	Medio Líquido Tioglicolato	10 x 300 ml
4663	Medio Líquido Tioglicolato	10 x 450 ml

Aerobic Bacteria and Fungi

CAT	PRODUCT	FORMAT
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Analysis of non-sterile products

Microbiological Count (TAMC & TYMC)

CAT	PRODUCT	FORMAT
1024	Agar Dextrosa Sabouraud	500 g
907	Agar Dextrosa Sabouraud	20 dishes
803	LC Agar Dextrosa Sabouraud. Doble Bolsa. Irradiado	20 dishes
807	LC Agar Dextrosa Sabouraud. Triple Bolsa. Irradiado	20 dishes
4214	Agar Dextrosa Sabouraud	20 tubes
5107	Agar Dextrosa Sabouraud	10 x 100 ml
5143	Agar Dextrosa Sabouraud	10 x 200 ml
1068	Agar Soja y Tripticaseína (TSA)	500 g
904	Agar Soja y Tripticaseína (TSA)	20 dishes
804	LC Agar Soja y Tripticaseína (TSA). Doble Bolsa. Irradiado	20 dishes
810	LC Agar Soja y Tripticaseína (TSA). Triple Bolsa. Irradiado	20 dishes
4003	Agar Soja y Tripticaseína (TSA)	20 tubes
5000	Agar Soja y Tripticaseína (TSA)	10 x 100 ml
5157	Agar Soja y Tripticaseína (TSA)	10 x 200 ml
1401	Agua Peptonada Tamponada	500 g
4035	Agua Peptonada Tamponada	20 tubes
4037	Agua Peptonada Tamponada	20 tubes
4638	Agua Peptonada Tamponada	10 x 90 ml
5180	Agua Peptonada Tamponada	10 x 100 ml
5154	Agua Peptonada Tamponada	10 x 200 ml
4699	Agua Peptonada Tamponada	10 x 225 ml
5170	Agua Peptonada Tamponada	10 x 450 ml
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Gram-negative bile tolerant bacteria

CAT	PRODUCT	FORMAT
1092	Agar Bilis y Rojo Violeta con Glucosa (VRBG)	500 g
911	Agar Bilis y Rojo Violeta con Glucosa (VRBG)	20 dishes
793	LC Agar Bilis y Rojo Violeta con Glucosa (VRBG)	20 dishes
5158	Agar Bilis y Rojo Violeta con Glucosa (VRBG)	10 x 100 ml
4670	Agar Bilis y Rojo Violeta con Glucosa (VRBG)	10 x 200 ml
1202	Caldo EE Mossel	500 g
4043	Caldo EE Mossel	20 tubes
5168	Caldo EE Mossel	10 x 100 ml
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes

CAT	PRODUCT	FORMAT
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Escherichia coli

CAT	PRODUCT	FORMAT
1052	Agar Macconkey	500 g
900	Agar Macconkey	20 dishes
790	LC Agar Macconkey	20 dishes
5003	Agar MacConkey	10 x 100 ml
1401	Agua Peptonada Tamponada	500 g
4035	Agua Peptonada Tamponada	20 tubes
4037	Agua Peptonada Tamponada	20 tubes
4638	Agua Peptonada Tamponada	10 x 90 ml
5180	Agua Peptonada Tamponada	10 x 100 ml
5154	Agua Peptonada Tamponada	10 x 200 ml
4699	Agua Peptonada Tamponada	10 x 225 ml
5170	Agua Peptonada Tamponada	10 x 450 ml
1210	Caldo MacConkey	500 g
4047	Caldo MacConkey	20 tubes
5146	Caldo Macconkey	10 x 100 ml
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Salmonella

CAT	PRODUCT	FORMAT
1080	Agar XLD (Agar Xilosa Lisina Desoxicolato)	500 g
930	Agar XLD (Agar Xilosa Lisina Desoxicolato)	20 dishes
794	LC Agar XLD (Agar Xilosa Lisina Desoxicolato)	20 dishes
1414	Caldo Rappaport Vassiliadis	500 g
4016	Caldo Rappaport Vassiliadis	20 tubes
5187	Caldo Rappaport Vassiliadis	10 x 90 ml
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml

CAT	PRODUCT	FORMAT
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Pseudomonas aeruginosa

CAT	PRODUCT	FORMAT
1102	Base de Agar Cetrimida	500 g
916	Agar Cetrimida	20 dishes
791	LC Agar Cetrimida. Irradiado	20 dishes
5122	Agar Cetrimida	10 x 100 ml
1401	Agua Peptonada Tamponada	500 g
4035	Agua Peptonada Tamponada	20 tubes
4037	Agua Peptonada Tamponada	20 tubes
4638	Agua Peptonada Tamponada	10 x 90 ml
5180	Agua Peptonada Tamponada	10 x 100 ml
5154	Agua Peptonada Tamponada	10 x 200 ml
4699	Agua Peptonada Tamponada	10 x 225 ml
5170	Agua Peptonada Tamponada	10 x 450 ml
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Staphylococcus aureus

CAT	PRODUCT	FORMAT
1062	Agar Sal y Manitol (MSA) (Medio Chapman)	500 g
917	Agar Sal y Manitol (MSA) (Medio Chapman)	20 dishes
789	LC Agar Sal y Manitol (MSA) (Medio Chapman)	20 dishes
5104	Agar Sal y Manitol (MSA) (Medio Chapman)	10 x 100 ml
1401	Agua Peptonada Tamponada	500 g
4035	Agua Peptonada Tamponada	20 tubes
4037	Agua Peptonada Tamponada	20 tubes
4638	Agua Peptonada Tamponada	10 x 90 ml
5180	Agua Peptonada Tamponada	10 x 100 ml
5154	Agua Peptonada Tamponada	10 x 200 ml
4699	Agua Peptonada Tamponada	10 x 225 ml
5170	Agua Peptonada Tamponada	10 x 450 ml

CAT	PRODUCT	FORMAT
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Clostridia

CAT	PRODUCT	FORMAT
1401	Agua Peptonada Tamponada	500 g
4035	Agua Peptonada Tamponada	20 tubes
4037	Agua Peptonada Tamponada	20 tubes
4638	Agua Peptonada Tamponada	10 x 90 ml
5180	Agua Peptonada Tamponada	10 x 100 ml
5154	Agua Peptonada Tamponada	10 x 200 ml
4699	Agua Peptonada Tamponada	10 x 225 ml
5170	Agua Peptonada Tamponada	10 x 450 ml
1104	Base de Agar Columbia	500 g
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L
1007	Medio Reforzado para Clostridium	500 g

Candida albicans

CAT	PRODUCT	FORMAT
1024	Agar Dextrosa Sabouraud	500 g
907	Agar Dextrosa Sabouraud	20 dishes
803	LC Agar Dextrosa Sabouraud. Doble Bolsa. Irradiado	20 dishes
807	LC Agar Dextrosa Sabouraud. Triple Bolsa. Irradiado	20 dishes
4214	Agar Dextrosa Sabouraud	20 tubes
5107	Agar Dextrosa Sabouraud	10 x 100 ml
5143	Agar Dextrosa Sabouraud	10 x 200 ml
1401	Agua Peptonada Tamponada	500 g
4035	Agua Peptonada Tamponada	20 tubes
4037	Agua Peptonada Tamponada	20 tubes

CAT	PRODUCT	FORMAT
4638	Agua Peptonada Tamponada	10 x 90 ml
5180	Agua Peptonada Tamponada	10 x 100 ml
5154	Agua Peptonada Tamponada	10 x 200 ml
4699	Agua Peptonada Tamponada	10 x 225 ml
5170	Agua Peptonada Tamponada	10 x 450 ml
1205	Caldo Dextrosa Sabouraud	500 g
4115	Caldo Dextrosa Sabouraud	20 tubes
4656	Caldo Dextrosa Sabouraud	10 x 100 ml
1224	Caldo Soja Tripticaseína (TSB)	500 g
4019	Caldo Soja Tripticaseína (TSB)	20 tubes
4657	Caldo Soja Tripticaseína (TSB)	10 x 90 ml
5119	Caldo Soja Tripticaseína (TSB)	10 x 100 ml
5070	Caldo Soja Tripticaseína (TSB)	10 x 200 ml
5098	Caldo Soja Tripticaseína (TSB)	10 x 450 ml
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Annexes

1. Aseptic Process Simulation (APS or Fill Medium)

2. Environmental Monitoring in the Pharmaceutical Industry

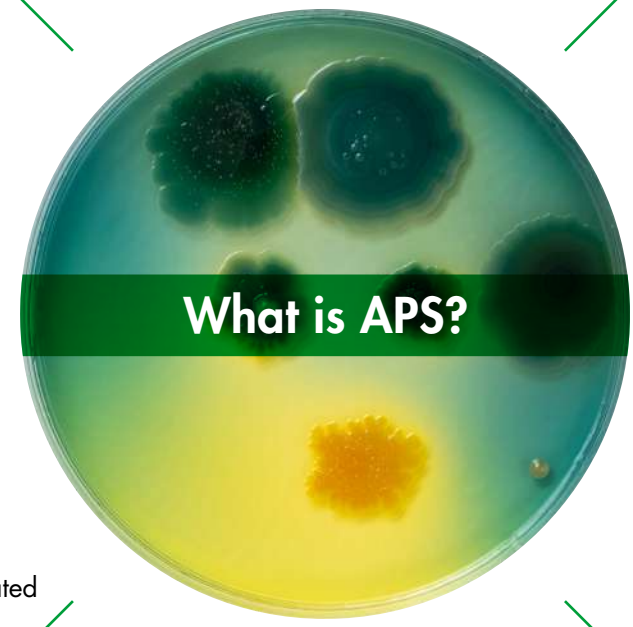
Aseptic Process Simulation (APS or Fill Medium)

Challenge the ability of the aseptic process

The APS is part of the guidelines and standards of Good Pharmaceutical Manufacturing Practices of different regulatory bodies and is a key test for aseptic preparations quality assurance.

Simulation of the aseptic process **from manufacturing to packaging**

The culture medium makes contact with all surfaces and process manipulations



The culture medium is incubated to verify the presence of **microbial growth**

It is used to evaluate possible **contaminated product** units

Trypticasein Soy Broth (TSB) irradiated or not irradiated

CAT	PRODUCT	FORMAT
1508	Medio Líquido Tioglicolato	500 g
1380	Caldo Peptona Vegetal (TSB Vegetal)	500 g
1224	Caldo Soja Tripticaseína (TSB)	500 g
6701	Caldo Soja Tripticaseína (TSB)	2x5L
6704	Caldo Soja Tripticaseína (TSB)	3x3L
6718	Caldo Soja Tripticaseína (TSB)	5x2L

Environmental Monitoring

Environmental monitoring at drug production sites: crucial for their sensitivity and regulatory requirements.

Its importance lies in:

. Quality assurance
. Compliance with regulatory agencies
. Prevention of pollution
. Validation of sterilisation processes
. Risk management
. Preservation of product integrity
. Consumer and public health safety

Trypticase Soy Agar (TSA)
+ Neutralisers
Double Wrapped. Irradiated

DISHES 90 MM (PETRI DISHES)

Irradiated dishes with double or triple wrapping for air monitoring by sedimentation in strict areas such as clean rooms.

CAT	PRODUCT	FORMAT
908	Agar Dextrosa Sabouraud con Cloranfenicol	20 dishes
843	Agar Dextrosa Sabouraud con Cloranfenicol. Doble Bolsa. Irradiada	20 dishes
842	Agar Dextrosa Sabouraud con Cloranfenicol. Triple Bolsa. Irradiada	20 dishes
838	Agar Dextrosa Sabouraud con Neutralizantes. Doble Bolsa. Irradiado	20 dishes
907	Agar Dextrosa Sabouraud	20 dishes
841	Agar Dextrosa Sabouraud. Doble Bolsa. Irradiado	20 dishes
840	Agar Soja y Tripticaseína (TSA) con Neutralizantes. Doble Bolsa. Irradiado	20 dishes
904	Agar Soja y Tripticaseína (TSA)	20 dishes
836	Agar Soja y Tripticaseína (TSA). Doble Bolsa. Irradiado	20 dishes
839	Agar Soja y Tripticaseína (TSA). Triple Bolsa. Irradiado	20 dishes
837	Agar Soja y Tripticaseína (TSA) TLHTh. Triple Bolsa. Irradiado	20 dishes

Sabouraud Dextrose Agar
with Chloramphenicol

RODAC CONTACT DISHES

Simple and convenient handling to simplify on-site monitoring of surfaces and validation of cleaning processes.

CAT	PRODUCT	FORMAT
4530	Agar Baird-Parker	30 dishes
4532	Agar Bilis Rojo Violeta con Lactosa (VRBL)	30 dishes
4524	Agar Bilis y Rojo Violeta con Glucosa (VRBG)	30 dishes
4527	Agar Cetrimida	30 dishes
4528	Agar Dextrosa Sabouraud con Cloranfenicol	30 dishes
4544	Agar Dextrosa Sabouraud con Cloranfenicol. Triple Bolsa. Irradiado	24 dishes
4545	Agar Dextrosa Sabouraud con Neutralizantes. Doble Bolsa. Irradiado.	30 dishes
4546	Agar Dextrosa Sabouraud con Neutralizantes. Triple Bolsa. Irradiado	24 dishes
4522	Agar Dextrosa Sabouraud	30 dishes
4542	Agar Dextrosa Sabouraud. Triple Bolsa. Irradiado	24 dishes
4523	Agar MacConkey	30 dishes
4521	Agar para Métodos Estándar (PCA)	30 dishes
4529	Agar Rosa Bengala con Cloranfenicol	30 dishes
4526	Agar Sal y Manitol (MSA) (Medio Chapman)	30 dishes
4520	Agar Soja y Tripticaseína (TSA)	30 dishes
4534	Agar Soja y Tripticaseína (TSA) con Neutralizantes. Triple Bolsa. Irradiado	24 dishes
4533	Agar Soja y Tripticaseína (TSA). Triple Bolsa. Irradiado	24 dishes
4538	Agar Soja y Triptocaseína (TSA) con Neutralizantes. Doble Bolsa. Irradiado	30 dishes
4525	Agar Agar Soja y Tripticaseína (TSA) Letheen. Irradiado	30 dishes
4561	Agar Agar Soja y Tripticaseína (TSA)con Penasa con Lecitina con Polisorbato	30 dishes

Environmental Monitoring

LOCK & BLOCK PHARMA PLATES

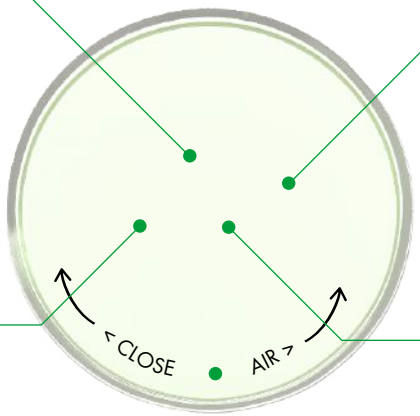
Line of dishes developed for the environmental control of drugs with side marking and locking system to ensure maximum security and safety in the control of air, surfaces and for the monitoring of BPM.

Effective blocking system

Two closing positions that allow a tight locking (CLOSE) and a minimal opening for incubation (AIR).

Ease of use

Thanks to its simple opening system, you can take samples in record time.



Comfort in reading results

The dishes have lateral marking to facilitate the reading of the dish.

Safety in transport

The locking system allows the safe transport of the dishes from the sampling site to the laboratory.

CAT	PRODUCT	FORMAT
4578	Lock&Block Agar Dextrosa Sabouraud con Cloranfenicol. Triple Bolsa. Irradiado	30 dishes
4576	Lock&Block Agar Dextrosa Sabouraud TLHTh. Triple Bolsa. Irradiado	30 dishes
4575	Lock&Block Agar Soja y Tripticaseína (TSA) TLHTh. Triple Bolsa. Irradiado	30 dishes
4577	Lock&Block TSA con Penasa Triple Bolsa. Irradiado	30 dishes
806	LC Agar Dextrosa Sabouraud con Cloranfenicol. Triple Bolsa. Irradiado	20 dishes
803	LC Agar Dextrosa Sabouraud. Doble Bolsa. Irradiado	20 dishes
807	LC Agar Dextrosa Sabouraud. Triple Bolsa. Irradiado	20 dishes
805	LC Agar Dextrosa Sabouraud TLHTh. Triple Bolsa. Irradiado	20 dishes
809	LC Agar Soja y Tripticaseína (TSA) TLHTh. Triple Bolsa. Irradiado	20 dishes
804	LC Agar Soja y Tripticaseína (TSA). Doble Bolsa. Irradiado	20 dishes
810	LC Agar Soja y Tripticaseína (TSA). Triple Bolsa. Irradiado	20 dishes
808	LC Agar Soja y Tripticaseína (TSA) con Penasa Triple Bolsa. Irradiado	20 dishes
793	LC Agar Bilis y Rojo Violeta con Glucosa (VRBG)	20 dishes
792	LC Agar R2A. Irradiado	20 dishes
790	LC Agar Macconkey	20 dishes
794	LC Agar XLD (Agar Xilosa Lisina Desoxicolato)	20 dishes
791	LC Agar Cetrimida. Irradiado	20 dishes
789	LC Agar Sal y Manitol (MSA) (Medio Chapman)	20 dishes

LC Sabouraud Dextrose Agar with Chloramphenicol Triple Wrapped. Irradiated

ADDITIONAL RESOURCES

Biofarma

Product list

Condalow®
Peptones intended for cell cultures

Starter packs fermentations

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