

## CONTROLES DE CALIDAD Y FICHAS TÉCNICAS MODIFICADAS

**Cambios** – todo aquello destacado en Amarillo supone un cambio respecto a la 6ª Edición de la Farmacopea Europea.

### Cat. 1224 - Trypticasein Soy Broth (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35 °C and observed after 18-24 hours.

Microorganisms	Growth
Brucella abortus ATCC 4315	Good
Staphylococcus aureus ATCC 6538	Good
Escherichia coli ATCC 25922	Good
Escherichia coli ATCC 8739	Good
Enterobacter aerogenes ATCC 13048	Good
Candida albicans ATCC 10231	Good
Streptococcus pyogenes ATCC 19615	Good
Streptococcus pneumoniae ATCC 6303	Good
Pseudomonas aeruginosa ATCC 9027	Good
Salmonella typhimurium ATCC 14028	Good

### Cat. 1210- MACCONKEY Broth (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 35 ± 2°C and observed after 18-24 hours.

Microorganisms	Growth	Acid	Gas
Enterobacter aerogenes ATCC 13048	Good	+	+
*Escherichia coli ATCC 25922	Good	+	+
* Escherichia coli ATCC 8739	Good	+	+
Salmonella choleraesuis ATCC 12011	Acceptable	-	-
Salmonella typhimurium ATCC 14028	Acceptable	-	-
Staphylococcus aureus ATCC 25923	Null	-	-
Staphylococcus aureus ATCC 6538	Null	-	-

\*Incubate at 42-44°C for 24-48 hours

### Cat. 1052 - MacConkey Agar (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 35 ± 2°C and observed after 18-24 hours.

Microorganisms	Growth	Colony color
Enterobacter aerogenes ATCC 13048	Good	pink-red
*Escherichia coli ATCC 25922	Good	pink-red (bile precipitate)
*Escherichia coli ATCC 8739	Good	pink-red (bile precipitate)
Proteus vulgaris ATCC 13315	Good	colorless
Salmonella enteritidis ATCC 13076	Good	colorless
Salmonella typhimurium ATCC 14028	Good	colorless
Shigella dysenteriae ATCC 13313	Good	colorless
Staphylococcus aureus ATCC 25923	Inhibited	colorless
Staphylococcus aureus ATCC 6538	Inhibited	colorless

\* incubate at 30-35°C for 18-72 hours

## QUALITY CONTROLS & TECHNICAL DATA SHEETS MODIFIED

### Cat. 1080 - XLD Agar (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35°C and observed after 18-48 hours.

<u>Microorganisms</u>	<u>Growth</u>	<u>Colony color</u>
<i>Escherichia coli</i> ATCC 25922	Moderate	Yellow (precipitate)
<i>Escherichia coli</i> ATCC 8739	Moderate	Yellow (precipitate)
<i>Salmonella typhimurium</i> ATCC 14028	Good	Clear red (black center)
<i>Shigella flexneri</i> ATCC 12022	Good	Red
<i>Staphylococcus aureus</i> ATCC 25923	Inhibited	----
<i>Staphylococcus aureus</i> ATCC 6538	Inhibited	----

### Cat. 1202 - Mossel EE (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35 °C and observed after 24-48 hours.

<u>Microorganisms</u>	<u>Growth</u>	<u>Ac. prod. yellow</u>
<i>Enterobacter aerogenes</i> ATCC 13048	Good	+
<i>Escherichia coli</i> ATCC 25922	Good	+
<i>Escherichia coli</i> ATCC 8739	Good	+
<i>Salmonella enteritidis</i> ATCC 13076	Good	±(could be slow)
<i>Salmonella typhimurium</i> ATCC 14028	Good	±(could be slow)
<i>Staphylococcus aureus</i> ATCC 25923	Inhibited	-
<i>Staphylococcus aureus</i> ATCC 6538	Inhibited	-

### Cat. 1092 - Violet Red Bile Agar with Glucose (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35 °C and observed after 18-24 hours.

<u>Microorganisms</u>	<u>Growth</u>	<u>Colony color</u>
<i>Escherichia coli</i> ATCC 11775	Good	Red
<i>Escherichia coli</i> ATCC 8739	Good	Red
<i>Salmonella gallinarum</i> NCTC 9240	Good	Red
<i>Staphylococcus aureus</i> ATCC 6538	Inhibited	----
<i>Shigella flexneri</i> ATCC 29903	Good	Red
<i>Streptococcus lactis</i> ATCC 19435	Inhibited	----

### Cat. 1102 - Cetrimide Agar Base (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium with 10 ml. of glycerol from type cultures after incubation at a temperature of 30-35 °C and observed after 18 - 72 hours.

<u>Microorganisms</u>	<u>Growth</u>	<u>Colony Color</u>
<i>Escherichia coli</i> ATCC 25922	Inhibited	-----
<i>Escherichia coli</i> ATCC 8739	Inhibited	-----
<i>Pseudomonas aeruginosa</i> ATCC 27853	Good	Yellow-green to blue
<i>Pseudomonas aeruginosa</i> ATCC 9027	Good	Yellow-green to blue
<i>Staphylococcus aureus</i> ATCC 25923	Inhibited	-----
<i>Staphylococcus aureus</i> ATCC 6538	Inhibited	-----

## QUALITY CONTROLS & TECHNICAL DATA SHEETS MODIFIED

### Cat. 1062 - Mannitol Salt Agar (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35 °C and observed after 18-72 hours.

<u>Microorganisms</u>	<u>Growth</u>	<u>Colony color</u>
<i>Escherichia coli</i> ATCC 25922	Inhibited	----
<i>Escherichia coli</i> ATCC 8739	Inhibited	----
<i>Enterobacter aerogenes</i> ATCC 13048	Inhibited	----
<i>Staphylococcus aureus</i> ATCC 25923	Good	Yellow
<i>Staphylococcus aureus</i> ATCC 6538	Good	Yellow
<i>Staphylococcus epidermidis</i> ATCC 12228	Acceptable	Red
<i>Staphylococcus epidermidis</i> ATCC 14990	Good	Red

### Cat. 1007 - Reinforced clostridal medium (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35 °C and observed after 48 hours under anaerobic conditions.

<u>Microorganisms</u>	<u>Growth</u>
<i>Clostridium bifermentans</i> ATCC 19299	Good
<i>Clostridium difficile</i>	Good
<i>Clostridium perfringens</i> ATCC 13124	Good
<i>Clostridium perfringens</i> ATCC 10543	Good
* <i>Clostridium sporogenes</i> ATCC 11437	Good

\*after incubation , make subcultures from each tube on Columbia agar (Cat: 1104) and incubate under anaerobic conditions at 30-35 °C for 48 hours

### Cat. 1205 - Sabouraud Dextrose Broth (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35°C and observed after 3-5 days.

<u>Microorganisms</u>	<u>Growth</u>	<u>pH 5,6 ± 0,2</u>
<i>Aspergillus niger</i> ATCC 16404	Good	
<i>Candida albicans</i> ATCC 26790	Good	
<i>Candida albicans</i> ATCC 10213	Good	
<i>Escherichia coli</i> ATCC 25922	partially inhibited	
<i>Escherichia coli</i> ATCC 8739	partially inhibited	
<i>Lactobacillus casei</i> ATCC 9595	Good	
<i>Sacharomyces cerevisiae</i> ATCC 9763	Good	

### Cat. 1024 - Sabouraud Dextrose Agar (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30°C and observed after 3-7 days.

<u>Microorganisms</u>	<u>Growth</u>
<i>Aspergillus niger</i> ATCC 16404	Good
* <i>Candida albicans</i> ATCC 10231	Good
<i>Escherichia coli</i> ATCC 25922	Moderate-Good
<i>Escherichia coli</i> ATCC 8739	Moderate-Good
<i>Lactobacillus casei</i> ATCC 9595	Good
<i>Saccharomyces cerevisiae</i> ATCC 9763	Good

\*Incubated at 30-35°C and observed after 24-48 hours.

## QUALITY CONTROLS & TECHNICAL DATA SHEETS MODIFIED

### Cat. 1068 - Trypticasein Soy Agar (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35 °C and observed after 18-24 hours (plates with or without blood).

<u>Microorganisms</u>	<u>Growth</u>	Growth with		<u>Hemolysis</u>
		5% sheep's blood		
<i>Staphylococcus aureus</i> ATCC 25923	Good	Good		beta
<i>Staphylococcus aureus</i> ATCC 6538	Good	Good		beta
<i>Staphylococcus epidermidis</i> ATCC 12228	Good	Good		---
<i>Streptococcus pneumoniae</i> ATCC 6303	Good	Good		alpha
<i>Streptococcus pyogenes</i> ATCC 19615	Good	Good		beta

Other aerobic micro-organisms to be incubated at 30-35°C and observed after 18-24 hours.

### Cat. 1401- Buffered Peptone Water (EUROPEAN PHARMACOPOEIA)

#### MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30-35°C and observed after 18-24 hours.

<u>Microorganisms</u>	<u>Growth</u>
<i>Staphylococcus aureus</i> ATCC 6538	Good
<i>Escherichia coli</i> ATCC 8739	Good
<i>Bacillus subtilis</i> ATCC 6633	Good
<i>Candida albicans</i> ATCC 10231	Good
<i>Aspergillus niger</i> ATCC 16404	Good

Los siguientes medios cumplen con la Farmacopea Europea. No tienen ningún cambio en sus tests microbiológicos, aunque han sufrido modificaciones en cuanto a la terminología de los ingredientes de sus fórmulas.

### Cat. 1067 - Desoxycholate Citrate Agar

**Formula:** Lactose **Monohydrate:** 10.0 g

### Cat. 1046 - Tripe Sugar Iron Agar (TSI)

**Formula:** Peptones (casein & beef): 20.0g

Lactose **Monohydrate:** 10.0g

Glucose **Monohydrate:** 1.0g

### Cat. 1401 – Buffered Peptone Water

**Formula:** Disodium **hydrogen** phosphate

### Cat. 1022 – Potato Dextrose Agar

**Formula:** **Infusion from potato** (200g): 4.00



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