

QUALITY CONTROL CERTIFICATE

PRODUCT: MACCONKEY AGAR EUROPEAN PHARMACOPOEIA, USP ISO 21567

CAT Nº: 1052

BATCH: 707191

RE-TEST DATE: 2021/07

QC Date: 2017/07/19

pH: 7.09



We hereby certify that the above mentioned culture medium has been approved by the Quality Control Laboratory.

FORMULA IN g/l:

| | | | |
|-----------------------------------|------|---------------------------|-------|
| Pancreatic Digest of Gelatin..... | 17.0 | Bile Salts..... | 1.5 |
| Lactose Monohydrate..... | 10.0 | Neutral Red | 0.03 |
| Sodium Chloride..... | 5.0 | Crystal Violet..... | 0.001 |
| Peptones (Meat & Casein) | 3.0 | Bacteriological Agar..... | 13.5 |

The pH after preparing the medium and at room temperature: 7.1 ± 0.2

PHYSICAL AND CHEMICAL TEST

Appearance: fine powder

Color: beige-pink

Solubility: w/o rests

Color of the prepared medium: violet-red.

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 24 hours.

| Microorganisms | Growth | Colony Color | Inoculum (cfu/ml) | Recovery Rate % |
|------------------------------------------|-----------|-----------------------------|----------------------------------|-----------------|
| <i>Enterobacter aerogenes</i> ATCC 13048 | Good | Pink-red | 10 ³ -10 ⁵ | ≥ 50 |
| * <i>Escherichia coli</i> ATCC 25922 | Good | Pink-red (bile precipitate) | 10 ³ -10 ⁵ | ≥ 50 |
| * <i>Escherichia coli</i> ATCC 8739 | Good | Pink-red (bile precipitate) | 10 ³ -10 ⁵ | ≥ 50 |
| <i>Proteus vulgaris</i> ATCC 13315 | Good | Colorless | 10 ³ -10 ⁵ | ≥ 50 |
| <i>Salmonella enteritidis</i> ATCC 13076 | Good | Colorless | 10 ³ -10 ⁵ | ≥ 50 |
| <i>Shigella dysenteriae</i> ATCC 13313 | Good | Colorless | 10 ³ -10 ⁵ | ≥ 50 |
| <i>Staphylococcus aureus</i> ATCC 6538 | Inhibited | Colorless | >10 ⁵ | ≤ 0.01 |

*According to European Pharmacopeia 7.0. Incubate at 30-35°C and observed after 18-72 hours.

Laboratory result: Satisfactory

Carmen Ramirez, QC Manager

