

CERTIFICATE OF ANALYSIS

BPW DRY BAG

Lot	Manufacturing date	Shelf-life
15661224BPW	27-dec-2024	23-dec-2026

Sterilization method

Gamma irradiation

Physical characteristics	Specification	Results
pH (25°C)	7.0 ± 0.2	7.0
Visual appearance	Sponge: yellow to orange-yellow, free of impurities, may contain dark spots. Medium: liquid, light yellow to very clear, clear.	Conform

Microbiology analysis

Sterility tests

Incubation	Specification	Results
35±2°C for 24h	Absence of microbial growth	Conform

Growth promotion tests

Strain	Inoculum	Incubation	Specification	Results
<i>Salmonella typhimurium</i> ATCC 14028	≤10 ² CFU	Aerobic, 35±2°C for 18-24h	Good growth	Conform
<i>Escherichia coli</i> ATCC 25922	≤10 ² CFU	Aerobic, 35±2°C for 18-24h	Good growth	Conform

Conclusion

This lot was analyzed and satisfy all the product specifications; therefore, it was **APPROVED** for use. bioBoaVista guarantees the quality of its products with sealed packages. The Instructions For Use are displayed overleaf.

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Quality Analyst



Document available on: www.bioboavista.com.br

BPW Dry Bag

Presentation

Bag of 10 liters with 200g, or 20 liters with 400g of sterile dehydrated BPW culture medium.
Includes a 0.22µm autoclavable non-sterile microbiological filter.
Does not include water pumping equipment for bag filling.

Sterilization method

Gamma irradiation.

Application

BPW (Buffered Peptone Water) is a culture medium used in the pre-enrichment of samples for the research of *Salmonella* spp in foods and other products.

Principle

Non-selective enriched medium that allows the growth of various microorganisms, particularly members of pathogenic Enterobacteria such as *Salmonella*. It promotes the recovery of injured cells by incubating the sample under non-selective conditions for at least 18 hours.

How to use

Before hydrating the bag, sterilize the microbiological filter by moist heat at 121°C for 15 minutes. The filter can withstand autoclaving up to 10 times. The production of the medium requires the use of a water pumping equipment, such as a peristaltic pump. Follow the procedure below to hydrate the bag, using aseptic manipulation technique to prevent contamination of the culture medium:

1. Using a laminar flow hood, remove the dry bag from its packaging.
2. Shake the bag to distribute the powder inside. Place the bag on the hood's surface.
3. Carefully remove the cap from the bag's hose connector and place it in a sterile Petri dish to prevent contamination.
4. Connect the bag's hose to the sterile microbiological filter.
5. Connect the filter to a purified water pumping device.
6. Open the red valve on the bag and the valve on the filter to allow air to escape.
7. Start the water pumping device to fill the bag. Once water enters the bag, close the filter valve.
8. While filling, shake the bag to dissolve the powder. After filtering the total volume of water, turn off the device. Close the red valve, disconnect the filter from the bag's hose, and cap the hose connector.
9. Distribute the medium into suitable sterile containers. Proceed with the laboratory's analysis methodology.

Quality Control

Test	Result
Sterility	Absence of microbial growth
<i>Salmonella enterica</i> ATCC 14028	Good growth with turbidity of the medium
<i>Escherichia coli</i> ATCC 25922	Good growth with turbidity of the medium
Appearance	Dry medium: fine powder, light beige, free-flowing, homogeneous, free from foreign material. 2% Solution: liquid medium, light yellow to very clear, clear, may contain slight precipitate.
pH at 25°C	7.0 ± 0.2

Results interpretation

Microbial growth is evidenced by the turbidity of the medium. If growth is observed, perform microscopic analysis, subculture on selective media, and biochemical tests to identify isolated genera and species, if necessary. Perform the reading according to official compendia or internal laboratory methodology.

Precautions and special care

The water used to fill the bag must meet the grade of water used in preparing culture media. As soon as the water begins to enter the bag, check for any air pressure formation in the filter. If air pressure builds up, quickly open and close the valve of the filter to allow the air to escape.

Product intended for *in vitro* diagnostic use only.

Restricted for use by professionals. Do not inhale or ingest.

Do not use the product beyond the expiration date, with signs of contamination, or if it has changed color. In the presence of contamination, the product should be immediately discarded.

Do not use the product if the packaging is damaged or tampered with.

Storage

Store between 10-35°C in a dry place and protect from light.

Shelf-life

1 year from the date of manufacture for the dehydrated medium at room temperature.

30 days for the hydrated medium stored at 2-25°C.

Disposal of the product

After use, the product must be handled at the generating unit before environmentally appropriate final disposal, in accordance with official regulations.

Quality Guarantee

bioBoaVista guarantees the quality of its products as long as they are used according to their respective instructions and in accordance with national and international references. bioBoaVista does not take responsibility for the use of its products for purposes other than those described and approved by the company. All clinical diagnoses should be analyzed in conjunction with clinical evidence and not solely based on laboratory results.

References

1. Becton, Dickinson and Company. Difco & BBL Manual. Manual of Microbiological Culture Media, 2nd ed., 2009.
2. ISO 6579-1:2017. Microbiology of food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella. Part 1: Detection of Salmonella spp.
3. ISO 11133:2014. Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media.
4. Manual de Métodos de Análise Microbiológica de Alimentos, Livraria Varela, 3ª ed., 2007.
5. Merck Microbiology Manual. 12th ed.